

# *Consulting Report*

## The Evolution of HTA in Emerging Markets Health Care Systems: Analysis to Support a Policy Response

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## Executive Summary

### Objectives of the Study

This project was commissioned by PhRMA to inform the development of policy positions with respect to the role (if any) for Health Technology Assessment (HTA) in emerging markets, with a particular focus on Brazil, China and Taiwan.

This project has been undertaken by OHE Consulting with the assistance of Lou Garrison and colleagues at VeriTech Corporation and the University of Washington, Seattle, and our local researchers Vanessa Teich, Michael Qin, and Ivy Tsai and who have undertaken research and interviews in Brazil, China, and Taiwan, respectively.

The objectives of the study are as follows:

- a) To develop:
  - i) a categorisation of health care systems which can be accepted by key institutions and experts in the field (WHO, World Bank and academia);
  - ii) a categorisation of types of HTA using definitions recognised by practitioners in the field. Inevitably, these are based on the experiences of high income countries, but can be expressed in a form that can support policy development in relation to the current and future healthcare systems of low and middle income countries;
- b) To combine these two strands to convey the key message that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system;
- c) To use the approach above to analyse current approaches to HTA, and options for planned development of HTA in three emerging markets: Brazil, China and Taiwan.

The outputs of this study are intended to enable PhRMA to:

- a) develop its public policy positions within a credible framework relating any potential use of HTA proposed by payers to the evolution of health care systems;
- b) develop an appropriate response within this framework to engage and shape HTA when it is put forward by a payer in these three countries; and
- c) begin to build a network of contacts within the three countries to help take its approach forward.

## Categorising and Applying Health Care System Frameworks

Our thinking is that the Murray and Frenk (2000) framework (illustrated in Figure 2 on page 26) is the most helpful one for understanding health care systems. In particular, the subdivision of financing to address questions of the nature of financing, of risk pooling and of purchasing, enable key organisational and incentive issues to be identified and differentiated between health care systems. We regard this framework as complementary to the WHO (2007) framework (illustrated in Figure 4 on page 29). In effect, the WHO framework makes an important subdivision of resource generation into: Health Workforce; Medical Products, Vaccines and Technologies; and Information.

Our understanding of the evolution of health care systems is that:

- The sophistication of “Financing” evolves slowly over time, with moves from predominantly out-of-pocket funding to elements of insurance through to more-or-less universal coverage, but varying from country to country. Typically employer based schemes for urban workers begin before schemes covering rural workers who are usually self-employed. Rural schemes therefore often begin as voluntary schemes for people to opt-in to for a relatively modest lump sum fee. Though intended to be self financing, some public subsidy is usually required. Communist and former communist countries such as China which collectivised agriculture are an exception to this – in effect the collective farm became the work place enterprise providing insurance. Access to health care for the very poor is usually provided initially through direct subsidy of health care providers – hospitals and clinics. Over time increasing numbers of this population group may be covered by a separate insurance scheme. Government and other public sector workers are usually insured through a separate scheme. The extent to which the various third party payer insurance schemes are combined over time varies from country to country. Some countries move to a single payer system, others keep multiple insurers and, in some cases, these insurers compete for enrolees.
- The element of Financing that arguably evolves the most slowly is Purchasing. Insurance cover typically develops around fee-for-service with the role of the third party payer being to passively pay the bills of the provider rather than actively decide what it is going to cover, who should provide it, and how they are to be paid. Direct public funding of services typically begins with block budget allocations to clinics and hospitals. In both cases – insurance and direct public funding - more sophisticated mechanisms for incentivising and rewarding providers tend to develop over time, notably capitation payments in primary care and DRG-type payments to hospitals. Where providers have limited resources from fee income or budget allocations, then they may begin providing services that are outside of the third party cover in order to generate additional revenues with out-of-pocket charges to patients. This can give rise to a misalignment of incentives, which can give providers perverse incentives to provide inappropriate or inefficient but profitable services.

We see these two elements of Financing as being key to an understanding of the potential role of HTA in the health care system.

## Categorising and Applying HTA Frameworks

Our assessment on the basis of the HTA literature as to how HTA can evolve and how it can be categorised is as follows:

- Garrison, et al. (2010) identify different types of “health technologies.” The EUnetHTA (2008) report includes in its definition of a health technology “organizational systems used in health care”. HTA is usually thought of as applying *only* to technologies applied within the health care system – a drug, a device, a surgical procedure or other medical intervention. We include in this the use of HTA to generate clinical practice guidelines to manage the patient through a care pathway, although using HTA to generate guidelines could well involve addressing organizational issues. The application of evidence-based analysis to *other* types of “health technology”, i.e. “organizational systems used in health care”, is, however a separate but crucial use of HTA that is often overlooked. Here HTA is being applied to elements of the *organisation, architecture or framework* of the health care system. This could include:
  - a) The architecture of service delivery. For example, is it more efficient to provide services in community facilities or in hospital?
  - b) Which types of payment mechanisms from purchasers to providers are likely to be most efficient?
  - c) How much autonomy should publicly owned enterprises have? Should more encouragement be given to private providers to supply services to meet the needs of patients within a publicly financed insurance scheme?
  - d) The mix of the clinical and related workforce. When can services be provided by nurses or other professions allied to medicine rather than a qualified doctor?

We term the first use of HTA as a focus on “*micro-technologies*”, such as new drugs, that are seen as incremental or “*marginal*” to the system. The second use for HTA is reviewing “*macro-technologies*” comprising elements of the architecture or framework such as how the system is organised (number and types of hospitals and physicians).

- The characterisation of HTA systems by Sorensen, et al. (2008) according to: governance; topic selection; evidence and assessment methods; and dissemination /implementation, is a useful reminder of the elements that need to be explicitly understood in any use of HTA. In the early use of HTA by health care systems, little systematic thought may be given to a number of these elements. The HTA process becomes a de facto “black box.”
- The natural history of HTA developed by Battista and Hodge (2009) is helpful to developing thinking about the use of HTA in Emerging Markets. Two particular points are of note.
  - a) HTA initially seems to emerge as an “ideas transfer” from academics and policy practitioners based in more developed health care systems and can appear to be a “product” without an obvious market. If HTA has no influence on the way patients



are treated because it is not disseminated or there are no incentives (professional or financial) to use the information, then the investment in HTA is wasted.

- b) Whilst we might expect the initial most valuable use of HTA to be identifying key public health and “low tech” interventions that can maximise health gain for little expenditure (targeting, for example, vaccinations or interventions to address maternal and neo-natal mortality) an early interest is often in its use to review expensive technologies (usually medical devices). This is because these technologies are seen as cost-drivers challenging the financial sustainability of emerging insurance systems or public subsidies to providers. New pharmaceuticals often fit into this category and become an early target for HTA. Yet the real concern is cost containment rather than identifying value.

Thus, it is not at all obvious that HTA is initially used in an effective way by health care systems.

## A Conceptual Model of HTA in relation to Health Care Systems

We developed the conceptual model depicted in Figure 10 below (taken from page 44) and seek to explain the interactions between health care system and HTA characteristics.

*Level of spend* is readily understandable. It inevitably shapes the nature and priorities of the health care system. By the “*degree of centralisation*” we are combining two related but distinct features of the financing arrangements for an evolving health care system:

1. The extent to which there is third party coverage and so an interest in the use of both “micro” and “macro” technologies that goes beyond the provider-patient relationship that dominates an out-of-pocket spend environment.
2. The extent to which there is active rather than passive purchasing by the third party insurer. Related to this is the degree of national level regulation as to what is included in the insurance package offered to enrollees.

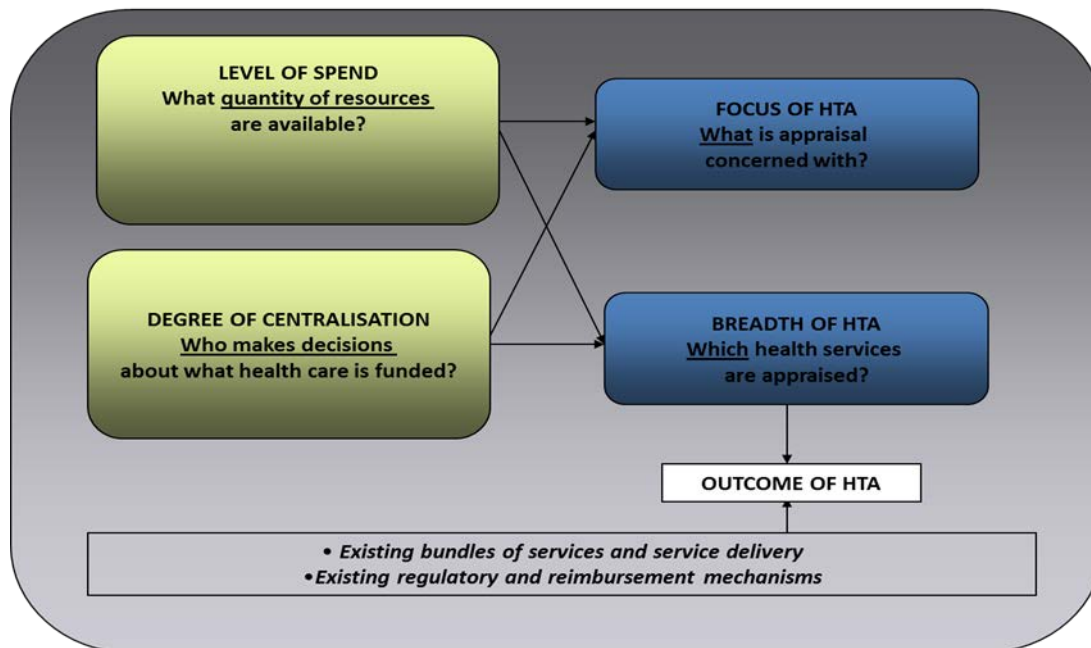
Our HTA taxonomy has two drivers

1. The *focus* or content of HTA in terms of the degree of complexity of the question that is asked, ranging from “is it safe?” to “is this good value given society’s preferences and resources?”
2. The types of technologies covered which we refer to as the *breadth of coverage* of HTA.

Putting the two typologies together, we develop the conceptual model depicted in Figure 10 below and seek to explain the interactions between the health care system and HTA characteristics.

Figure 10: A Conceptual Model of Health Care Systems and HTA

## The conceptual model



The focus of HTA: what is the appraisal concerned with?

### The impact of spending levels

Very low levels of spending are associated with high levels of preventable mortality. Where used, HTA will be concerned primarily with the *effectiveness* of services to address the most serious causes of death. International aid funding will act to accelerate the adoption of formalised approaches to HTA, adapted from those of donor countries, concerned about maximising the beneficial effect of aid. As levels of spending increase, there is a shift to chronic disease management and the number of feasible treatment options within any given disease area increases; the focus shifts to the *relative* effectiveness of various options. Higher levels of spending coincide with an acceleration of the ‘epidemiological transition’: at the same time, the availability of substitute technologies will continue to increase. These factors, together, act to raise the issue of *cost-effectiveness*. As we have noted, the availability of imported expensive technologies may create an early concern around cost containment, which may motivate an early interest in the use of HTA as an entry hurdle.

### The degree of centralisation

Where health care decisions are made by passive purchasers, there are limited incentives to conduct HTA. Such HTA as is performed will be to meet whatever regulatory barriers exist to bring products/services to the market, e.g., *safety and efficacy*. We have noted the potential interest of doctors in “what works” but in a decentralised health care system it is unclear who has an incentive to generate or disseminate this evidence. As third-party funding increases, those controlling budgets will be concerned to establish *effectiveness* of services to which the ensured population is eligible, as

a means of managing demand. As the balance of decision making shifts from local to more centralised bodies and there is also a shift to more active purchasing, there will be increased willingness to use of HTA knowledge to inform decisions about (limiting) access to health care. Where decisions are made centrally, there is no competitive advantage in offering services that are effective, but poor value for money: then, cost-effectiveness may become the dominant consideration. A concern only with cost-effectiveness is unlikely to be acceptable to patients, doctors and the insured. A broader perspective including ethical issues will need to be taken into account. As centralisation increases, there is also a greater interest in “macro” HTA issues around the design and architecture of the health care system so improve efficiency and effectiveness.

## The Breadth of HTA: Which Health Technologies are Appraised?

### Level of Spend

At low levels of resources, HTA will tend to focus on identifying which *basic services and interventions* are priorities. System architecture issues should also evolve with spending. Initially, there should be a concern about the configuration of health care delivery. Where will preventative services be delivered? International agencies and funding bodies may well provide assistance in transferring HTA knowledge on these issues from elsewhere or in enabling local HTA to be conducted. As spending increases, immediate pressure on resources may ease, but increases in spending will inevitably be out-matched by increases in expectations and demands. In particular, tackling chronic disease is likely to become more of a problem. There will be potential for HTA to look at clinical practice guidelines for disease management. HTA processes will often also focus on new potential sources of demand, i.e., *new health care technologies*, because these are seen as a driver of cost. At high levels of spend, concerns about the inability for supply to match demand will lead to pressure to extend the use of HTA into *extant services*, as well as new technologies, and the identification of *candidates for disinvestment*. Questions of how the health care system is best organized will arise at all levels of spending, although the nature of the issues will change, in part reflecting the relationship between financing and economic growth, impacting on the nature of the disease burden and the demography of the population, but reflecting the cumulative experience and history of financing and delivery arrangements in a particular country.

### The degree of centralisation

Where health care is predominantly paid for out of pocket, which health care services and products are funded is a product of the decisions made by individual patients and their doctors. There is little incentive for collective decision making about health care technologies, other than in relation to questions as to whether services such as vaccination are provided by the public sector. Whilst, in principle, there would be a role for HTA in a self-pay market in providing evidence to doctors and patients about “what works,” opportunities for dissemination may be limited and it is not clear who would fund such an exercise. As third party funding develops, it is in the insured group’s interest to ensure that claims on those funds are justified. Decisions become localised at the level of the health care plan. However, it may be some time before insurers begin to actively manage providers. Initially, they may simply pay bills on a “fee-for-service” basis. Over time, however, more active purchasing is likely to evolve. The initial focus may be on those services which are *highest cost*. Where health care funding is predominantly collective (for example, in a fully tax-payer funded system) decisions about health care may become increasingly centralised. Governments and third

party payers will argue it is in the interests of all members of society as enrollees or taxpayers that funds are used efficiently. Ultimately, all services will be seen as candidates for HTA. Key aspects of system architecture such as payment mechanisms and incentives will also come under scrutiny and so candidates for “macro” HTA to assess their cost-effectiveness in delivering health gain and broader societal objectives for the health care system.

## Lessons for the Three Markets in the Context of the Model

We drew on the detailed case studies of Brazil, China and Taiwan, set out in the Appendices and summarised in Section 7, using the conceptual framework of our model, to:

- Identify common themes, issues and lessons across these health care systems with respect to their evolving use of HTA;
- Make specific comments in relation to each of the three health care systems.

*Lesson 1: Incomes are growing in emerging markets, but resulting increases in funding for health care are likely to be out-paced by rising demands and expectations. In such situations, HTA may have a role in assisting the health care system to reconcile rapidly expanding demand with more slowly expanding resources. HTA can provide a potential means of handling this in a more explicit and transparent way, and in promoting public debate about priorities.*

- However, addressing ‘rationing’ in this way requires a willingness to engage in active debate about ways of addressing demand and supply.
- Such a debate will inevitably refer to the appropriate balance between national procurement and individual clinician decision making.

*Lesson 2: HTA of individual technologies is not a substitute for the reform of health care systems. Where health care systems create obviously bad incentives, this type of micro HTA is unlikely to compensate for these failings.*

- HTA should not be approached out of context. HTA should be tied, in a case-by-case way, to what else is going on in the health care system.

*Lesson 3: ‘One size fits all’ HTA processes and methods are unlikely to be appropriate for emerging markets. There needs to be clarity over the purpose of HTA – and the methods and processes which are adopted need to be fit for purpose.*

- HTA is not an objective ‘tool kit’ that is transferable to any setting.
- “Value” of new drugs varies, and is subjective and based on local preferences and other values.
- Real value depends in a “second-best” world on the match between costs and the value of all other inputs (hospitals, physician, nurses, equipment, etc.).

*Lesson 4: HTA and pricing regulations work hand in hand: the approach to HTA should be appropriate to, and work sensibly in combination with, the particular approach to pricing technologies.*

- For example, HTA based on reimbursement levels ignores what providers actually have to pay for new drugs. This would tend to under-estimate real-world cost-effectiveness

*Lesson 5: There is no single prescription for HTA methods and processes which will be welfare-increasing in all contexts.*

- Further, trade-offs between competing objectives are likely if not inevitable; and health care systems may differ in the relative value placed on them, for example, the achievement of equity goals; technical efficiency; cost containment; and patient choice. Every health care system is on a slightly different trajectory: as it develops, and as spending increases, the way that HTA evolves will be a reaction to the possibilities and pressures that new technologies present.
- The key message is that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system.

## Options for the development of HTA in the three markets

In positioning HTA, it is important to understand that its value depends on the existing architecture of the health care system. This will in turn reflect the type of HTA that is appropriate. We have categorised HTA into three types, one “macro” and two “micro”:

- “macro-level” HTA which is about the efficiency of the “technologies” or architecture of the health care system, e.g. incentive systems or configurations of facilities. Issues around the effectiveness of, or reform options for, system level technologies arise at all stages of health system development either for government as a regulator or, more typically, for government as a direct owner of, and/or a purchaser of, health care services;
- micro-level” HTA aimed at appraisal of individual technologies, or groups of related technologies. Initially, some sort of market entry or licensing requirements are introduced for certain technologies (notably drugs and some devices), but at some point a greater understanding of value may be sought, either in the sense of relative or comparative effectiveness, or of incremental cost-effectiveness. In theory, again, these assessments could be generated and adopted by clinicians in self-pay markets, but it hard to see how this type of HTA would be funded in such a situation given its public good characteristics and the asymmetry of information between doctors and patients. More typically, it is generated by public bodies and used by public and private sector payers to either (i) support doctors and patients making treatment choices or (ii) to define the boundaries of the “benefit package.” Use to inform listing or reimbursement can be as part of a “passive” fee-for-service system or more “active” purchasing.
- “micro-level” HTA aimed at developing clinical practice guidelines or the way in which individual technologies are combined within a delivery system to manage patients efficiently. Designing clinical practice guidelines becomes an issue in systems that are seeking to actively manage chronic disease. In theory, these could also be generated and adopted by clinicians in self-pay

markets, but it is hard to see how this type of HTA would be funded in such a situation given its public good characteristics and the asymmetry of information between doctors and patients. More typically, developing guidelines becomes an issue for a health system when one or both of variability in treatment patterns and poor health outcomes becomes apparent.

All of these uses of HTA make sense in the right context if the five lessons we set out above are observed. The bottom line is that HTA uses scarce resources. To be of value it has to deliver improved resource allocation and resource use that exceeds the opportunity cost of the effort involved in undertaking the HTA. If skills are scarce, as is often the case in an emerging market health care system, the opportunity cost may substantially exceed the wages and overheads associated with the HTA body.

Many elements of HTA—both in terms of process and findings—are not only public goods, but global public goods. Clinical benefit-risk determination for an individual drug, for example, is likely to be similar in different countries. If both the FDA and EMA have decided that a product’s benefit-risk balance is favourable enough to allow a product on the market, it makes sense for emerging markets not to spend substantial scarce resources to re-address this question in their local context. The ‘efficient’ solution will involve some degree of free-riding on this information. In the case, however, of a drug or other technologies comparative effectiveness or cost-effectiveness, local evidence will be needed to supplement reviews of evidence by HTA bodies elsewhere. Likewise with clinical practice guidelines, it makes sense to draw on relevant research from elsewhere. In the case of “macro-HTA” even more care is needed. Reforms to health system delivery or payment and incentive structures that appear to have worked in another country may not translate into other health care systems.

All three case study markets demonstrate the use of HTA is at its early - emergent – stages, albeit with some early signs of consolidation in Brazil.

- In China, there are a number of reforms to health system architecture underway and others are needed. Where HTA seems to be emerging as important is in the key area of clinical practice guidelines. The initiative with the UK NICE appears to be targeted at generating evidence-based clinical practice guidelines. The safety and efficacy of drugs is assessed by the SFDA. HTA in the sense of appraising the cost-effectiveness of individual drugs is not used. It could, in theory, be used by: (a) MoH in determining listings for inclusion in the EDL; (b) MoHRSS in setting reimbursement prices or determining reimbursement decisions for drugs to be covered in the two schemes it administers; or (c) the NRDC in setting prices for pharmaceuticals not covered by its cost-plus formula. None of these uses have been proposed to our knowledge although there is interest in the use of HTA on the part of all three Ministries and leading academics continue to promote dialogue on guidelines for good practice. Furthermore, to our knowledge there is no use of HTA for other individual technologies outside of drugs.
- In Brazil, the CITEC sometimes appears to work slowly and to be under-resourced. This has the effect of delaying reviews of, and decisions on, access to new technologies. (A new law, about to be signed, would place a 180-day limit for CITEC review reflecting a recognition that the process has been too slow as well a societal willingness to address these access decisions.) There are aspects of the HTA process that could be improved, notably around transparency of process and of selection criteria. However, it is also unclear how the role of CITEC fits alongside a constitutional right of access to healthcare (which is clearly not consistent with the levels of funding available) and regulation by the ANS of the minimum requirements of the private insurance package. If emerging markets allow marketing authorisation, their citizens will have

expectations of access. The situation in Brazil exemplifies this, as once products are approved for marketing authorisation and for innovative products, an initial price is set via external reference pricing rules (and adjusted subsequently by SUS/CMED for inflation, affordability, etc.), then citizens can sue for access even though the public system has not yet approved the product for use in the public plan.

- In Taiwan, the role of HTA appears to be exclusively in the area of drug reimbursement, and here it is unclear how it fits logically alongside an international reference price system. In theory, drugs showing incremental value can get higher prices within the range of reference price comparisons. There are also some issues around process such as the degree of transparency of the assessment and the relationship between the assessment and the drug licensing process. Our understanding is that expertise for the conduct of pharmacoeconomic assessments is drawn from the licensing body but used separately. However, this arrangement clearly causes concern for the industry that assessments of safety and efficacy may be conflated in some way with assessments of relative effectiveness and cost-effectiveness.

## Issues for PhRMA in developing public policy positions

The PhRMA, EFPIA, and IFPMA principles for good practice in HTA and Evidence-based Medicine provide a consistent approach to “micro HTA” and continue to provide a solid framework for approaching HTA issues globally. They are intended to be applied in a reactive way – in the event of a payer and/or government proposing the use of “micro HTA”.

We have sought to develop a framework for putting such a position into the context of health care system development and HTA evolution. Our key points are that HTA is resource intensive and that an appropriate initial focus for skilled people may well be on “macro HTA” or other health system issues rather than “micro HTA”.

This gives rise to several issues:

- As compliance with good HTA principles is resource-intensive for governments (and for industry), countries may seek to “free ride” on the systems of other countries to avoid using scarce skills and resources. Indeed, as we have noted earlier, the global public good nature of much evidence means that “not reinventing the wheel” can make sense and be efficient.
- However, use of alternative “low resource” options may be *less* efficient than an efficient use of HTA. For example, the use of international reference pricing to countries at a similar stage of income-per-capita and with similar health care systems can make sense if the referenced countries have used appropriate methods to derive their prices. However, international reference pricing in practice can lead individual country markets to seek lower-than-optimal price levels not consistent with long-term, global dynamic efficiency (Danzon et al, 2010). HTA may therefore be preferable to international reference pricing if it is used to assess value in a way that reflects local willingness to pay for health gain;
- The use of therapeutic reference pricing requires less input than HTA but can discourage innovation and reduce the likelihood of efficient use of the product (Drummond et al, 2010). It

saves input resources by assuming medicines are the same instead of exploring the appropriate use of different treatments in a given therapy area.

This suggests that the industry be willing to support 'efficient' HTA, i.e. appropriate to a given country market and subject to the lessons we have set out above.



## 2 Introduction and Context

### 2.1 Purpose of this report

This project was commissioned by PhRMA to inform the development of policy positions with respect to the role (if any) for Health Technology Assessment (HTA) in emerging markets. PhRMA's policy stance is not to promote the use of HTA where it doesn't exist but to be prepared with an appropriate response to engage and shape HTA when it is put forward by a payer.

The purpose of the study is to help inform such an approach. This project was commissioned to inform the development of policy positions with respect to the role (if any) for Health Technology Assessment (HTA) in emerging markets, with a particular focus on Brazil, China and Taiwan.

The term 'emerging markets' is generally applied to the set of countries that are experiencing rapid economic growth and/or a shift toward industrialisation. The definition of emerging markets is somewhat loose: it is used somewhat broadly to refer countries which are considered to be in a transitional phase between developing and developed status. The lack of a precise definition is reflected in the variation between the various classification systems that exist. For example, MSCI Barra list 21 economies as being emerging markets; and Dow Jones 35. FTSE distinguish between 'Advanced' and 'Secondary' emerging markets, on the basis of both their national income and the state of development of the economic infrastructure.

Emerging markets, however defined, are of particular interest to the pharmaceutical industry. Most obviously, the increases in incomes in these countries mean they are becoming an important source of potential demand for pharmaceutical products. Economic growth in these countries is accompanied by changes in the way the economy is organised, and this typically extends to changes in arrangements about the way health care is financed, provided and regulated. Understanding the way in which these changes are likely to unfold, and the implications for market access and pricing of pharmaceuticals, is of key interest to industry.

### 2.2 Structure of this Report

This report is structured as follows:

- Section 2 recaps the Terms of Reference for the project
- Section 3 sets out the approach we are taking
- Section 4 seeks to categorise the development of health care systems
- Section 5 looks at the evolution of HTA
- Section 6 links together HTA and health care systems
- Section 7 describes the main results from our review of the health care systems and use of HTA in Brazil, China and Taiwan

- Section 8 sets out our overall findings including recommendations to inform PhRMA's policy position with respect to the use of HTA in emerging economies and to the three countries Brazil, China and Taiwan in particular.

## 2.3 Acknowledgements

This project has been undertaken by OHE with the assistance of Lou Garrison and colleagues at VeriTech Corporation and the University of Washington, Seattle, and our local researchers Vanessa Teich, Michael Qin, and Ivy Tsai and who have undertaken research and interviews in Brazil, China, and Taiwan, respectively.

### 3 Terms of Reference

This project was commissioned to inform the development of policy positions with respect to the role (if any) for Health Technology Assessment (HTA) in emerging markets. PhRMA's policy stance is not to promote the use of HTA where it doesn't exist but to be prepared with an appropriate response to engage and shape HTA when it is put forward by a payer. The purpose of the study is to help inform such an approach.

The objectives of the study are as follows:

- a) To develop:
  - iii) categorisation of health care systems which can be accepted by key institutions and experts in the field (WHO, World Bank and academia);
  - iv) a categorisation of types of HTA using definitions recognised by practitioners in the field. Inevitably these are based on the experiences of high income countries, but can be expressed in a form that can fit into policy development in relation to the current and future healthcare systems of low and middle income countries;
- b) To combine these two strands to convey the key message that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system;
- c) To use the approach above to analyse current approaches to HTA, and options for planned development of HTA, in three emerging markets: Brazil, China and Taiwan.

The outputs of this study are intended to enable PhRMA to:

- d) develop its public policy positions within a credible framework relating any potential use of HTA proposed by payers to the evolution of health care systems;
- e) develop an appropriate response within this framework to engage and shape HTA when it is put forward by a payer in these three countries; and
- f) begin to build a network of contacts within the three countries to help take its approach forward.

## 4 Our Approach

### 4.1 Workstreams

To fulfil the study objectives we have divided the work into four separate, interrelated, workstreams.

#### 4.1.1 Workstream 1: Categorisation of health care systems

We started our analysis with a classification of health care systems to help understand the roles of payers – distinguishing between a single national/public payer and multiple private payers/insurers – and the roles of doctors and patients in the final choice of treatments and/or the management of disease.

To do this we did the following:

1. Reviewed relevant literature including reports published by the World Health Organization (WHO), Organisation for Economic Co-operation and Development (OECD), World Bank, and academic groups such as The European Observatory on Health Systems and Policies (which produces country profiles for western Europe, central and eastern Europe and the central Asian republics);
2. Identified in the literature review references to the three countries of particular interest in the study - Brazil, China and Taiwan;
3. Developed possible 'evolutionary pathways' that countries are in principle following in an attempt to improve their health care systems as income per-capita increases. There are several different starting points and potential pathways, but from a dynamic viewpoint it is possible to identify the key trends.

In the second part of the project we used the theoretical framework to review the experience of the three countries.

#### 4.1.2 Workstream 2: Categorisation of HTA

Based on the experience of developed countries and current policy and academic debate in Europe and North America, we set out to analyse different definitions and approaches to HTA (e.g. decentralised versus centralised, comparing effectiveness versus cost-effectiveness) to understand how HTA can work in different settings and how it has worked in practice in a number of countries...

In our literature reviews for Workstreams 1 and 2, we searched for and reviewed published literature, including papers and reports commissioned or conducted by key international organisations that are in the public domain but are not part of the peer-reviewed journal literature (the so-called grey literature). Our approach was not meant to be exhaustive or comprehensive: we followed a selective approach mainly driven by:

1. Our accumulated knowledge and experience and that of our expert advisers as to the most relevant literature;
2. Core references from past reviews of HTA processes to help in identifying key authors in the fields.

#### 4.1.3 Workstream 3: Mapping HTA onto health care systems in emerging economies

The third element of the project is to map the outputs of the Workstream 1 analysis of the evolution of health care systems onto the Workstream 2 analysis of options for HTA. This is intended to enable us set out policy recommendations as to whether and in what way HTA processes can help lower income and emerging economy countries to obtain more value for money from their health care expenditure whilst providing access to innovative technologies, including new medicines, which can significantly improve health outcomes within their systems. We do this in the context of PhRMA's perspective that it does not wish to promote the use of HTA where it doesn't exist but to be prepared with an appropriate response to engage and shape HTA when it is put forward.

#### 4.1.4 Workstream 4: Developing options for HTA development in the three countries

We have complemented this approach with a more detailed analysis in the second part of the project on the use of and proposed use of HTA within the three countries Brazil, China and Taiwan.

These three countries are selected as important markets in their own right, and because they span a range of different sorts of emerging markets with respect to size and state of development. For example, Brazil and China, along with India and Russia, comprise the large, powerful 'BRIC' economies, although Brazil is considered in some classifications (e.g. FTSE) to have a higher state of development than China. Taiwan is smaller than both, but in some classifications (e.g. Dow Jones) is considered to have achieved a level of development that puts it outside the emerging markets category.

	China	Taiwan	Brazil
Dow Jones	√		√
MSCI	√	√	√
FTSE Advanced Emerging markets		√	√
FTSE Secondary Emerging markets	√		

By linking appropriate HTA use to the stage of health care system evolution we sought to translate the general analysis undertaken for the previous workstreams to indicate potential HTA reform pathways relevant for these three countries when HTA is proposed by the government and/or payers. As part of this we have examined how these markets are currently planning to use or using HTA. In particular we reviewed whether it is seen as a tool to improve effectiveness or as a cost-containment tool. We aimed to identify reform options for PhRMA to consider and also to identify relevant opinion leaders for these three countries. We took note of the PhRMA, IFPMA, and EFPIA

position papers and other policy articles available in the health economic literature. We were asked not to assume the use of HTA is an appropriate policy response for payers, but, conditional on a payer decision on the use of HTA, exploring how one can understand types of HTA, and their strengths and weaknesses, including in different contexts

An essential component of this part of our work has been to undertake an interview programme in the three countries to underpin the literature review and analysis. We have chosen to contact:

- Policy people involved in health services based in the three countries;
- Academics familiar with the three countries;
- Key pharmaceutical industry respondents from both global offices and national affiliates with a direct experience of the three countries, or key individuals from local trade associations or PhRMA groups.

In defining our list of interviewees, we relied on our already established network of contacts in many companies to help us in identifying the names of appropriate 'points of entry' in other organisations. We ensured the 'appropriateness' of the selected interviewees in discussions with the Project Steering Group.

We contacted potential interviewees initially by email, followed up by a telephone call to try and book a time for a later telephone interview. As an incentive to participate in the interview, we offered to send to all respondents a summary of some elements of the report and for some non-government interviewees we offered honoraria.

We intended to obtain a maximum of 18 interviews – around two representatives of each of the categories listed above (i.e. policy people, academic experts and industry people) for each country – recognising that the number of interviewees might well be slightly lower, considering that for certain countries the local expert may represent both the academic and the policy side, or that some academics will have expertise on more than one country.

In practice we obtained 19 and the list of potential interviewees is set out in Annex 5.

## 4.2 Project Steering Group

We have worked with the Project Steering Group established by PhRMA during the course of the project. We held a meeting by telecon on 21st January 2010 shortly after initiation of the project. On subsequent occasions we have used the Steering Group for comment on our Interim Report issued on 5<sup>th</sup> June 2010 and on the individual country summaries issued on 18<sup>th</sup> October 2010.

We are now seeking feedback from Project Steering Group on this draft of the Final Report.

In addition, we have liaised with Stephanie Lane of PhRMA as the single point of contact for the duration of the project. We would like to thank Stephanie for her support and advice during the project.

### 4.3 Deliverables

The Final Report is intended to enable PhRMA to:

- (1) develop its public policy positions within a credible framework relating any potential use of HTA proposed by payers to the evolution of health care systems;
- (2) develop an appropriate response within this framework to engage and shape HTA when it is put forward by a payer in these three countries; and
- (3) begin to build a network of contacts within the three countries to help take its approach forward.

In addition, as set out in the proposal, we will produce a Working Paper based on sections 4, 5, and 6 of this Report which could be put in the public domain. No material relating to possible PhRMA policy options would be included in any Working Paper.

## 5 Health Systems Categorisation

### 5.1 Literature search strategy

In this strand of the work programme, we focussed our attention on categorization of healthcare systems to help us understand the roles of healthcare payers – distinguishing between single national/public payers and multiple private payers/insurers – and the role of doctors and patients in the final choice of treatments and/or management of diseases.

For this purpose, we conducted a number of literature searches by exploring specific websites, such as Yahoo, Google, WHO, the European Observatory, OECD and the World Bank. A PubMed search has also been conducted using the following key words: ("health care systems") and (classification OR taxonomy OR categorisation OR categorization OR taxonomies), these results were then narrowed down based on the title, excluding papers which were disease specific. From the relevant literature identified, we identified various methods by which healthcare systems can be categorized depending on the objective of the analyst(s).

We collected a number of publications which refer to health care systems classifications; however, most of these are mainly descriptive with a limited number providing a specific typology. However, from the literature examined, it is apparent that one can focus on the various functions of the component parts of health systems, the overall goals of health systems and the various functions affecting health system performance.

Some publications mentioned factors which may indicate the 'progression' of a health system or systems, such as, the balance of trade for pharmaceuticals and health care products (see for instance, Banta and Almeida 2009), whether the system was centralised or decentralised (Byrkjeflot and Neby, 2008), and more specific elements such as a classifications based on career pathways (see for instance, Lawrence 2005). Other papers provided a framework for classifying best practice in healthcare (see for instance, Perleth, Jakubowski and Busse [2001]).

In all, we note that there are various frameworks and taxonomy, each of which has been developed in ways to fit various objectives. We provide below a distillation of analytical frameworks and healthcare systems categorization systems that we deemed as the most relevant to this stream of the work programme.

### 5.2 Types of healthcare payers (insurers)

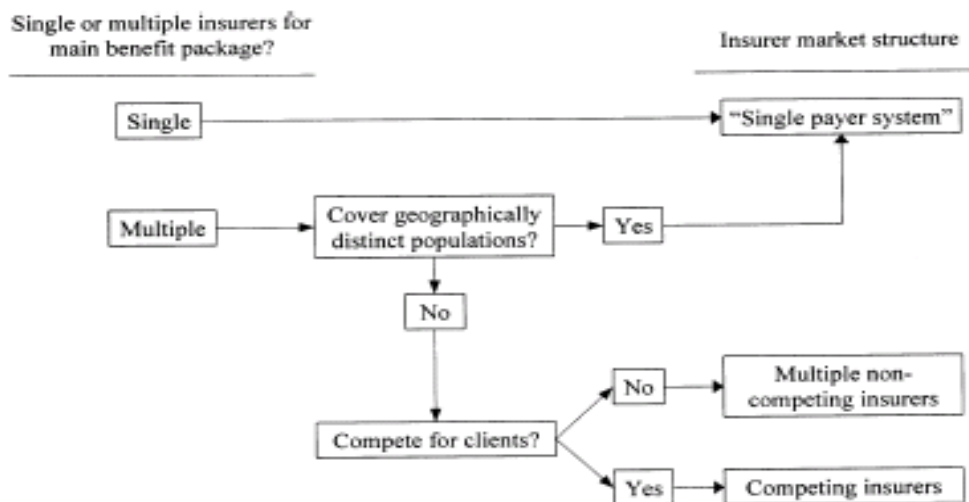
One of the first widely recognized attempts to classify healthcare systems is Kutzin's (2001) framework for classifying healthcare purchasers (or more generally insurers). Under this framework (see Figure 1 below), healthcare purchasers are classified as 'single payers' if there is one purchaser or there are multiple purchasers but covering geographically distinct populations. When there are multiple purchasers who do not cover geographically distinct populations, one has a 'multiple payers' system. In such a multiple-payer system, healthcare purchasers could be competing or not depending on the system for patients' demand for health insurance and medical care.

Kutzin (2001) notes that the issue at hand is not what is the theoretically best structure for healthcare financing and/or provision (i.e., whether it is a single-payer or otherwise) but rather,



given the existing institutional arrangements, what is the appropriate direction for policy changes that will facilitate the functioning of health systems in ways that are publicly accountable, or at least, accountable to the population covered by each healthcare payer/purchaser. Irrespective of whatever is considered 'theoretically best', the starting point for policy analysis and reform in any particular country is the existing system.

**Figure 1: Framework for understanding healthcare purchasers/insurers: Kutzin (2001)**



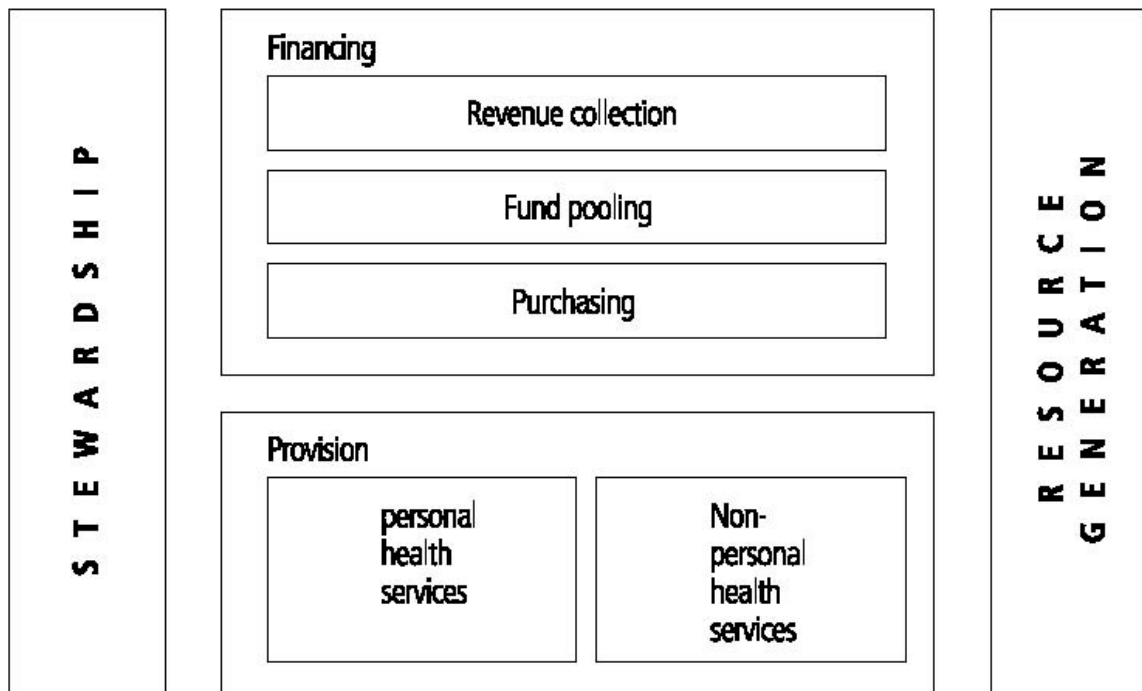
### 5.3 Functions of health systems

Related to Kutzin's (2001) work is Murray and Frenk's (2000) framework for assessing health system performance. Although, this framework doesn't actually offer a taxonomy of healthcare systems, it is useful tool for understanding the varying differences between healthcare systems in terms of four functions that all healthcare system perform irrespective of their heterogeneity and of differences in underlying philosophical and economic rationales for health system design. The four functions of healthcare systems are depicted below in Figure 2. Note that this framework is the same one used by Mossialos, et al. (2002) in the monograph "Healthcare funding options in Europe". The four functions of health systems are: (1) Financing (2) Provision (3) Stewardship, and (4) 'Resource' generation. Given the importance of this framework we set out below more detail on the individual components.

**Financing:** There are three dimensions to this: (1) revenue collection (2) fund pooling and (3) purchasing tasks. Revenue collection refers to mobilization of needed finance for medical care provision. Pooling refers to the extent of any redistributive and insurance element of the system in which revenues are collected in ways that ensure fairness in financial contribution and used in a way which provides health insurance protection. Purchasing refers to the process by which revenues collected are transferred to healthcare providers for the provision of medical services. It can be passive (for example meeting fee-for-service claims from providers) or active (agreeing what will be bought and negotiating payments with providers.) In between could come purchasing tasks such as

budget-specification exercises for providers or the development of formulae for the allocation of healthcare funding to lower levels of the system. The term ‘strategic purchasing’ has also been employed to reflect more active purchasing, including decisions made with respect to what is purchased, how it is purchased and from whom it is purchased. This applies to purchasing of medical inputs, the choice of which services to provide, the type of healthcare providers to be used to deliver these services, and how to pay these providers.

**Figure 2: The four functions of health systems: Murray and Frenk (2000)**



Provision (of personal and non-personal healthcare services) refers to the combination of staff and non-staff medical inputs in the production of personal and non-personal services that takes place in specified organisation/institutional settings. Personal healthcare services refers to care that will be delivered to an individual; be it preventive, diagnostic, therapeutic or rehabilitative that generate consumption externalities or not. Non-personal healthcare services refer to healthcare interventions that are collectively consumed (for instance mass health education programmes) or that which involve non-human components of the environment (for instance sanitation, housing, transportation and air pollution).

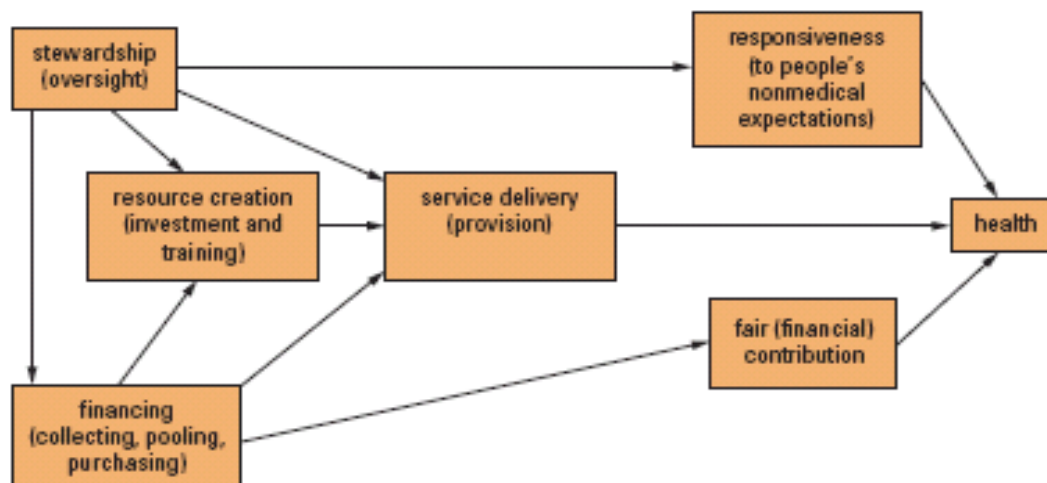
Stewardship: This refers to how healthcare systems are governed. There are six sub-functions to stewardship: (1) overall system design (i.e., policy formulation at the macro-level) (2) performance assessment (3) priority setting (this includes an element of consensus building and has both technical and political attributes) (4) intersectoral advocacy (5) regulation, and (6) consumer protection.

Resource generation: This covers skill and technology development, recognising that healthcare providers need medical inputs in terms of skilled trained labour and relevant technologies for the production of medical care.

## 5.4 Functions and goals of health systems

Gottret and Scheiber (2006) report a framework that was put forward by WHO (see also WHO [2000, 2003]) and is consistent with Figure 2 above. That is a categorization of health systems according to the four principal functions of stewardship, resource creation, service delivery and financing and the three principal objectives, i.e., health, fair financial contributions and responsiveness to non-medical expectations (Figure 3).

**Figure 3: Functions and goals of health systems: Gottret and Scheiber (2006)**



According to these frameworks, the observed variation in the structure and organization of health systems depends on how the various functions and its components (especially financing, provision and stewardship functions) have been integrated or segmented, vertically or horizontally. This level of integration could be partial or complete. In this regard the framework itself is consistent with the paradigm of purchaser provider split.

## 5.5 A 3-model typology of health systems

Our conclusions about significant differences in how healthcare systems are categorized was noted by Lee, et al. (2008) work in which they identified a 3-model typology (into National Health System [NHS], Social Health Insurance [SHI] and Private Health Insurance [PHI]) as the most common and well known. They document previous typologies dating back to work done in 1973. Lee, et al. (2008), however, develop their own framework for assessing the nature of the healthcare systems. The

typology developed was based on the following criteria: first, what group of people does the national healthcare system protect, i.e., is it all citizens, the vulnerable or some pre-specified group of insured individuals? The second is: which sector is the main provider of healthcare, i.e., is it public or private? The third is: is there state intervention in the financing of healthcare, and if there is, is it concentrated or dispersed?

Using two main dimensions: (1) financing administration, and (2) provision of healthcare, Lee, et al. (2008), describe a health system as NHS if financing administration is single or concentrated and if provision of healthcare is 'public'. A health system is characterised as NHI if financing administration is single/concentrated and if there is private provision of healthcare. A health system is characterised as SHI if financing administration is multiple/dispersed and provision of healthcare is 'public'. Finally, a health system is characterised as a 'Liberal model' if financing administration is private and there is private provision of healthcare. Lee, et al (2008) use their typology to classify the healthcare system in Taiwan and South Korea by adding in a fourth criterion of ratio of public to total healthcare expenditure and the ratio of public hospital beds to total hospital beds.

## 5.6 Weberian taxonomy of health systems

One other classification system we identified is that by Wendt, et al. (2009). In brief, their approach is based on what is called the Weberian method of 'ideal types', which is a tool used for comparative research of welfare regimens. The ideal-type 'is formed by one-sided accentuation of one or more points of view and by the synthesis of a great many diffuse, discrete, more or less present and occasionally absent concrete individual phenomena...' This welfare regimen analyses is meant to identify the 'ideal-typical' case that is, roughly speaking the type of health system that is commonly observed.

On the basis of this framework, Wendt, et al. (2009) identified 27 types of healthcare systems; there are three instances of 'ideal types' in which there is uniformity in all dimensions (1. finance, 2. service provision and 3. regulation/governance). These are pure state healthcare systems, societal healthcare systems and private healthcare systems. For each ideal-type, there are six combinations of mixed types in which identical features can be seen in two of the three dimensions. In six other combinations of mixed types, there is no uniformity in any of the dimensions; these are referred to as pure mixed-types. Their classification is rather complex and over-elaborate and not helpful for our work.

## 5.7 WHO's 'single' framework

To the best of our knowledge, the most recent healthcare classification system is what WHO (2007) calls a 'single framework with six building blocks' to promote understanding of what a health system is and what constitutes health system strengthening. These building blocks highlight the basic functions of health systems (regardless of how they are organized). The six building blocks shown in Figure 4, which have some similarity to the features of Figure 2, are:

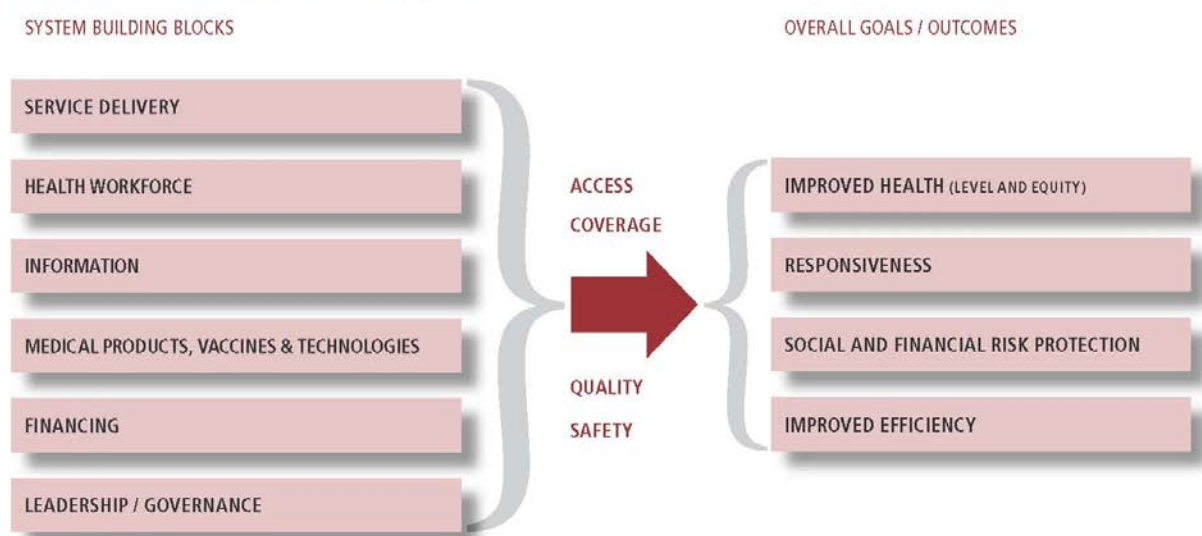
- **Service delivery.** This captures issues relating to the delivery of effective, safe and quality personal and non-personal health interventions (with the minimum waste of resources)

- **Health workforce.** A good health system is one that employs a well-performing health workforce in ways that are fair and efficient to achieve the best health outcomes possible, i.e., there should be sufficient quantity of health staff that is competent, responsive, productive and fairly distributed
- **Health information systems.** Having well-functioning information systems is needed to ensure reliable and timely production, analysis and dissemination of information on health determinants, health system performance and health status
- **Medical products, vaccines and technologies.** A key, basic objective of health systems is to ensure equitable access to medical products, vaccines and technologies of assured quality, safety and efficacy (and cost-effectiveness) as well as ensuring their use is scientifically sound and cost effective
- **Healthcare financing.** A good health system should have means of raising adequate funds for healthcare (and health) provision in ways that ensure people can use needed services and are protected from the financial risks of ill healthcare demands (and the impoverishment associated with having to pay for these demands)
- **Leadership and governance (stewardship).** This focuses on the development (and existence) of strategic policy frameworks that are combined with effective oversight, coalition-building, regulation, attention to system-design and accountability.

WHO's six-building-blocks framework seems to be the most recent framework to have to been developed for classification and understanding the functions of healthcare systems. It places special emphasis on medical products, vaccines and technologies (and separates it from health workforce). This building block framework is particularly relevant as it focuses on promoting equitable access and rational use of medical products and health technologies which fits with one objective of HTA which is to resolve uncertainty about the value of health technologies and their appropriate use in the delivery of medical care.

Figure 4: Six building blocks of a health system: WHO (2007)

### THE WHO HEALTH SYSTEM FRAMEWORK



## 5.8 Applying Health Care System Frameworks

None of these frameworks has a dynamic or evolutionary element to them. They are intended to assess or categorise health care systems at a particular point in time. Even in this context they do not explicitly address some key questions in categorising health care systems, notably how they are organised. However, our thinking is that the Murray and Frenk (2000) framework illustrated in Figure 2 is the most helpful one for understanding health care systems. In particular the subdivision of financing to address questions of the nature of financing, of risk pooling and of purchasing, enable key organisational and incentive issues to be identified and differentiated between health care systems. We regard this framework as complementary to the WHO (2007) framework illustrated in Figure 4. In effect the WHO framework makes an important subdivision of resource generation into: Health Workforce; Medical Products, Vaccines and Technologies; and Information.

Our understanding of the evolution of health care systems is that:

- The sophistication of “Financing” evolves slowly over time, with moves from predominantly out-of-pocket funding to elements of insurance through to more-or-less universal coverage varying from country to country. Typically employer based schemes for urban workers begin before schemes covering rural workers who are usually self-employed. Rural schemes therefore often begin as voluntary schemes for people to opt-in to for a relatively modest lump sum fee. Intended to be self financing some public subsidy is usually required. Communist and former communist countries such as China which collectivised agriculture are an exception to this – in effect the collective farm became the work place enterprise providing insurance. Access to health care for the very poor is usually provided initially through direct subsidy of health care providers – hospitals and clinics. Over time increasing numbers of this population group may be covered by a separate insurance scheme. Government and other public sector workers are usually insured through a separate scheme. The extent to which the various third party payer insurance schemes are combined over time varies from country to country. Some countries move to a single payer system, others keep multiple insurers and, in some cases, these insurers compete for enrolees.
- The element of Financing that arguably evolves the most slowly is Purchasing. Insurance cover typically develops around fee-for-service with the role of the third party payer being to passively pay the bills of the provider rather than actively decide what it is going to cover, who should provide it, and how they are to be paid. Direct public funding of services typically begins with block budget allocations to clinics and hospitals. In both cases – insurance and direct public funding - more sophisticated mechanisms for incentivising and rewarding providers tend to develop over time, notably capitation payments in primary care and DRG-type payments to hospitals. Where providers have limited resources from fee income or budget allocations then they may begin providing services that are outside of the third party cover in order to generate additional revenues with out-of-pocket charges to patients. This can give rise to a misalignment of incentives, which can give providers perverse incentives to provide inappropriate or inefficient but profitable services.

We see these two elements of Financing as being key to an understanding of the potential role of HTA in the health care system. We return to this in our conceptual model in Section 6.

We should also note the potential importance of the evolution of the quality level and skill mix of the health workforce and of the amount and quality of information over time. The ability to use HTA effectively in relation to clinical practice guidelines will depend on this, as well as on the point in the development of the health care system at which the disease burden moves to predominantly chronic conditions. At this point, the potential for successful management of chronic disease becomes an important way to manage health care expenditures efficiently and achieve better population health.

## 6 Categorisation of health technology assessment (HTA) systems

### 6.1 Literature search strategy

This stream of the work programme aimed to analyse different definitions and approaches to HTA, drawing mostly on experience of developed countries and current policy and academic debate in Europe and North America. The objective was not to provide a rationale for HTA (specifically we do not aim to answer the question of whether HTA is an appropriate policy response or not) but, conditional on the use of HTA (without an implicit endorsement of the appropriateness of HTA), we aimed to explore how one can understand types of HTA, and their strengths and weaknesses, in different contexts.

For this purpose, we carried out a number of searches using the following search words: “health technology assessment”, “HTA”, “classification”, “taxonomy” and “categorization”) in various electronic databases and general search engines including PubMed and Google. Within a selected set of relevant articles, we also looked at references sections to identify articles that might be of relevance to our work programme but were picked out by our searches. We found, unlike the work programme for health system categorisation that very little has been done in terms of categorising HTA systems. Below we present summaries of relevant literature with a distillation of some of the issues concerning the implementation and execution of HTA (policy) discussed in the papers identified and which, we deem useful for developing taxonomy of HTA systems.

### 6.2 Some relevant literature for HTA classification

EUnetHTA (2008) draws various issues underlying the adoption and use of HTA as an aid to decision-making in health systems. It describes how HTA has allowed a move from sole reliance on clinical evidence (in which it includes “unilateral” industry information), clinical opinion/consensus or ‘gut feelings’. It embraces expansion of the scope of HTA to include not just assessment of the value for money of new health technologies but also reviewing existing technologies, interventions and organisation structures and potentially disinvesting from those that are ineffective and obsolete.

The report advocates expanding the breadth of technologies to be evaluated (albeit this raises the question of whether the same methods, tools and principles will apply to different technologies) and emphasises continuing methodological research and development in HTA, educational and training programmes and appropriate supporting policies and legislation (to anchor and mandate HTA), proactive identification of technologies that will improve healthcare quality and reduce costs, and the need for greater convergence between health priorities and innovation.

The report also advocates a step-wise approach to institutionalization of HTA (i.e., ‘promoting the structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes’.) The report also highlights a number of issues relevant to classification of HTA systems.



First is having a definition of what is a 'health technology' and what health technology assessment is or involves. According to the EUnetHTA report, a health technology is 'any [health] intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organizational systems used in health care'. In the EUnetHTA (2008) report health technology assessment is defined as 'a multidisciplinary process that summarizes information about medical, social, economic and ethical issues related to the use of health technology in a systematic, transparent, unbiased, robust manner. The aim of HTA should be to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve the best value'.

Second, EUnetHTA (2008) recommends labelling HTA systems according to:

- The working level of the HTA organization (i.e., whether it is local-regional, national, local-regional and national, international, national and international, local-regional, national and international)
- Profile of the HTA organization (i.e., whether it is a governmental agency, compulsory health insurance, other private company, professional association, private medical insurance or other)
- Who took the initiative in establishment of HTA organizations (i.e., whether it is only governmental, governmental, decision-makers and researchers, only health researchers, health researchers and decision-makers, only decision-makers and other)
- Whether there is collaboration, at the international level, between HTA institutions. The type of collaboration is separated into: academia, governmental agency, professional associations, hospital, industry, patient associations and other
- Who are the results and findings of HTA disseminated to (is it public healthcare providers, policy makers, health professionals, professional associations, health-related professionals, health service researchers, researchers, compulsory healthcare insurance, pharmaceutical/ devices industry, patient groups/carers, private healthcare providers, media, general public, private medical insurance, consumer associations?)

Third, the EUnetHTA (2008) report considers the possibility of adapting HTA results from one context to another (something which requires greater 'standardisation' of country-specific methods) although it recognises the lack of generalisability of clinical and most economic data; for instance, there are problems of generalising data collected in clinical trials to routine clinical practice as well as economic (cost) data from one place to another. When there is no evidence at all, or it is impossible to adapt HTA findings from one context to another, performing and commissioning primary research (where feasible) to answer the assessment question will be needed.

Another relevant report is that by Sorenson, et al. (2008), which provides a general look at the role and functions of HTA and supports this with a number of case studies on European countries.

The article presents country HTA case studies under a number of headings that we considered as a potential useful and helpful guide in developing taxonomy of HTA systems. These headings are depicted in Table 1 below. To this list of headings we add from Hailey and Juzwishin (2006) another useful dimension for classification of HTA systems. This article's objective was to identify issues (referred to as 'risks') that institutions that perform HTA should consider and how these risks could be managed. These risks and approaches to their management were compiled from opinions of members of the International Network of Agencies for Health Technology Assessment (INATHA). The authors identified 21 'risks' categorized under the headings: formulation of HTA questions, preparation of the HTA product, dissemination and contracting.

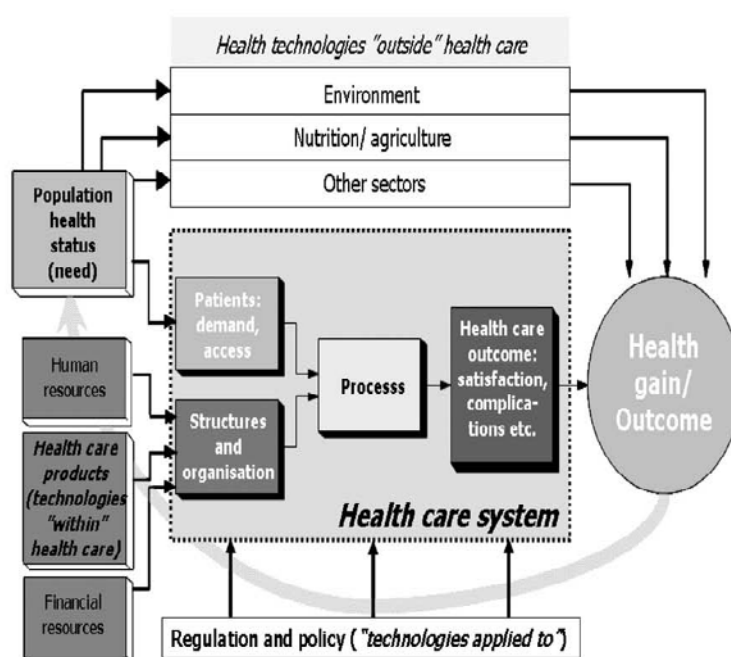
**Table 1: A characterization of HTA systems**

HTA governance and organization	<ul style="list-style-type: none"> <li>▪ <b>Institutions/committees</b></li> <li>▪ <b>Entities responsible for reviewing HTA evidence for priority setting and decision-making</b></li> <li>▪ <b>HTA agenda-setting body</b></li> <li>▪ <b>Reimbursement requirements and limitations</b></li> <li>▪ <b>Stakeholder involvement</b></li> <li>▪ <b>International collaboration</b></li> </ul>
HTA topic selection and analytical design	<ul style="list-style-type: none"> <li>▪ <b>Governance of topic selection</b></li> <li>▪ <b>Criteria for topic selection</b></li> <li>▪ <b>Criteria for assessment</b></li> <li>▪ <b>Criteria outlined or publicly available</b></li> <li>▪ <b>Analysis perspective</b></li> <li>▪ <b>Duration required to conduct assessments</b></li> </ul>
Evidence requirements and assessment methods	<ul style="list-style-type: none"> <li>▪ <b>Documents required from manufacturer</b></li> <li>▪ <b>Systematic literature review and synthesis</b></li> <li>▪ <b>Unpublished data/grey literature</b></li> <li>▪ <b>Preferred clinical study type/evidence</b></li> <li>▪ <b>Type of economic assessment preferred or required</b></li> <li>▪ <b>Availability of guidelines outlining methodological requirements</b></li> <li>▪ <b>Methodological requirements covering issues such as choice of comparator, specification of (preferred) outcome variable, subgroup analyses, type of costs (direct or indirect), incremental analysis required, time horizon, equity issues, discounting, modelling, sensitivity analyses, CE or WTP threshold, sensitivity analyses, missing or complete data and support for methodological development</b></li> </ul>
HTA dissemination and implementation	<ul style="list-style-type: none"> <li>▪ <b>Channels for HTA dissemination</b></li> <li>▪ <b>Use of HTA results</b></li> <li>▪ <b>Evidence considered in decision-making</b></li> <li>▪ <b>Any reported obstacles to effective implementation such as legal proceedings etc.</b></li> <li>▪ <b>Formal processes to measure impact</b></li> <li>▪ <b>Process for re-evaluation or appeals</b></li> <li>▪ <b>Accountability for stakeholder input</b></li> <li>▪ <b>Transparent/public decision-making process</b></li> </ul>

### 6.3 Where does HTA fit into the healthcare system?

Garrido, et al. (2010) discuss a way of fitting HTA into health systems. They start by describing an input-output model (Figure 5) where the health system contributes to the production of health through processing two types of inputs: (1) risk-related inputs (i.e., the incidence and prevalence of disease and disability that affects the health status of the population) and (2) resource-related inputs (i.e., the financial, human and technological resources devoted to the production of healthcare). The paper broadens the definition of 'health technologies' to include more than just medical products since health production requires healthcare and non-healthcare inputs.

Figure 5: Input-output model of the healthcare system: Garrido et al (2010)



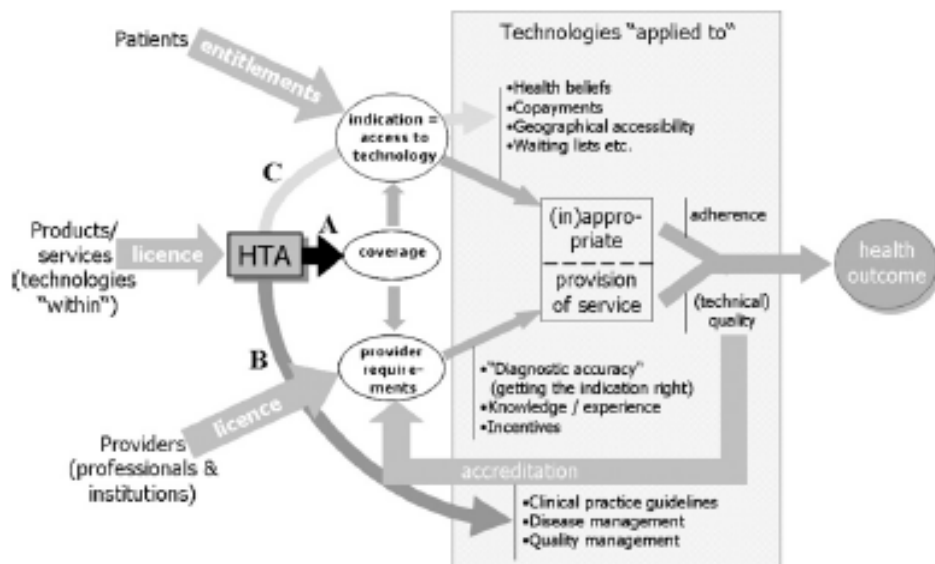
They describe three types of 'health technologies': (1) healthcare products like drugs, devices and procedures used for the production of health services [so-defined as technologies applied within the healthcare system] (2) technologies applied to the healthcare system in order to organize access, service delivery, payment of providers etc. [i.e., regulatory and policy measures on 'patient demand/access', 'structures and organisations', 'processes', 'healthcare outcomes'] (3) technologies that promote and protect health outside of the health system (for instance public transportation, educational and social services etc.). Health is produced from a combination of these three types of 'health technologies'.

The authors argue that selecting the right 'health technologies' is important for everyday management, organisation and delivery of healthcare and health. They note that policy-makers and health planners rely on different sources of information on health technologies: evidence from research and 'colloquial evidence' including expert and profession opinion, political judgement,

interpretation of values and traditions, and views from stakeholders. HTA is defined as systematic knowledge that fills the gap between scientific knowledge and decision-making; HTA is a tool for knowledge management and an aid to decision-making.

The paper argues that HTA needs to be developed further (in response to demand for information by decision-makers) in two areas: the underlying methodological approach, and extension of HTA to assessment of other health technologies besides healthcare products. So far HTA has been almost exclusively applied to decisions regarding availability and reimbursement of healthcare products and services. It is better, the paper argues, to extend HTA to cover other health technologies (as they are also inputs for healthcare and health production). Figure 6 below shows the current focus on HTA and its possible extension to other two types of health technologies.

**Figure 6: HTA within the healthcare system: current application to coverage decisions (A) and proposed expansion of HTA role (B and C): Garrido et al (2010)**



By assessing the clinical and economic value of the three types of health technologies, HTA can contribute to achieving 'community effectiveness' (in routine clinical practice) that is as close as possible to efficacy levels measured in controlled clinical trial settings. The paper concludes by suggesting that countries embarking on HTA (including low- and middle-income countries) should not consider establishing completely separate agencies for HTA, quality development, performance measurement and health services development; but rather combine these agencies into a common knowledge or evidence synthesis strategy for evidence-informed decision-making.

## 6.4 A dynamic perspective to HTA development

Battista and Hodge (2009) conclude from analysing a number of country’s experiences with implementation and operation of HTA that HTA goes through three different phases of development: namely, the ‘emergence’, ‘consolidation’ and ‘expansion’ of HTA. Under each phase, one needs to answer the following questions: the rationale for HTA (Why?); the definition of the scope and breadth of HTA (What [HTA is about]?), the methods and organizational models of HTA (How [HTA is conducted]?); and the knowledge transmission strategies (Then what [happens next]?). This pathway of HTA development fits very much with the characterisation of HTA system presented in Table 1 and Figure 6. In this case, ‘what’ will cover issues around HTA topic selection and analytical design; ‘how’ will cover issues around ‘HTA governance and organisation’ and ‘evidence requirements and assessment methods’; and ‘then what’ will cover issues relating to ‘HTA dissemination and implementation’.

**Figure 7: The ‘natural’ history of HTA development: Battista and Hodge (2009)**

	Emergence	Consolidation	Expansion
Why?	<ul style="list-style-type: none"> <li>● Convergence of needs, demands, and supply</li> <li>● Key individuals are “Champions” of HTA</li> <li>● Receptive policy/political environment</li> </ul>	<ul style="list-style-type: none"> <li>● Early successes attract interest of more decision makers</li> <li>● Expansion of demand for HTA products</li> <li>● Formalized priority setting process</li> </ul>	<ul style="list-style-type: none"> <li>● HTA as part of official political discourse</li> <li>● Increased demand for diversified products</li> </ul>
What?	<ul style="list-style-type: none"> <li>● Narrow interpretation of health technology</li> <li>● Focus on high intensity technology (Imaging)</li> <li>● Exclusion of pharmaceuticals</li> </ul>	<ul style="list-style-type: none"> <li>● Broadening of scope of HTA</li> <li>● Possible addition of pharmaceuticals</li> <li>● Shift from specific technologies to care processes for the management of health conditions</li> </ul>	<ul style="list-style-type: none"> <li>● Further broadening of scope of HTA (pharmaceuticals, public health, delivery models, social services)</li> <li>● Existing practices and new interventions</li> </ul>
How?	<ul style="list-style-type: none"> <li>● Modest resources, at times project or deliverable specific</li> <li>● Minimal scientific capacity</li> </ul>	<ul style="list-style-type: none"> <li>● Expansion of scientific team</li> <li>● Modest addition of resources</li> <li>● Research partnerships sought</li> </ul>	<ul style="list-style-type: none"> <li>● Significant increase in resources</li> <li>● Expansion of scientific team and partnerships</li> <li>● Diversification of products</li> <li>● Clinical practice guidelines</li> </ul>
and, Then What?	<ul style="list-style-type: none"> <li>● Knowledge translation minimal</li> <li>● Efforts directed to policy makers, often by means of personal communication</li> </ul>	<ul style="list-style-type: none"> <li>● Progression of knowledge translation efforts</li> <li>● Broadening of target audiences</li> </ul>	<ul style="list-style-type: none"> <li>● Consolidation of multiple target audiences</li> <li>● Specialization of KT instruments</li> <li>● Increased proportion of resources to KT</li> </ul>

Figure 7 above summarizes the ‘natural’ history of HTA. This framework suggests that one can initially adopt a narrow definition of ‘health technology’ and over time as HTA systems mature in terms of scientific capability (or generally speaking having adequate managerial and operational capacity), apply the methods and concepts of HTA to all other ‘health technologies’ as broadly defined by Garrido, et al. (2010). However, Battista and Hodge (2009) note that this ‘natural history’ will vary from country to country as determined by the timings and determinants of transitions from one phase to the other; which in turn will be influenced by contextual factors such as culture and how the tensions between the academic side of HTA and decision-makers is managed.

In a commentary on the paper by Battista and Hodges (2009), Zavalla (2009) notes that the level of economic development has a major influence on the pathway for HTA: countries will only develop

interests in HTA only when basic needs have been met and the country-specific health system can deliver a 'reasonable level of healthcare'. Zavalla (2009) notes that commitment; dedication and persistence are essential materials for continued sustenance of an HTA program.

## 6.5 Applying HTA Frameworks

The HTA literature is helpful in understanding how HTA can evolve and how it can be categorised. Our assessment is as follows:

- The Garrido, et al (2010) identification of different types of “health technologies” is important. It is echoed by the EUnetHTA (2008) report which includes in its definition of a health technology “organizational systems used in health care”. HTA is usually thought of as applying only to technologies applied within the health care system – a drug, a device, a surgical procedure or other medical intervention. We include in this type the use of HTA to generate clinical practice guidelines to manage the patient through a care pathway where a mix of technologies will be applied in sequence depending on the condition and characteristics of the patient, although HTA of guidelines could well involve addressing organizational issues. The application of evidence-based analysis to the other type of “health technology”, i.e. “organizational systems used in health care”, is a separate but crucial use of HTA that is often overlooked. Here HTA is being applied to elements of the architecture or framework of the health care system. This could include:
  - e) The architecture of service delivery. For example, is it more efficient to provide services in community facilities or in hospital?
  - f) Which types of payment mechanisms from purchasers to providers are likely to be most efficient?
  - g) How much autonomy should publicly owned enterprises have? Should more encouragement be given to private providers to supply services to meet the needs of patients within a publicly financed insurance scheme?
  - h) The mix of the clinical and related workforce. When can services be provided by nurses or other professions allied to medicine rather than a qualified doctor?

We term the first use of HTA as a focus on “micro-technologies”, such as new drugs, that are seen as incremental or “marginal” to the system. The second use for HTA is reviewing “macro-technologies” comprising elements of the architecture or framework such as how the system is organised (number and types of hospitals and physicians).

We note the suggestion by Garrido, et al (2010) that countries embarking on HTA (including low- and middle-income countries) should combine agencies looking at micro and macro HTA, quality development, performance measurement and health services development. This is because this work should involve a common core set of skills for evidence synthesis to underpin evidence-informed decision-making. Again, countries do not currently tend to do this. Most HTA bodies do not even address “macro” HTA issues, let alone broader design and

performance issues. In the UK, for example, NICE in England has now been given a greater role in “macro” HTA issues relating to quality development and the efficient delivery of health care services, but has no role in performance management. In the US, we can note that the Institute of Medicine Report (Institute of Medicine, 2009) on priorities for US Comparative Effectiveness Research set out 100 priority topics of which

*“Almost one-fourth of the committee’s recommended priority topics are classified primarily in the health care delivery system (HCDS) research area. This is a broad category that includes topics related to dissemination of CER study results; patient decision making, health behaviour and care management, comparing settings of care, and utilization of surgical, radiological, and medical procedures”* (page 117)

It remains to be seen whether CER work in the “macro” HTA area will be commissioned in the US. In most countries issues related to system design tend to be kept “in-house” within the Ministry of Health. This may lead to them being less evidence based.

2. The characterisation of HTA systems by Sorensen, et al. (2008) according to: governance; topic selection; evidence and assessment methods; and dissemination /implementation is a useful reminder of the elements that need to be explicitly understood in any use of HTA. In the early use of HTA by health care systems little systematic thought may be given to a number of these elements. The HTA process is a de facto “black box.”
3. The natural history of HTA developed by Battista and Hodge (2009) is helpful to developing thinking about the use of HTA in Emerging Markets. Two particular points are of note.
  - c) HTA initially seems to emerge as an “ideas transfer” from academics and policy practitioners based in more developed health care systems and can appear to be a “product” without an obvious market. If HTA has no influence on the way patients are treated because it is not disseminated or there are no incentives (professional or financial) to use the information then the investment in HTA is wasted.
  - b. Whilst we might expect the initial most valuable use of HTA to be identifying key public health and “low tech” interventions that can maximise health gain for little expenditure (targeting for example vaccinations, maternal and neo-natal mortality) an early interest is often in its use to review expensive technologies (usually medical devices). This is because these technologies are seen as cost-drivers challenging the financial sustainability of emerging insurance systems or public subsidies to providers. New pharmaceuticals often fit into this category and become an early target for HTA. Yet the real concern is cost containment rather than identifying value.

Thus it is not at all obvious that HTA is initially used in an effective way by health care systems.



## 7 Our conceptual model for understanding HTA in emerging markets

### 7.1 Developing the conceptual model

In this section, our aim is to develop a simple conceptual model to describe, and propose hypotheses about, the relationship between the use of HTA and the characteristics of health care systems. Relying on material from previous sections of this report, we begin by proposing a simple taxonomy of health care system and of HTA characteristics respectively. We then propose a conceptual model in which the evolution of HTA is related to two key characteristics of the health care system.

Health technology appraisal (HTA) is defined, for our purposes, as the application of any given set of principles, methods and processes to evaluate one or more of specific health care technologies, combinations of health technologies to manage patient pathways (clinical practice guidelines) or other elements of system architecture (“technologies applied to the health system” as described by Garrido et al, 2010). We have used the terms “micro” and “macro” technologies to distinguish between these. Micro technologies are those that relate to specific treatments or combinations of interventions. Macro technologies relate to the way specific treatments or services are delivered within the infrastructure or architecture of the health care system. The latter includes, in its broadest sense, the state of technology that underpins the way health care is organised and managed at the system wide level. HTA in both cases entails an evaluation process which occurs within the context of a health care system.

HTA can be considered as a response to the concerns of that system, and to be shaped by the health care system’s characteristics. For example, the outputs of HTA – knowledge about effectiveness and cost effectiveness of health care – have ‘public good’ characteristics. This has implications for its use in a competing health care insurer environment. It is not obvious that any single insurer has an incentive to invest in evidence generation that will benefit all insurers. The impact of HTA therefore depends on a wider set of health system factors that define the underlying ‘architecture’ of the health care system. That ‘architecture’ might be thought of as comprising of an existing bundle of healthcare services, health technologies, medical practices and traditional ways of organising and delivering these services. The regulatory framework, reimbursement systems for providers and system of fees/subsidies to patients together define the incentives and behaviours of the actors in the system. As we have stated that architecture might itself be considered to comprise set of related ‘macro-technologies’, i.e., an (imperfect) state of knowledge about the way health care can be delivered and organised.

The effects of HTA outputs, in terms of behavioural change by commissioners and providers of care, and on technical and allocative efficiency, are therefore also determined by the wider set of factors we have characterised as the ‘architecture’ of the health care system. For example, the adoption of new technologies recommended by HTA may depend not only on the dissemination of HTA findings but on incentives to commissioners and providers to invest in new technologies (and to disinvest in ‘old’ technologies).

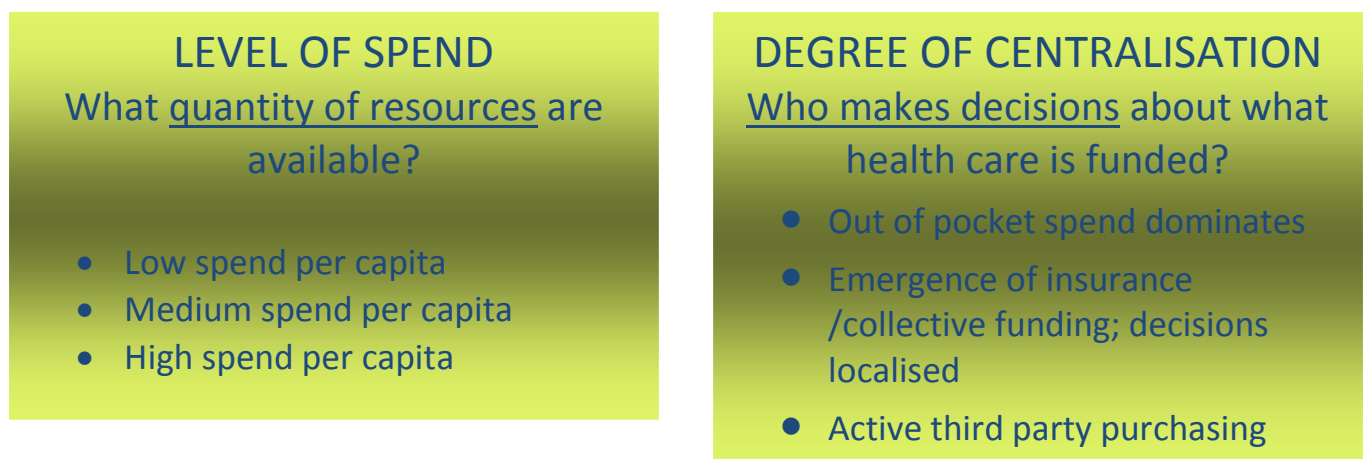
We noted from the literature reviews conducted that many health systems typologies exist (see Section 2). While the purpose of these taxonomies is to usually describe health systems, developing these classification systems is unavoidably normative: which categories are selected relies on researcher value judgements, which will be influenced by prior beliefs about what is important, and by what question is being asked and so forth. Taxonomies are ‘stylised models’ of the real world and there is a tension between keeping it simple (to enable comparisons and contrasts to be drawn) and the ability of such models to provide an adequate account of the reality of any given health care system.

The health system taxonomy we propose is highly stylised: it focuses on just two criteria we hypothesise are most likely directly to relate to the evolution of approaches to HTA: the level of spending, and the degree of centralisation in decision making. The HTA taxonomy also comprises two criteria: which technologies are appraised; and what that appraisal process is concerned with.

## 7.2 The health care system typology

Our health care system typology is depicted in Figure 8 below.

**Figure 8: Health care system typology: two key attributes/variables and levels**



Level of spend is readily understandable. It inevitably shapes the nature and priorities of the health care system. By the “degree of centralisation” we are combining two related but distinct features of the financing arrangements for an evolving health care system:

1. The extent to which there is third party coverage and so an interest in the use of both “micro” and “macro” technologies that goes beyond the provider-patient relationship that dominates an out-of-pocket spend environment.

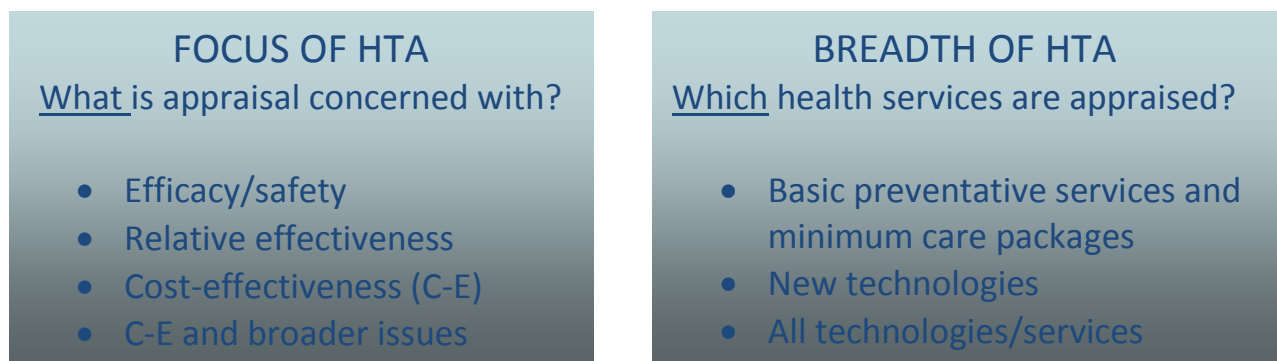
2. The extent to which there is active rather than passive purchasing by the third party insurer. Related to this is the degree of national level regulation as to what is included in the insurance package offered to enrollees.

Our HTA taxonomy is depicted in Figure 9 below. The two drivers are:

1. The focus or content of HTA in terms of the degree of complexity of the question that is asked, ranging from “is it safe?” to “is this good value given society’s preferences and resources?”
2. The types of technologies covered which we refer to as the breadth of coverage of HTA.

We apply this taxonomy to the “macro” as well as “micro” use of HTA. Changes in health system architecture such as an organisational change are included in the “breadth of HTA” within “all technologies/services” appraised, and the focus of any appraisal of such an organisational change would typically go beyond a consideration of cost and potential health gain (cost-effectiveness) to include broader issues, for example relating to the responsiveness of the system and its ability to deliver access.

**Figure 9: HTA typology: three key HTA system attributes/variables and levels**



### 7.3 Considering these typologies together

Using Figures 8 and 9, we can seek to describe (characterise) any given health care system and its HTA processes. We can also develop hypotheses about how the characteristics of a health care system (and the way that system evolves) might be reflected in its HTA processes (and how those processes evolve). Furthermore, we can generate an overall framework for predicting how the ultimate effects of HTA (for example, in terms of behavioural change by health care commissioners and providers; and impacts on technical and allocative efficiency) will be influenced by the underlying health system ‘architecture’. Putting the two typologies together, we develop the conceptual model depicted in Figure 10 below and seek to explain the interactions between health care system and HTA characteristics.

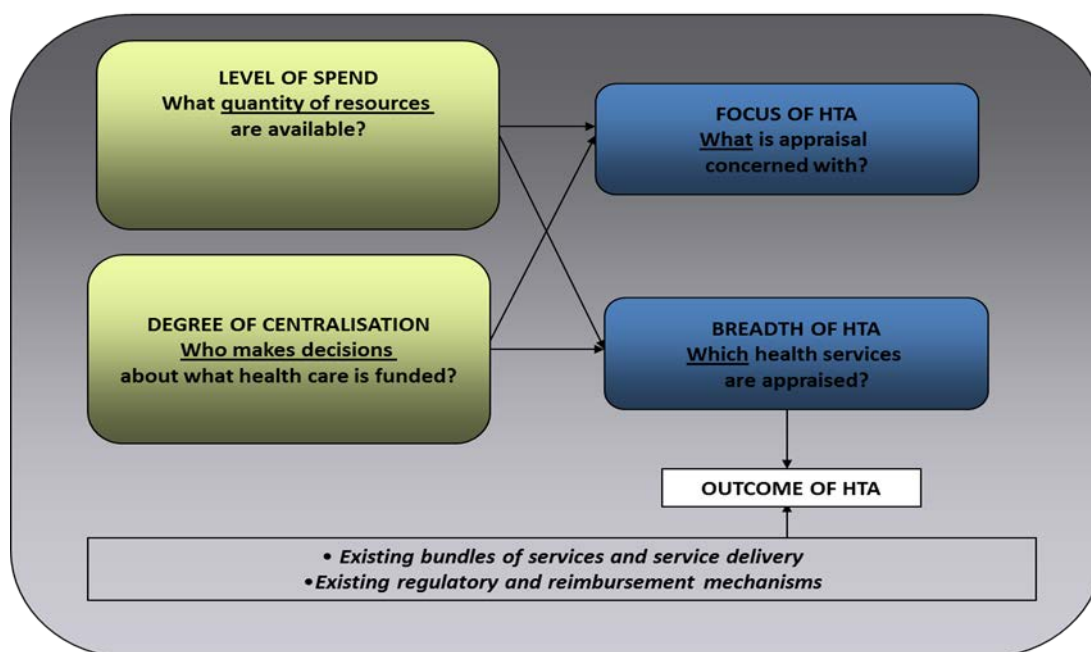
### 7.3.1 The breadth of HTA: which health technologies are appraised?

#### The impact of spending levels

At low levels of resources, HTA will tend to focus on identifying which basic services and interventions are priorities. System architecture issues should also evolve with spending. Initially there should be a concern about the configuration of health care delivery. Where will preventative services be delivered? International agencies and funding bodies may well provide assistance in transferring HTA knowledge on these issues from elsewhere or in enabling local HTA to be conducted. As spending increases, immediate pressure on resources may ease, but increases in spending will inevitably be out-matched by increases in expectations and demands. In particular, tackling chronic disease is likely to become more of a problem. There will be potential for HTA to look at clinical practice guidelines for disease management. HTA processes will often also focus on new potential sources of demand, i.e., new health care technologies, because these are seen as a driver of cost. At high levels of spend, concerns about the inability for supply to match demand will lead to pressure to extend the use of HTA into extant services, as well as new technologies, and the identification of candidates for disinvestment. Questions of how the health care system is best organized will arise at all levels of spending, although the nature of the issues will change, in part reflecting the relationship between financing and economic growth, impacting on the nature of the disease burden and the demography of the population, but reflecting the cumulative experience and history of financing and delivery arrangements in a particular country.

Figure 10: A Conceptual Model of Health Care Systems and HTA

### The conceptual model



## The degree of centralisation

Where health care is predominantly paid for out of pocket, which health care services and products are funded is a product of the decisions made by individual patients and their doctors. There is little incentive for collective decision making about health care technologies, other than in relation to questions as to whether services such as vaccination are provided by the public sector. Whilst, in principle, there would be a role for HTA in a self-pay market in providing evidence to doctors and patients about “what works,” opportunities for dissemination may be limited and it is not clear who would fund such an exercise. As third party funding develops, it is in the insured group’s interest to ensure that claims on those funds are justified. Decisions become localised at the level of the health care plan. However, it may be some time before insurers begin to actively manage providers. Initially they may simply pay bills on a “fee-for-service” basis. Over time, however, more active purchasing is likely to evolve. The initial focus may be on those services which are *highest cost*. Where health care funding is predominantly collective (for example, in a fully tax-payer funded system) decisions about health care may become increasingly centralised. Governments and third party payers will argue it is in the interests of all members of society as enrollees or taxpayers that funds are used efficiently. Ultimately, all services will be seen as candidates for HTA. Key aspects of system architecture such as payment mechanisms and incentives will also come under scrutiny and so candidates for “macro” HTA to assess their cost-effectiveness in delivering health gain and broader societal objectives for the health care system.

### 7.3.2 The focus of HTA: what is the appraisal concerned with?

#### The impact of spending levels

Very low levels of spending are associated with high levels of preventable mortality. Where used, HTA will be concerned primarily with the *effectiveness* of services to address the most serious causes of death. International aid funding will act to accelerate the adoption of formalised approaches to HTA, adapted from those of donor countries, concerned about maximising the beneficial effect of aid. As levels of spending increase, there is a shift to chronic disease management and the number of feasible treatment options within any given disease area increases; the focus shifts to the *relative* effectiveness of various options. Higher levels of spending coincide with an acceleration of the ‘epidemiological transition’: at the same time, the availability of substitute technologies will continue to increase. These factors, together, act to raise the issue of *cost effectiveness*. As we have noted, the availability of imported expensive technologies may create an early concern around cost containment, which may motivate an early interest in the use of HTA as an entry hurdle.

#### The degree of centralisation

Where health care decisions are made by passive purchasers, there are limited incentives to conduct HTA. Such HTA as is performed will be to meet whatever regulatory barriers exist to bring products/services to the market, e.g., *safety and efficacy*. We have noted the potential interest of doctors in “what works” but in a decentralised health care system it is unclear who has an incentive to generate or disseminate this evidence. As third-party funding increases, those controlling budgets will be concerned to establish *effectiveness* of services to which the ensured population is eligible, as

a means of managing demand. As the balance of decision making shifts from local to more centralised bodies and there is also a shift to more active purchasing, there will be increased willingness to use of HTA knowledge to inform decisions about (limiting) access to health care. Where decisions are made centrally, there is no competitive advantage in offering services that are effective, but poor value for money: cost effectiveness may become the dominant consideration. A concern only with cost-effectiveness is unlikely to be acceptable to patients, doctors and the insured. A broader perspective including ethical issues will need to be taken into account. As centralisation increases there is also a greater interest in “macro” HTA issues around the design and architecture of the health care system so improve efficiency and effectiveness.

### **Using the conceptual model**

In the next section of the report we use this framework to inform our understanding of the three emerging market health care systems. Several issues immediately become apparent:

1. The early interest in the use of HTA for new technologies is usually driven by a concern about cost rather than any system wide focus on achieving value.
- The potential importance of evidence-based clinical practice guidelines in managing chronic disease in a decentralised health care system.
3. The conventional focus on the use of HTA for “micro-technologies” rather than other aspects of system architecture.

## 8 Health Care systems and HTA in Brazil, China and Taiwan

### 8.1 Sources of Information

Information relating to healthcare systems and HTA use in the three countries, Brazil, China and Taiwan, was obtained using a number of different processes. These are outlined below. Throughout, local information relates to that published within the country.

- 1) A number of literature searches were performed using PUBMED, Google and Google scholar. Key words utilised in these searches included: (“Health technology assessment” OR “HTA”) and (Brazil OR China OR Taiwan). The article section based on these results was then refined using the title and filtering out studies that were disease or drug-specific. These searches were supplemented by reviewing a number of key papers identified by the steering group or based on the knowledge of team members.
- 2) Key health statistics, such as healthcare spend per capita, can help to complement the literature in creating a broad picture of the healthcare system of a country. As such, a number of statistics for each of the countries was identified using key international data sources, primarily WHOSIS and WHO global health indicators. Google searches were also performed. Where information was not available through international sources or where the internationally published data conflicted with the local information, it was supplemented by the local team members, with preference given to the locally published data, where this was considered to have a greater degree of accuracy. The findings are included in Table 2
- 3) In order to gain a more in-depth and up-to-date understanding of the healthcare systems and HTA processes in these countries, a number of local experts in the field were identified, and local team members utilised to conduct interviews with these experts. A scope for the interviews was formulated by considering the information available in the international literature and ensuring that the scope would be sufficient to form a broad picture of the healthcare systems in conjunction with HTA processes for the three countries. To help ensure that the interview scope would cover the key features and provide sufficient information to classify HTA within that country, available information based on the international literature was utilised to complete a pre-existing classification system (Chalkidou, 2009), and questions were incorporated that would ensure this classification could be fully completed with the completed interview scripts. See Appendix 4 for the interview scope. In total, six interviews of local experts were performed by the local team members. The local experts were identified by a process of consultation between team members, including the local members of the team, with valuable input from members of the steering group. Additional potential experts were identified based on the key international literature. See Appendix 5 for a list of those interviewed. See Appendix 6 for a summary of the findings from the interviews.
- 5) In addition to the international literature identified as described in 1), local/grey literature also provides useful insights into the healthcare systems and HTA processes for these countries.

Table 2 Key health statistics relating to the three countries and comparative groups of countries by income.

	Brazil	China	Taiwan	Low income	Low middle income	Upper middle income	High income
Total population	193million (2010) <sup>3</sup>	1,344,920 (2008)	23,119 772(2009) <sup>7</sup>	975,322	3,770,921	954,057	1,037,180
Gross National income per capita (PPP int \$)	10,070	6,020	28,005 (2006) <sup>5</sup>	1,372	4,363	12,337	37,750
GDP per capita \$	10,471 (2010) <sup>5</sup>	4,283 (2010) <sup>5</sup>	18,304 (2010) <sup>5</sup>	GDP per capita in OECD \$33,700(2008) <sup>2</sup>			
Infant mortality rate	18 per 1000 live births	18 per 1000 live births	5.3 per 1,000 live births <sup>4</sup>	76 per 1000 live births	44 per 1000 live births	19 per 1000 live births	6 per 1000 live births
Life expectancy	73yrs (2008)	74yrs (2008)	78 yrs <sup>4</sup>	57yrs	67yrs	71yrs	80yrs
Total healthcare % GDP	8,4% (yr 2007)	4.5% (yr2006)	6.17% (2007)	4.7%	4.4%	6.2%	10.2%
Total healthcare per capita	US\$ 606 (average exchange rate) or 837 (PPP int \$)	\$90 (yr2006)	\$744 (2001) <sup>8</sup>	\$14	\$34	\$221	\$2657
Hospital beds per capita	24 per 10,000 (yr 2000-2009)	22 per 10,000 (yr2000-2009)	42.2 per 10,000 (yr 2009) <sup>7</sup>	15 per 10,000	18 per 10,000	39 per 10,000	58 per 10,000
Physicians per capita	17 per 10,000 (yr 2000-2009)	14 per 10,000 (yr2000-2009)	18.7 per 10,000 (yr 2009) <sup>7</sup>	4 per 10,000	10 per 10,000	24 per 10,000	28 per 10,000
Out-of-pocket expenditure as percentage of private expenditure on health	58.8% (2007)	85.30% (2005)	58.9% (2006) <sup>6</sup>	83.1%	90.5%	69.0%	36.1%
Private expenditure on health as percentage of total expenditure on health	58.4% (yr 2007)	58.0 (yr2006)	40% (2007) <sup>6</sup>	58.1%	57.6%	44.8%	38.7%
Private prepaid plans as percentage of private expenditure on health	39.4% (2007)	7.1% (2007) <sup>6</sup>	32.5% (2006) <sup>6,9</sup>	3.7%	5.3%	26.4%	51.4%
How healthcare is financed	Brazil has a Unified Health System called SUS that in theory covers 100% of the	China relies on various health insurance schemes	National health insurance program since 1995. Under				



	<p>population. Its funding comes from taxes and social contributions. There's a mix of federal, state and municipal funds. No co-payment is applied.</p> <p>For the private sector, funding comes from individuals and also from companies that pay private insurance for their employees.</p>	<p>to cover its urban and rural populations. Private medical insurance mainly in the form of offering complementary or supplementary health insurance benefits.</p>	<p>this scheme employers pay 60%, employees 30% and government 10%</p>				
Coverage	<p>From the Brazilian constitution (1988), health is a citizen's right and an obligation of the State. So in theory 100% of the population is covered by the Brazilian Unified Health System (Public Health Care System). The incorporation of technologies is however very slow and many "old" treatments are still offered. 21% of the Brazilian population is covered by the private health care system. The private HMOs pay for everything that is used in ambulatory or in-hospital setting. Treatments that can be taken at home are not covered. This has raised many problems for oral expensive treatments like oncology drugs, for example. Many patients go to court to get their private insurers or the government pay</p>	<p>There are four major medical insurance schemes: (i) the New Rural Cooperative Medical Insurance covering nearly 850 million people or more than 90% of the rural population In China; (ii) the Urban Resident Basic Medical Insurance which covers over 100 million urban residents (iii) the Urban Employment Basic Medical Insurance, which covers more than 200 million urban employed population (iv) Private Medical Insurance which</p>	<p>National Health Insurance (NHI) is a premium-based, single-payer, mandatory, near-universal insurance program run by the government to allocate health-care funds. The system promises access to all necessary health care for citizens with national identity cards. In 2000, the coverage already amounted to over 96% of the total eligible population, and that percentage has increased each year since NHI first</p>				

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	for their treatments.	covers 6% of urban dwellers and 8% of rural individuals.	began.				
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**Sources:**

- 1 Unless referenced otherwise data is taken from WHO - Global Health Indicators Part II [http://www.who.int/whosis/whostat/EN\\_WHS10\\_Part2.pdf](http://www.who.int/whosis/whostat/EN_WHS10_Part2.pdf)
- 2 OECD Factbook 2010, OECD
- 3 Brazilian Institute of Geography and Statistics (IBGE) - Projection for year 2010; available at [www.ibge.gov.br](http://www.ibge.gov.br)
- 4 CIA World Factbook. Online
- 5 World Economic Outlook Database 2010, International Monetary Fund
- 6 Department of Health Executive Yuaj, Taiwan, accessed on 25.08.2010
- 7 Year book 2010, R.O.C, Department of Health Executive Yuaj, Taiwan
- 8 Table 10, Policy Options for Health Insurance and Long-term Care Insurance, Y Iwamoto et al, ESRI collaboration project
- 9 OHE calculation based on private expenditure by households not classified as out-of-pocket expenditure

**Definitions:**

**Total expenditure on health (THE)** is the sum of general government health expenditure and private health expenditure in a given year, calculated in national currency units in current prices. It comprises the outlays earmarked for health maintenance, restoration or enhancement of the health status of the population, paid for in cash or in kind.

**Private health expenditure (PvtHE)** is defined as the sum of expenditures on health by the following entities:

**Prepaid plans** and risk-pooling arrangements (prepaid HE): the outlays of private insurance schemes and private social insurance schemes (with no government control over payment rates and participating providers but with broad guidelines from government)

**Firms' expenditure on health:** the outlays by private enterprises for medical care and health-enhancing benefits other than payment to social security or other pre-paid schemes.

**Non-profit institutions serving mainly households (NGOs):** outlays of those entities whose status do not permit them to be a source of financial gain for the units that establish, control or finance them. This includes funding from internal and external sources.

**Household out-of-pocket spending (OOPs):** the direct outlays of households, including gratuities and in-kind payments made to health practitioners and to suppliers of pharmaceuticals, therapeutic appliances and other goods and services. This includes household direct payments to public and private providers of health-care services, non-profit institutions, and non-reimbursable cost-sharing, such as deductibles, copayments and fees for services.

## 8.2 Summary of findings on the three countries

We set out our detailed findings on the health care systems and use of HTA in these countries in Appendices to this report. In this section, we describe some key attributes of the three systems in the context of our discussion of the evolution of health care systems and of HTA.

### 8.2.1 Brazil

We have noted that health care financing evolves over time, moving from predominantly out-of-pocket funding to elements of insurance through to more-or-less universal coverage varying from country to country. Typically employer-based schemes for urban workers begin before schemes covering rural workers who are usually self-employed. In Brazil this was the case with the 1923 Eloi Chaves Law providing for employer-based insurance. The extent to which the various third party payer insurance schemes are combined over time varies from country to country. Some move to a single payer system, others keep multiple insurers and, in some cases, these insurers compete for enrollees. Brazil's current system is the United Health System (SUS) introduced in 1988. It is a single payer universal coverage scheme with significant regional and local variation. There is, however, separate supplementary Private Insurance regulated by the National Agency for Supplementary Health (ANS). Regulated private insurance is the main provider of health care for many citizens (25% of the population) because of the limited financing of the SUS. The ANS fixes maximum premiums and procedures to be covered. These private plans need not cover oral drugs or home treatment.

The element of any developing health care system that arguably evolves the most slowly is purchasing. Initially, insurance coverage typically accepts fee-for-service with the role of the third party payer being to passively pay the bills of the provider rather than actively decide what it is going to cover, who should provide it, and how they are to be paid. Over time, more sophisticated mechanisms for incentivising and rewarding providers tend to be used, notably capitation payments and 'prospective' or case-mix adjusted payments to hospitals. SUS uses diagnosis-related groups (DRGs). HMOs in Brazil are seeking to negotiate DRG-type packages.

Brazil has three programmes for insurance coverage for pharmaceuticals. Covered drugs in all three programs are offered free to patients prescribed them, though, like in most countries, actual access and use vary geographically and by socioeconomic status. The National Commission for Technology Incorporation of the Ministry of Health (CITEC) reviews drugs on the Component of Specialised Pharmaceutical Assistance, which have a high budget impact.

### Issues around the use of HTA in Brazil

Despite the creation of an HTA body (CITEC) focussing on "micro" HTA and hundreds of submissions, the delays in reviews and lack of transparency about the decision-making process have resulted in great uncertainty about its ultimate impact. The following issues and trends arise:

- HTA can be seen as a "black box" with little thought given to appropriate processes to ensure the involvement of stakeholders: clear parameters for decisions have not been made transparent.

- There appears to be unrealised potential for the use of HTA to support the use of evidence-based clinical practice guidelines to manage chronic diseases.
- HTA in Brazil could be a “product” without a customer if HTA decisions do not change the way in which patients are treated. Ambitions for the availability of health care (universality of health care by constitution) are not matched by public financing. It is not clear what role HTA plays in managing this discrepancy.
- Other “macro” elements of system architecture, such as incentives to prescribe and the importance of trading margins, are not being addressed by HTA or other review mechanisms.

Other challenges for the Brazilian health care system:

- There is ambiguity about the role of private insurers. Limited budgets for public health care suggest that a heterogeneous public/private insurer market is likely to continue. Over-regulation of the private sector (i.e. fixing both premiums and minimum packages) has led to many exits. This has also led to a lack of clarity about the appropriate focus of HTA. Is HTA for the private sector also or just for the public sector?
- There is a lack of genuine “arm’s length” bodies and regulation – with direct political influence in specific operational decisions. This links to the fundamental need to distinguish between the different elements of government stewardship of the health care system.

### 8.2.2 China

In China, major health care reform has been underway since 2003 with government-led attempts to re-establish universal coverage lost during the disruption of the early years of market reform in the economy.

- The Urban Employment Basic Medical Insurance (UEBMI) is a mandatory insurance scheme for formal sector workers in urban areas covering 200 million urban employed people.
- The other two insurance schemes are subsidised but voluntary.
  - The New Rural Cooperative Medical Scheme (NRCMS, also known as the NCMS) is a subsidized health insurance scheme for rural populations offering benefits covering primarily inpatient care and major outpatient expenses, with voluntary enrolment on a family basis. The intention is to move the benefit package away from insurance for expensive hospital care to one risk pool for inpatient and outpatient services, encouraging coverage for treatments for chronic conditions.

- The Urban Resident Basic Medical Insurance (URBMI) is a voluntary subsidized insurance scheme for urban residents not in formal employment including children and students.

The Ministry of Human Resources and Social Security (MoHRSS) is responsible for the UEBMI and the URBMI. The Ministry of Health (MoH) is responsible for the NRCMS. The Provinces also play an important role.

### Major issues

- The need to move away from hospital-based services, building a strong primary care based health delivery system with infrastructure building (township health centres (THCs)/village clinics in rural areas; community health centres (CHCs) in urban areas) with the government paying the costs of THCs and CHCs and these centre becoming “gatekeepers.” However, the costs of investing in this additional infrastructure will be high, especially as such reconfigurations are unlikely to lead to hospital closures.
- The need to restructure hospital finances. Many fee-for-service charges are now far below the market price levels. Hospitals are unable to cover costs without other revenue sources including providing services that are not included in the insurance package, so they do not have the right incentives to provide quality care.
- The need for new payment systems. One route currently being developed in some areas is improvements in payment mechanisms for hospitals with the development of “case based” payments, seeking to move away from fee-for-service towards DRG-type payments. These can be linked to clinical protocols derived from practice guidelines providing a “bottom up” way of paying for good clinical practice.
- The need to tackle chronic disease with better prevention and disease management.
- Reducing the incentives for over-prescribing. Given the ability to earn much-needed revenue from the margins allowed in pharmaceutical sales, hospitals therefore tend to provide incentives for doctors to over-prescribe. Drug over-prescription and inconsistent prescription has become a serious problem. Reform is under discussion to replace the 15% margin with a flat rate amount.
- The need to rationalise drug spending. The MoH has also introduced an Essential Drugs List with Provincial procurement to reduce hospital drug expenditures.

A number of these issues are “macro HTA” ones around system architecture and incentives. In relation to the use of HTA, interest in “micro HTA” has been limited:

- The use of HTA is conceptually accepted in government’s documents (for example documents from the NRDC, MoHRSS and MoH) but nothing has been outlined as to the specifics of HTA other than the recent Memorandum of Understanding with NICE. This

focuses on the development of clinical practice guidelines. NICE is looking to “help the MoH build capacity (institutional and technical) and to pilot the development/adaptation of evidence-informed clinical standards for best practice, taking account of efficiency and equity considerations” and with the aim of supporting the Chinese government with the NRCMS reform;

- The use of HTA in the context of pharmaceuticals is a newly developed discipline in China and approaches and methods for conducting HTA are not standardized. Pharmacoeconomic data have not been widely used in management of hospital formularies. However, an increasing number of (international) pharmaceutical companies in China have started using pharmacoeconomic evaluations as supportive evidence in marketing activity.

### 8.2.3 Taiwan

Taiwan has a centralized National Health Insurance plan covering virtually all of the population. Providers are paid on a fee-for-service basis, but are subject to global budget caps that can be used to reduce fee levels across the board. Reimbursement levels for drugs are established based on the degree of “clinical improvement” and in relation to the median of 10 reference countries or to comparable drugs (if no or minimal improvements). HTA applied to drugs has been established only as a “pilot project” in Taiwan and is linked to the reference pricing system. However, providers are free to negotiate lower prices with drug manufacturers. The fact that the reimbursement level is higher than the acquisition cost means that providers are paid more by government than the amount they pay to purchase the drugs. This gives them an incentive to prescribe more. There is a misalignment of incentives which can give providers perverse incentives to provide inefficient but profitable services.

#### Major issues

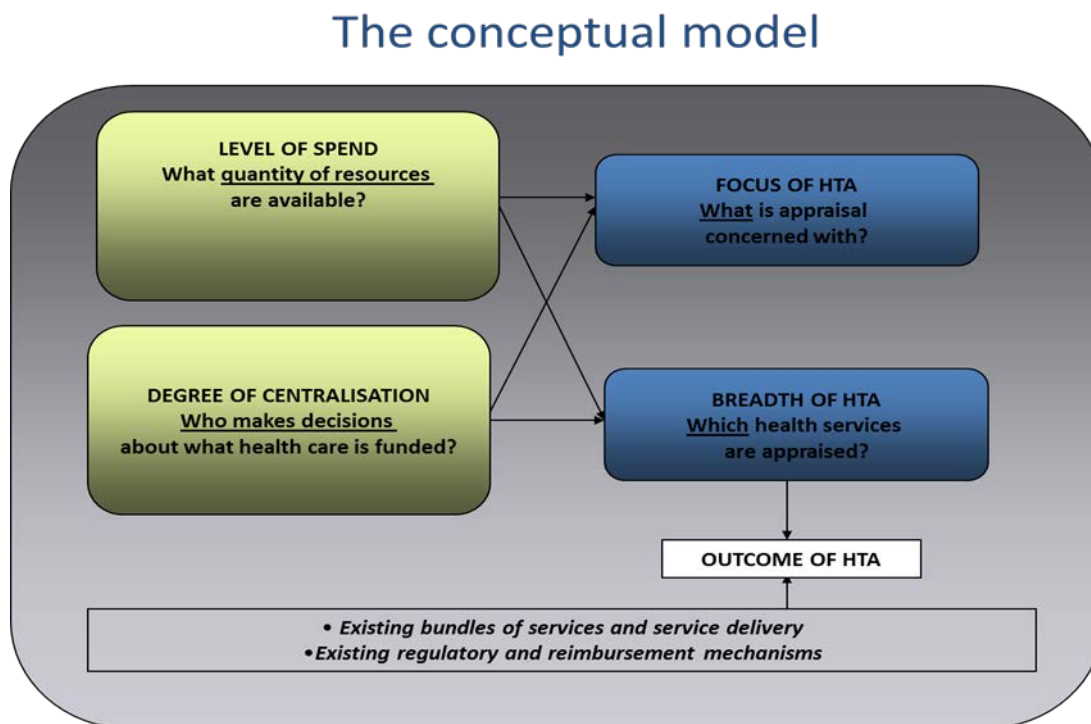
- Whether the new “second generation” of NHI under review in the legislative Yuan, which is expected to be completed in early December of 2010, more clearly defines the role of HTA?
- Whether reimbursement levels will eventually be directly tied to the HTA review and the estimated health gain, or will continue to be based on reference pricing?
- Whether the HTA process will become more open and transparent, involving more structured stakeholder involvement and a more well-defined timeline?
- The need to ensure the independence of the HTA process from undue government and political influence.
- The lack of HTA review of non-drug micro and macro-technologies.

## 9 What role does HTA have in emerging markets? Lessons from Brazil, Taiwan, and China

### 9.1 The Three Markets in the Context of the Model

The objectives of this project, as noted in Section 1, were to produce (i) a categorisation of health care systems and (ii) a categorisation of types of HTA relevant to policy development in the evolving health care systems of low and middle income countries. In Section 6, we proposed simplified taxonomies of health care systems and of HTA approaches, and combined these to provide an overall conceptual model which is summarised in Figure 11 below:

Figure 11: A Conceptual Model of Health Care Systems and HTA



In this section, we draw on the detailed case studies on Taiwan, China, and Brazil included in the Appendices and summarised in Section 7 to:

- Identify common themes and issues across these health care systems with respect to their evolving use of HTA;



- Consider country-specific evidence and issues in HTA in relation to the conceptual framework described earlier in Section 6;
- Critically assess the extent to which there are generalisable conclusions, i.e., lessons, about the role of HTA in emerging markets, and what the limits to those conclusions might be;
- Offer conclusions about how HTA might most usefully evolve in each system, and whether there are generalisable recommendations regarding HTA in emerging markets.

We can see from the Tables and from our analysis that the three countries can be categorised as follows with respect to level of spend and degree of centralisation.

### **Level of spend**

In each of the three countries examined in this report, their economic status as emerging markets is matched by, and reflected in, the development of their health systems to meet the growing expectations about and demands for health care and health.

Brazil is spending around 8% of GDP on health as compared to 4% for China and 6% for Taiwan. Brazil is closest to the OECD average of 10% in 2008 (OECD Health Database, 2010). China is seeking to increase spending on health rapidly to around 6% of GDP.

The development of health care systems in these economies comprises, with varying degrees of speed and ambition, movements toward greater national coordination and consistency – i.e. a planned health system, emerging from the diverse, localised arrangements that characterise lesser developed countries. Especially in the larger emerging markets, such as Brazil and China, this process represents a very considerable challenge. In part, the evolution of health care systems in emerging markets (and the speed with which that takes place) reflects the pace of development of better infrastructure more generally in these economies.

The rapid economic growth and development of these economies is, of course, also a facilitator for the development of the health care system: industrialisation leads to more economic activity being channelled into the formal economy, increasing the potential tax base; and economic growth generates increases in taxation revenue generated from any given tax base. Together these factors make it possible, in principle, to increase the supply of collectively-funded health care and to reduce the reliance on out-of-pocket payments. Each of the three health care systems examined in this report are, to some extent, working toward increasing universality - that is, increasing the share of the population covered by these schemes (although the starting points in each case are very different).

Each is also struggling (in different ways) to reconcile rapidly rising expectations regarding health care with what is currently available in health care terms given available budgets. HTA represents one means by which these tensions may be reconciled – although where, as appears to be the case in Brazil, limits on the resources to conduct the reviews result in substantial delays in access, which is unlikely to be a satisfactory response in the longer term.

The development of collective funding arrangements in itself has the potential to drive up expectations about access to health care. This was particularly evident in Brazil: the emphasis there on health care as a 'constitutional right' creates demands that outstrip available resources. Although the share of Government spend (12% of tax revenue at the state level) is not too far behind developed economies, this still represents a relatively low absolute spend per person (US\$837 compared to \$4028 in OECD countries in 2008 (OHE calculations based on OECD Health database for 2010)).

*Lesson 1: Incomes are growing in emerging markets, but resulting increases in funding for health care are likely to be out-paced by rising demands and expectations. In such situations, HTA may have a role in assisting the health care system to reconcile rapidly expanding demand with more slowly expanding resources. HTA can provide a potential means of handling this in a more explicit and transparent way, and in promoting public debate about priorities.*

- However, addressing 'rationing' in this way requires a willingness to engage in active debate about ways of addressing demand and supply.
- Such a debate will inevitably refer to the appropriate balance between national procurement and individual clinician decision making.

### **Degree of centralisation**

As we have noted, in all three countries the degree of centralisation is relatively high or increasing:

- Brazil has public and private systems but the private system is centrally regulated. There is regional and local control of the public system, but there is a constitutional right to health care, and the three major pharmaceutical programmes are national entitlements;
- China is increasing central control through an expansion of its three public schemes. National oversight is shared with Provincial administration;
- Taiwan introduced a single payer system in 1995, and operates a national benefit package.

In all three countries, however, there appears to be little "active third party purchasing" as we define this in our model in which the payer moves beyond passively administering fee-for-service systems (occasionally cutting or capping fees to contain costs) to deciding actively what it is going to cover, who is going to provide it, and how they are going to be paid. In Brazil, there is some use of DRGs, and in China, an interest in cost-per-case tariffs is emerging. However, there is some way to go before priorities are set and services purchased to meet those priorities.

Another impact of "fee-for-service" as used in China and Taiwan is an incentive to provide additional services, especially those on which additional income can be earned – either because fees exceed costs or because additional revenues can be earned on services not covered by the fee scale. In China, artificially low prices are set for 'basic services': this creates strong incentives for overuse of new technologies, where providers are free to set higher prices. And in Taiwan, the difference between drug acquisition cost and reimbursement payments provides strong incentives to over-

prescribe medications. In each case, the wider ‘architecture’ of the health care system, in terms of reimbursement and corresponding incentives for providers and patients, is resulting in distorted behaviours that in turn result in “second-best” outcomes. In this situation, where some prices (e.g., payments to physicians) differ substantially from true opportunity costs, economic theory suggests that it will not be straightforward to determine optimal prices of other products, such as drugs. Similarly, HTA (in the sense of ‘micro’ appraisals of individual technologies) offers a ‘defensive’ means of countering perverse incentives affecting the uptake of technologies. However, in these circumstances it is likely that there may be less to gain from HTA per se, than from a fundamental review and reform of the underlying reimbursement mechanisms. HTA, in the micro sense, may seem rational, but if it is built upon an underlying structure that is flawed, it may not improve things. If the architecture of the system needs to be changed, then reforms that address this are needed. We have termed the assessment of such reforms as “macro HTA”.

*Lesson 2: HTA of individual technologies is not a substitute for the reform of health care systems. Where health care systems create obviously bad incentives, this type of micro HTA is unlikely to compensate for these failings.*

- HTA should not be approached out of context. HTA should be tied, in a case-by-case way, to what else is going on in the health care system.

#### **HTA typology: the focus and breadth of HTA**

More generally, we observed that in each of the three countries examined in this report, there was a lack of clarity about the purpose of HTA and what role it could (or should) play. Possible objectives, some of which were mentioned in key informant interviews, include:

- Keeping costs down
- Improving clinical quality
- Improving allocative efficiency
- Improving equity in access

It is helpful in this context to remind ourselves of Figure 7 taken from Battista and Hodge (2009) which we reproduce below as Figure 12 which summarises a “natural history of HTA” as they see it.

Arguably:

- China is at the “Emergence” category, with an interest expressed and now a modest investment of resources, notably in the new initiative with NICE around clinical practice guidelines. These are likely to focus on efficacy and relative effectiveness;
- Brazil is between “Emergence” and “Consolidation” with CITEC appraising pharmaceuticals and other procedures. The focus of HTA is cost-effectiveness and the breadth is new technologies. However, resources are modest and the priority setting process is informal;
- Taiwan is at the “Emergence” stage, albeit with an exclusive focus on pharmaceuticals, but with modest resources and minimal scientific capacity. Use seems to be to establish the

degree of innovation by an examination of relative efficacy and then to use reference pricing to establish a price for the product.

**Figure 12: The “natural” history of HTA development**

	Emergence	Consolidation	Expansion
Why?	<ul style="list-style-type: none"> <li>● Convergence of needs, demands, and supply</li> <li>● Key individuals are “Champions” of HTA</li> <li>● Receptive policy/political environment</li> </ul>	<ul style="list-style-type: none"> <li>● Early successes attract interest of more decision makers</li> <li>● Expansion of demand for HTA products</li> <li>● Formalized priority setting process</li> </ul>	<ul style="list-style-type: none"> <li>● HTA as part of official political discourse</li> <li>● Increased demand for diversified products</li> </ul>
What?	<ul style="list-style-type: none"> <li>● Narrow interpretation of health technology</li> <li>● Focus on high intensity technology (Imaging)</li> <li>● Exclusion of pharmaceuticals</li> </ul>	<ul style="list-style-type: none"> <li>● Broadening of scope of HTA</li> <li>● Possible addition of pharmaceuticals</li> <li>● Shift from specific technologies to care processes for the management of health conditions</li> </ul>	<ul style="list-style-type: none"> <li>● Further broadening of scope of HTA (pharmaceuticals, public health, delivery models, social services)</li> <li>● Existing practices and new interventions</li> </ul>
How?	<ul style="list-style-type: none"> <li>● Modest resources, at times project or deliverable specific</li> <li>● Minimal scientific capacity</li> </ul>	<ul style="list-style-type: none"> <li>● Expansion of scientific team</li> <li>● Modest addition of resources</li> <li>● Research partnerships sought</li> </ul>	<ul style="list-style-type: none"> <li>● Significant increase in resources</li> <li>● Expansion of scientific team and partnerships</li> <li>● Diversification of products</li> <li>● Clinical practice guidelines</li> </ul>
and, Then What?	<ul style="list-style-type: none"> <li>● Knowledge translation minimal</li> <li>● Efforts directed to policy makers, often by means of personal communication</li> </ul>	<ul style="list-style-type: none"> <li>● Progression of knowledge translation efforts</li> <li>● Broadening of target audiences</li> </ul>	<ul style="list-style-type: none"> <li>● Consolidation of multiple target audiences</li> <li>● Specialization of KT instruments</li> <li>● Increased proportion of resources to KT</li> </ul>

The set of methods and approaches to clinical and economic evaluation that have come to comprise HTA in developed economies developed alongside (and were shaped by) the particular context and issues encountered in those health systems. The UK NICE, for example, could be thought of as a particular response to issues relevant to the English NHS. The NHS is characterised by public funding, with most health care being ‘free at the point of demand’, but with an increasing shift toward private sector provision. Developing economies and emerging markets typically comprise more complex and varied financing and provision arrangements, and are likely to have different sorts of issues. There is more likely to be a mix of public and private involvement in both financing as well as provision of health care. The way in which the private and public sectors arrangements interact may create specific challenges for the role of HTA. For example, in Brazil it is not clear how the use of HTA by CITEC impacts on the private sector.

However, the HTA methods and processes they are likely to consider adopting come ‘fully formed’ – NICE’s processes, for example, have been particularly effectively disseminated. In Taiwan there is use of drug appraisals by NICE and other HTA bodies around the world, although it is not clear exactly how they are used and combined to reach a conclusion. While NICE’s approach to technical appraisal may well be appropriate to some emerging markets, simply transferring those outcomes or indeed those processes *in toto* raises challenges in terms of local data, expertise, and resourcing (Chalkidou et al., 2010). Moreover, there is a risk that simply adopting influential HTA processes developed elsewhere leads HTA down a path which does not meet the particular needs of local health care systems, and does not reflect locally-relevant values and priorities. While there have been attempts to develop key principles for the conduct of HTA (Drummond et al., 2008), there is a lack of consensus among HTA organisations internationally about the importance or relevance of some of these principles (Neumann et al., 2010), as we discuss below. What is clear is that before adopting HTA, countries should be clear about the problems which HTA is intended to address, and should develop or adapt HTA processes to achieve that.

The sort of HTA processes which are suggested may be different in each case, depending on the particular issues evident in the health care system. For example, in Brazil, the cost-effectiveness of services is relevant to addressing resource allocation in the public system and in providing a basis for modifying expectations about entitlement to care. In contrast, in China the principal requirement is for clinical protocols to manage chronic disease and to assist in countering the perverse incentives toward non-basic treatments.

*Lesson 3: 'One size fits all' HTA processes and methods are unlikely to be appropriate for emerging markets. There needs to be clarity over the purpose of HTA – and the methods and processes which are adopted need to be fit for purpose.*

- HTA is not an objective 'tool kit' that is transferable to any setting.
- "Value" of new drugs varies, and is subjective and based on local preferences and other values.
- Real value depends in a "second-best" world on the match between costs and the value of all other inputs (hospitals, physician, nurses, equipment, etc.).

In particular, it is important to give careful thought to the way in which HTA processes work alongside the pricing and reimbursement systems for health care technologies – which in turn are part of the wider health system 'architecture' in each country. HTA processes may need to be tailored to meet the particular means by which pricing regulations work in each country. The outcomes of the health care system, for patients and the public, will be a product of both. Both reference pricing and HTA represent ways of obtaining value for money from new health care technologies. Drummond, et al. (2010) argue that the most efficient approach is likely to comprise a combination of these.

*Lesson 4: HTA and pricing regulations work hand in hand: the approach to HTA should be appropriate to, and work sensibly in combination with, the particular approach to pricing technologies.*

For example, HTA based on reimbursement levels in Taiwan ignores what providers actually have to pay for new drugs. This would tend to under-estimate real-world cost-effectiveness.

#### **Limits to the lessons that may be drawn**

Beyond the broad lessons and insights noted above, there are limits on the ability to draw broad conclusions from three case studies about the way that health care systems and HTA are evolving in emerging markets.

While the issues we discussed above are common to emerging markets, many more of the observations about issues evident in three countries are specific to the three countries examined. Each has its own particular characteristics in terms of arrangements for funding and provision of health care, and sits in the context of a wider economy which also has its own distinctive

characteristics. This limits the appropriateness of generalising to all emerging markets: ‘when you’ve seen one health care system, you’ve seen one health care system’.

Especially with respect to understanding the interplay of incentives that drive behaviours regarding the adoption of new health care technologies, the relevant considerations are the particular, and often very complex, combinations of system-wide and local reimbursement arrangements facing the ‘players’ in the market, and the regulatory framework that guides and limits their behaviours. In our model we described these factors as the ‘architecture’ of the health care system, in itself can be thought of as a set of related technologies, i.e., a state of knowledge about the way health care can be delivered and provided.

That state of knowledge is imperfect: there is no single, agreed, ‘best’ way to organise a health care system. Each system comprises a ‘second best’ set of arrangements. This has implications for the role HTA can and should have.

*Lesson 5: There is no single prescription for HTA methods and processes which will be welfare-increasing in all contexts.*

Further, trade-offs between competing objectives are likely if not inevitable; and health care systems may differ in the relative value placed on them, for example, the achievement of equity goals; technical efficiency; cost containment; and patient choice. Every health care system is on a slightly different trajectory: as it develops, and as spending increases, the way that HTA evolves will be a reaction to the possibilities and pressures that new technologies present.

The key message is that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system.

## 9.2 Options for the development of HTA in the three markets

In positioning HTA it is important to understand that its value depends on the existing architecture of the health care system. This will in turn reflect the type of HTA that is appropriate. We have categorised HTA into three types:

- “macro-level” HTA which is about the “technologies” or architecture of the health care system, e.g. incentive systems or configurations of facilities. Issues around the effectiveness of, or reform options for, system level technologies arise at all stages of health system development either for government as a regulator or, more typically, for government as a direct owner of, and/or a purchaser of, health care services;
- micro-level” HTA aimed at appraisal of individual technologies, or groups of related technologies. Initially, some sort of market entry or licensing requirements are introduced for certain technologies (notably drugs and some devices), but at some point a greater understanding of value may be sought, either in the sense of relative or comparative effectiveness, or of incremental cost-effectiveness. In theory, again, these assessments could be generated and adopted by clinicians in self-pay markets, but it hard to see how this type of HTA would be funded in such a situation given its public good characteristics and the asymmetry of information between doctors and patients. More typically, it is generated by public bodies and

used by public and private sector payers to either (i) support doctors and patients making treatment choices or (ii) to define the boundaries of the “benefit package.” Use to inform listing or reimbursement can be as part of a “passive” fee-for-service system or more “active” purchasing.

- “micro-level” HTA aimed at developing clinical practice guidelines or the way in which individual technologies are combined within a delivery system to manage patients efficiently. Designing clinical practice guidelines becomes an issue in systems that are seeking to actively manage chronic disease. In theory, these could also be generated and adopted by clinicians in self-pay markets, but it hard to see how this type of HTA would be funded in such a situation given its public good characteristics and the asymmetry of information between doctors and patients. More typically, developing guidelines becomes an issue for a health system when one or both of variability in treatment patterns and poor health outcomes becomes apparent.
- All of these uses of HTA make sense in the right context if the five lessons we set out in section 8.1 are observed. The bottom line is that HTA uses scarce resources. To be of value it has to deliver improved resource allocation and resource use that exceeds the opportunity cost of the effort involved in undertaking the HTA. If skills are scarce, as is often the case in an emerging market health care system, the opportunity cost may substantially exceed the wages and overheads associated with the HTA body.

Many elements of HTA—both in terms of process and findings—are not only public goods, but global public goods. Clinical benefit-risk determination for an individual drug, for example, is likely to be similar in different countries. If both the FDA and EMA have decided that a product’s benefit-risk balance is favourable enough to allow a product on the market, it makes sense for emerging markets not to spend substantial scarce resources to re-address this question in their local context. The ‘efficient’ solution will involve some degree of free-riding on this information. In the case, however, of a drug or other technologies comparative effectiveness or cost-effectiveness, local evidence will be needed to supplement reviews of evidence by HTA bodies elsewhere. Likewise with clinical practice guidelines, it makes sense to draw on relevant research from elsewhere. In the case of “macro-HTA” even more care is needed. Reforms to health system delivery or payment and incentive structures that appear to have worked in another country may not translate into other health care systems.

All three case study markets demonstrate the use of HTA is at its early - emergent – stages, albeit with some early signs of consolidation in Brazil.

- In China, there are a number of reforms to health system architecture underway and others are needed. Where HTA seems to be emerging as important is in the key area of clinical practice guidelines. The initiative with the UK NICE appears to be targeted at generating evidence-based clinical practice guidelines. The safety and efficacy of drugs is assessed by the SFDA. HTA in the sense of appraising the cost-effectiveness of individual drugs is not used. It could, in theory, be used by: (a) MoH in determining listings for inclusion in the EDL; (b) MoHRSS in setting reimbursement prices or determining reimbursement decisions for drugs to be covered in the two schemes it administers; or (c) the NRDC in setting prices for pharmaceuticals not covered by its cost-plus formula. None of these uses have been proposed to our knowledge although there is interest in the use of HTA on the part of all three Ministries and leading academics continue to promote dialogue on guidelines for good practice. Furthermore, to our knowledge there is no use of HTA for other individual technologies outside of drugs.

- In Brazil, the CITEC works slowly and appears to be under-resourced. This has the effect, intentional or otherwise, of delaying reviews of, and decisions on, access to new technologies. There are aspects of the HTA process that could be improved, notably around transparency of process and of selection criteria. However, it is also unclear how the role of CITEC fits alongside a constitutional right of access to healthcare (which is clearly not consistent with the levels of funding available) and regulation by the ANS of the minimum requirements of the private insurance package. If emerging markets allow marketing authorisation, their citizens will have expectations of access. The situation in Brazil exemplifies this, as once products are approved for marketing authorisation and a price is set via external reference pricing rules, then citizens can sue for access even though the public system has not yet approved the product for use in the public plan.
- In Taiwan, the role of HTA appears to be exclusively in the area of drug reimbursement, and here it is unclear how it fits logically alongside an international reference price system. In theory, drugs showing incremental value can get higher prices within the range of reference price comparisons. There are also some issues around process such as the degree of transparency of the assessment and the relationship between the assessment and the drug licensing process. Our understanding is that expertise for the conduct of pharmacoeconomic assessments is drawn from the licensing body but used separately. However, this arrangement clearly causes concern for the industry that assessments of safety and efficacy may be conflated in some way with assessments of relative effectiveness and cost-effectiveness.

### 9.3 An industry perspective on HTA: IFPMA, PhRMA and EFPIA Principles

In order to help put HTA developments in the context of industry thinking, we reviewed the following published industry statements on HTA:

- PhRMA's Health Outcomes Principles and also its Principles for Use of Evidence-Based Medicine: Advancing Patient Care and Health Care Value;
- EFPIA's The Use of Health Technology Assessments (HTA) to Evaluate Medicines. Key Principles
- IFPMA's Position Statement. Health Technology Assessment and the Value of Medicines.

There is a substantial amount of overlap among the statements, as would be expected. The key points that stand out and are of concern for industry are as follows:

1. HTA should not just be applied to medicines but to all health technologies and interventions. It should be undertaken as part of a broad agenda to improve health care quality and efficiency, rather than used as a cost containment tool. Likewise "silo budgeting," where medicines are put into a separate cost bucket, runs counter to optimising health gains across the system;
2. A broad perspective of value should be used including the impact on productivity, and on caregivers and personal time, and societal health priorities, for example in terms of disease burden, should be recognised.
3. HTA when applied to determine access to or reimbursement for pharmaceuticals should be kept separate from marketing authorisation.



4. HTA should be inclusive, open, transparent and balanced, involving external experts and all stakeholders. It should include rights of appeal. The evaluating body should be independent of the payer.
5. Payers should commit to rewarding value. Positive HTA appraisals should attract the budgetary resources necessary to fund use.
6. Appraisals should recognise that value emerges through use and additional evidence over the product life cycle and recognise the need to include new data. To this same point, uncertainty around cost-effectiveness has to be dealt with in a flexible way, including the use of in-market data collection, which requires putting in place the necessary infrastructure. A full range of types of evidence including observational data can play an important role. It is important that patients get speedy access to new technologies.
7. Patient preferences and needs matter in any choice of medicine. HTA guidance should give clinicians enough freedom to address individual clinical situations. In this context, the incremental nature of innovation should be recognised as should the importance of having multiple treatment options.

The Drummond, et al. (2008) criteria are similar. They are set out below, together with the assessment from Neumann, et al. (2010) of the performance against these criteria of Anvisa (CITEC) and DHTA (CDE). In the case of Brazil, Anvisa (CITEC), they find that it subscribes to a number of key principles but there is no evidence of adoption. In the case of Taiwan, the DHTA (part of the CDE), they found more evidence of adoption. However, there are clear gaps in both cases as we have discussed:

- CITEC is lacking transparency of process and of priority setting;
- CDE is part of the marketing authorisation body;
- Neither body takes a societal perspective;
- Neither body addresses implementation, and there is no clear link between findings and decision making.

**Table 3 – The Neumann et al Analysis of the Use of Key HTA principles across selected organisations**

	<b>Key Principle</b>	<b>Anvisa (Brazil)</b>	<b>DHTA (Taiwan) <sup>c</sup></b>
	<b>Year of inception</b>	<b>1999</b>	<b>1998</b>
	<b>Structure of HTA program</b>	<b>+</b>	<b>++</b>
<b>1</b>	The goal and scope of the HTA should be explicit and relevant in its use	<b>+</b>	
<b>2</b>	HTA should be an unbiased and transparent exercise	<b>+</b>	
<b>3</b>	HTA should include all relevant technologies		<b>++</b>
<b>4</b>	A clear system for setting priorities for HTA should exist		
	<b>Methods of HTA</b>		
<b>5</b>	HTA should incorporate appropriate methods for assessing costs and benefits	<b>+</b>	
<b>6</b>	HTAs should consider a wide range of evidence and outcomes	<b>+</b>	<b>++</b>
<b>7</b>	A full societal perspective should be considered when undertaking HTAs		
<b>8</b>	HTAs should explicitly characterize uncertainty surrounding estimates	<b>+</b>	
<b>9</b>	HTAs should consider and address issues of generalisability and transferability		
	<b>Process for conducting HTAs</b>		
<b>10</b>	Those conducting HTAs should actively engage all key stakeholder groups		
<b>11</b>	Those undertaking HTAs should actively seek all available data	<b>+</b>	<b>++</b>
<b>12</b>	The implementation of HTA findings need to be monitored		
	<b>Use of HTA in decision making</b>		
<b>13</b>	HTA should be timely	<b>+</b>	<b>++</b>
<b>14</b>	HTA findings need to be communicated appropriately to different decision makers		
<b>15</b>	Links between HTA findings and decision making processes needs to be transparent and clearly defined		

**Note. “+” signifies that the organization “supported” the principle in question in written guidelines or other form, regardless of whether they actually follow it.**

**“++” means that the organization “implemented” the principle in published reports and decisions based on these reports demonstrate adoption of the specific principle.**

**Anvisa = National Health Surveillance Agency (Office of Economic Evaluation of Health Technologies).**

**DHTA = Division of Health Technology Assessment. DHTA is within the Center for Drug Evaluation in Taiwan**

## 9.4 Issues for PhRMA in developing public policy positions

The PhRMA, EFPIA, and IFPMA principles for good practice in HTA and Evidence-based Medicine provide a consistent approach to “micro HTA” and continue to provide a solid framework for approaching HTA issues globally. They are intended to be applied in a reactive way – in the event of a payer and/or government proposing the use of “micro HTA”.

We have sought to develop a framework for putting such a position into the context of health care system development and HTA evolution. Our key points are that HTA is resource intensive and that an appropriate initial focus for skilled people may well be on “macro HTA” or other health system issues rather than “micro HTA”.

This gives rise to several issues:

- As compliance with good HTA principles is resource-intensive for governments (and for industry), countries may seek to “free ride” on the systems of other countries to avoid using scarce skills and resources. Indeed, as we have noted earlier, the global public good nature of much evidence means that “not reinventing the wheel” can make sense and be efficient.
- However, use of alternative “low resource” options may be *less* efficient than an efficient use of HTA. For example, the use of international reference pricing to countries at a similar stage of income-per-capita and with similar health care systems can make sense if the referenced countries have used appropriate methods to derive their prices. However, international reference pricing in practice can lead individual country markets to seek lower-than-optimal price levels not consistent with long-term, global dynamic efficiency (Danzon et al, 2010). HTA may therefore be preferable to international reference pricing if it is used to assess value in a way that reflects local willingness to pay for health gain;
- The use of therapeutic reference pricing requires less input than HTA but can discourage innovation and reduce the likelihood of efficient use of the product (Drummond et al, 2010). It saves input resources by assuming medicines are the same instead of exploring the appropriate use of different treatments in a given therapy area.

This suggests that the industry be willing to support ‘efficient’ HTA, i.e. appropriate to a given country market and subject to the lessons we have set out in 8.1 above.

## Appendix I: Overview of the Brazilian Health Care System and the Use of Health Technology Assessment for the Evaluation of Pharmaceuticals

### Key Brazilian Health System Acronyms

ANS	Agência Nacional de Saúde Suplementar (National Agency for Supplementary Health)
ANVISA	Agência Nacional de Vigilância Sanitária (National Agency for Health Surveillance)
ATS	Avaiiação de Tecnologias em Saúde (HTA—Health Technology Assessment)
BRATS	Boletim Brasileiro de Avaliação de Tecnologias em Saúde (Brazilian Bulletin of HealthTechnology Assessment)
CCTI	Conselho de Ciência, Tecnologia e Inovação (Science, Technology and Innovation Council)
CGATS	Coordenação Geral de Avaliação de Tecnologias em Saúde (CG-HTA--Health Technology Assessment General Coordination) (WG-HTA—Permanent Work Group on Health Technology Assessment)
CITEC	Comissão para Incorporação de Tecnologias (National Commission for Technology Incorporation)
CMED	Câmara de Regulação do Mercado de Medicamentos (Pharmaceutical Price Council or Chamber for Regulation of the Pharmaceutical Market)
DECIT	Departamento de Ciência e Tecnologia (Department of Science and Technology)
FIOCRUZ	Oswaldo Cruz Foundation
MS	Ministério da Saúde (Ministry of Health)
REBRATS	Rede Brasileira de Avaliação de Tecnologias em Saúde (Brazilian Network of Health Technology Assessment)
RENAME	Relação Nacional de Medicamentos Essenciais (National List of Essencial Medicines)
SAMU	Serviço de Atendimento Móvel de Urgência (Service of Ambulances)
SCTIE	Secretaria de Ciência, Tecnologia e Insumos Estratégicos (Secretariat of Science, Technology, and Strategic Goods)
SUS	Sistema Único de Saúde (Unified Health System)

### Recent Brazilian Health Care System Timeline

- 1988 Approval of the new National Constitution, which created the Brazilian Unified Health System (SUS). In the constitution, health is defined as a right of all citizens and an obligation from the state.
- 1998 Definition of criteria for resource allocation from the federal government to states and municipalities.
- 1998 Law 9.656/98 regulates private health care plans.
- 1999 Creation of the National Agency for Health Surveillance (ANVISA), responsible for the registration of new drugs.
- 2000 Approval of the Constitutional Amendment number 29 that defines the percentage of budgets from the federal, state and municipal level that should be allocated to health care.
- 2000 Creation of the National Agency for Supplementary Health (ANS) that regulates the private health care system in Brazil.
- 2003 Creation of the Chamber for Regulation of the Pharmaceutical Market (CMED), responsible for the pricing of new drugs.
- 2004 National Agenda of Priorities in Health Research - for the 2nd National Conference on Science, Technology, and Innovation in Health.
- 2006 Creation of the National Commission for Technology Incorporation of the Ministry of Health (CITEC).
- 2008 Creation of the Brazilian Network of Health Technology Assessment (REBRATS).
- 2009 Methodological Guidelines for HTA issued by Ministry of Health.

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## A1.1 Overview of Brazilian Health Care Financing and Delivery System

The current Brazilian public health care system dates from 1988, with the creation of the Unified Health System (SUS). With the new constitution, health was declared to be a citizen right and a duty of the State. SUS was created to provide universal, comprehensive, and equitable health care to the Brazilian population. To this day, the discussion about which right—universal coverage vs. comprehensive coverage—should prevail has not been answered, since without enough funding, one or both of these will be affected.

The Brazilian healthcare system has gone through a number of changes over the years. In 1923, the landmark Eloi Chaves Law was passed, which brought into existence a form of ‘regulated citizenship’ where social welfare benefits were restricted to private sector workers with regular wages. Social security and coverage of healthcare benefits (based on compulsory contributions from employers and employees and delivered mainly through the private health sector) were tied to the workplace: an outcome similar to the situation in the US. This left millions of agricultural and informal sector workers uninsured. Elias and Cohn (2003) have argued that as long as the Eloi Chaves Law governed the structure of the Brazilian health system, implementation of the principles of universality and equality (in healthcare access and provision) was impeded.

However, the new constitution that came into effect in 1988 changed the existing two-tier healthcare system that operated. The new constitution paved the way for SUS, based on a regionalized and decentralized framework—under which the private sector’s involvement in medicine was relegated to a ‘complementary function’ with priority given to philanthropic and not-for-profit organizations. However, the SUS is not a single payer healthcare system covering the whole population. People may buy private insurance but cannot opt out of the public system, and they must continue to pay taxes devoted to health care. In effect, the reform moved from one two-tier system to another two-tier system (SUS plus the Supplementary Health Care System), but with obviously a different mode of operation. This ‘new’ form of segmentation created opportunities for adverse risk selection into the publicly-funded SUS (Elias and Cohn, 2003).

The provision of health services was decentralized with a hierarchy among the federal level, state level, and municipal level. The rules of provision are: 1) integral care, with priority to prevention activities without damage to assistance activities; 2) decentralization with unique direction in each level of government; and 3) participation of the community. The SUS was defined as composed by the actions and health services provided by public bodies and institutions at the federal, state, and municipal levels. Private institutions may participate in SUS as a complement, but philanthropic and not-for-profit organizations are given preference.

### **Population and Coverage**

- Population: 193 million people (IBGE, 2010)
- Total health care expenditure per capita in 2007 (WHO, 2010): US\$ 606 (average exchange rate) or \$ 837 (PPP int \$)
- Total health care expenditure (WHO, 2010) = 8.4% of Gross Domestic Product
  - Private expenditure on health as percentage of total expenditure on health: 58.4%
  - Private prepaid plans as percentage of private expenditure on health: 39.4%

- Out-of-pocket expenditure as percentage of private expenditure on health: 58.8%
- The public healthcare system is universal and covers 100% of the population. In practice, people covered by the private health care system do not use the public system, except for the access to drugs not covered by the private system.
- The private healthcare system covers 22% of the population. This coverage also varies by region, to health care services. This access is heterogeneous among regions in Brazil, being higher in the South and Southeast regions when compared to the Mid-West, North and Northeast regions (ANS, 2010).

## A1.2 Public Healthcare

### Financing

Financing comes from taxes charged on the revenue and profit of companies, and these are responsible for almost 70% of the federal health budget. From the year 2000 onwards, after the constitutional amendment number 29, States must allocate 12% of their revenues from taxes to healthcare, and municipalities should allocate 15% of their revenues from taxes to healthcare.

### Budget Allocation

The budget is allocated for five different categories:

#### I. Basic Attention

Budget is allocated from the federal government to municipalities based on a fixed per capita value named as Fixed PAB (Basic Attention, “PISO”—a fixed minimum value per capita), used for basic health care focused on strategic assistance areas, related to health problems of national coverage (women’s health, men’s health, child health, control of hypertension, and diabetes); and a variable PAB, allocated to priority and strategic programs, namely:

- Program of Family Health
- Communitarian Health Agents
- Oral Health
- Compensation for Regional Specificities
- Factor for Incentive of Basic Attention to Natives (Indians)
- Health Attention to Penitentiary Health

These services are provided by municipalities. Municipalities may also define other areas for investment depending on the peculiarities of each municipality.

#### II. Medium and High Complexity of Ambulatory and Inpatient Care

Resources are transferred from the federal government to states and municipalities to account for dental and medical care, ambulatory and hospital care, diagnostic exams, treatment surgeries and procedures, and for the Service of Ambulances (SAMU) and Transplants.

### **III. Health Vigilance**

Focused on actions for epidemiological vigilance, devoted to vigilance, prevention and control of diseases, also including vaccination campaigns; and sanitary vigilance.

### **IV. Pharmaceutical assistance**

The pharmaceutical assistance budget allocation will be detailed below.

### **V. Management of SUS**

Focused on strengthening the Unified Health System, costing actions specific to the organization and broadening of access to health services.

#### **Pharmaceutical Spending**

The pharmaceutical assistance is segmented into three components.

#### **Basic Component of Pharmaceutical Assistance**

Devoted to the acquisition of medications related to basic health attention. Its financing is composed by a fixed budget transfer from the federal government to states and municipalities, which must use the budget allocated to basic pharmaceutical assistance. To define which drugs will be provided by states and municipalities, the federal government defines a National List of Essential Medicines (RENAME), which constitutes a recommendation for which drugs should be provided, but the exact list provided by each state is defined by their own State List of Essential Medicines, which may vary from state to state depending on local needs. The same happens for municipalities and each municipality creates its own Municipal List of Essential Medicines to be distributed to the population. The purchase of drugs from these programs may be made at the federal level or decentralized to states and municipalities. In this component there is a variable financing budget devoted to the acquisition of drugs for the programs of hypertension and diabetes, asthma, mental health, women health, nutrition support, and smoking cessation.

#### **Component of Strategic Pharmaceutical Assistance**

Dedicated to financing drugs for the programs of:

- Control of endemics, such as tuberculosis, leprosy, malaria, leishmaniasis, Barber bug fever, and other endemic diseases in regional or national level;
- Drugs to treat HIV/AIDS;



- Blood and blood products and immunobiologics.

### **Component of Specialized Pharmaceutical Assistance**

This component is devoted to financing drugs on a list of specialized drugs. These are defined as drugs with potential of having a high budget impact, either due to treating high prevalent diseases or because of a high unit cost. The inclusion of new drugs in the list of this component should be evaluated by the National Commission for Technology Incorporation (CITEC), and all new inclusions should be accompanied by a clinical protocol and therapeutic guideline. In this list, there are three categories:

- 1A – Drugs purchased centralized by the federal government;
- 1B – Drugs purchased by states with funds from the federal government;
- 2 – Drugs purchased by states with their own funds;
- 3 – Drugs purchased by municipalities with their own funds.

The drugs included in the three programs above are offered free of charge to patients. In addition to this, the Popular Pharmacy Program was created in 2004. This program is implemented in two ways:

- Pharmacies are owned by the State and managed by Oswaldo Cruz Foundation (FIOCRUZ). There are currently 521 pharmacies offering access to 107 drugs at cost. These drugs cover diseases with high incidence in Brazil –gastric ulcers, depression, asthma, infections, migraine, burns, alcoholism, among others. FIOCRUZ buys the drugs preferably from official public pharmaceutical laboratories and, whenever necessary, from private laboratories.
- Private pharmacies in a partnership with the public system: 7,292 pharmacies are eligible to offer drugs included in the program, covering treatments for diabetes, hypertension and contraceptives. The federal government pays for 80% of the reference list price and the difference should be paid by patients out-of-pocket. This is part of the initiative to universalize access to health care.

### **The legal right to access to drugs for health**

Given constitutional right to health, Brazilian citizens sometimes sue the government for access to specific medicines that are not on the national formulary. The suit applies only to the specific patient who brings it: it is not a “class action.” Some would argue that this is an untenable approach in the long run. Effectively, it becomes a route around HTA as well as the negative decisions by CITEC). Clearly, it is a costly and inefficient method to reach these societal decisions.

### **Provision and Reimbursement**

Services are provided by primary care units and public hospitals in the federal, state, and municipal level. Services may be also provided by private hospitals and clinics dedicated to the public system.

Currently, services are offered by more than 64,000 primary care units (performing 2.7 billion ambulatory visits per year), and 5,900 hospitals (performing 12 million hospital admissions).

Providers are paid on a fee-for-service basis for ambulatory care, including outpatient visits, exams and ambulatory procedures. Currently, there are a large number of procedure codes for these services in SUS. For inpatient hospital care and for cancer treatment, facilities are reimbursed under a prospective payment system, using diagnosis-related groups (DRGs). Hospital providers, including physicians, are usually paid a salary.

## A1.3 Private Health Care System

### Financing

Most of the financing for private insurance comes from employers and employees, who pay for different shares of private insurance costs. Individuals may also purchase individual health plans out of pocket. The maximum value to be charged for individual health plans is regulated by the National Agency for Supplementary Health (ANS). The premiums charged to companies for executive health plans are not regulated and open to negotiation between private HMOs and companies. That is why most HMOs are stimulating the growth of executive plans instead of individual plans.

ANS also defines the prohibition of HMOs to refuse coverage for any patient due to their risk profile. Premiums may vary by age for individual plans.

### Provision and Reimbursement

ANS defines every two years the list of procedures covered by private payers. As a general rule, all treatments registered in Brazil for the indications covered by International Classification of Disease codes and provided in ambulatory or in-hospital should be reimbursed by HMOs. Treatments received at home and oral drugs are not covered by the private system. Originally, when this rule was created, it did not cover drugs for high cholesterol, hypertension, etc., that could be purchased by patients out of pocket. There is now a controversy over oral drugs for oncology treatment due to their high cost and the impossibility of most patients to pay for these treatments out of pocket.

Provision of services is through private hospitals and outpatient clinics that are dedicated providers to specific HMOs. Providers may be dedicated to more than one HMO, which is the usual practice. Individual physicians may also own their offices and provide outpatient visits to patients. In the majority of cases, services are charged on a fee-for-service basis. The reference reimbursement values for exams and surgical procedures come from reference lists like the Brazilian Hierarchical Classification of Medical Procedures (CBHPM) and the list of the Brazilian Medical Association (AMB99).

Drugs and materials are reimbursed based on their listed Maximum Prices to Consumer registered by the Chamber for Regulation of the Pharmaceutical Market (CMED). Discounts over the reference values may be negotiated between HMOs and providers on a case-to-case basis.

Daily hospitalization costs in ward and ICU are negotiated between HMOs and hospitals. Some HMOs are pressing hospitals to create “packages” for surgical procedures, in a DRG-like reimbursement system. But these values are not standardized and are negotiated between HMOs and providers.

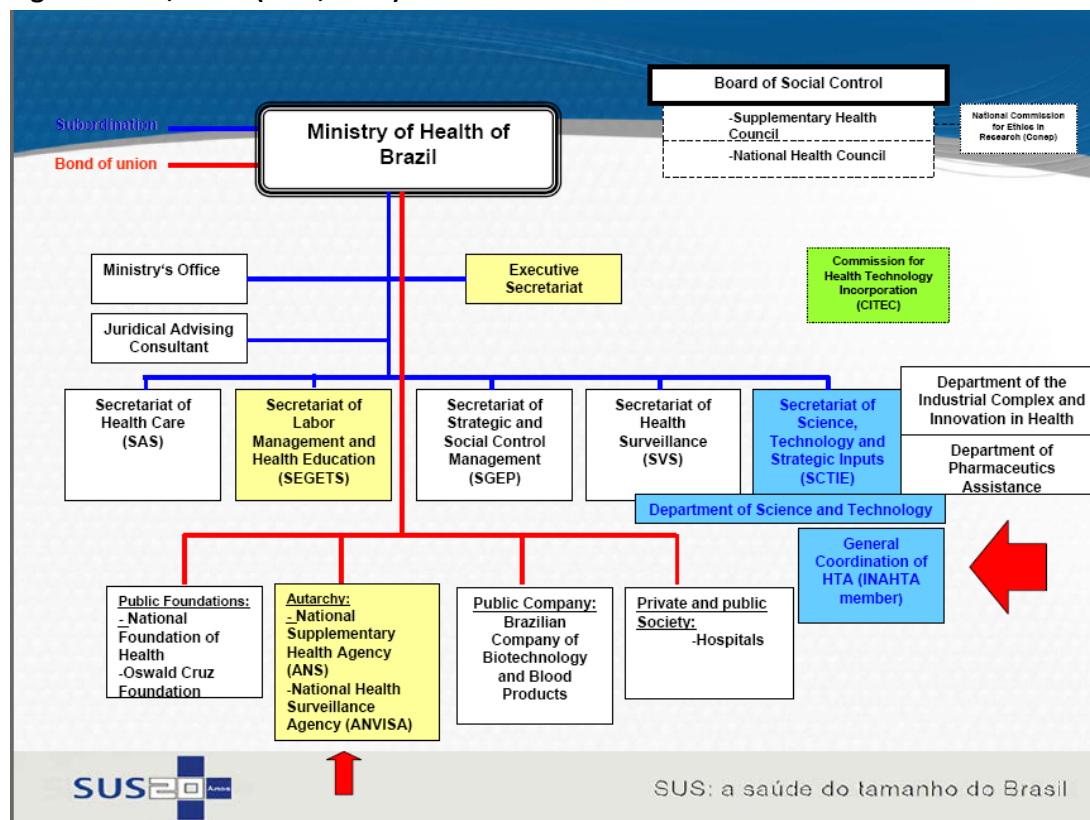
In private outpatient clinics, physicians are usually paid on a fee-for-service basis, receiving a percentage of the revenue they generated to the facility. In private hospitals, some physicians are paid with a salary and others are paid on a fee-for-service basis. Physicians may also charge patients extra fees out-of-pocket to perform specific surgeries.

## A1.4 Health Technology Assessment in Brazil

### Overview

As reflected in the chart in Figure 1, HTA is an integral and relevant part of a Policy for Management of Health Technologies created by the Secretary for Science and Technology of the Ministry of Health (MS) in 2003. There is an official guideline from the MS, published in the website of the Department of Science and Technology (DECIT) for the evaluation of technologies in the Brazilian Unified Health System (SUS) and the Supplementary Healthcare System (ANS; Private).

Figure 1. MS, SCTIE (Elias, 2009)



CITEC staff is financed by the budget of the Secretary for Science and Technology. The studies and analyses demanded by DECIT for ad hoc consultants (from public universities) are financed by

federal agencies of investment in research (CNPq, FINEP). There are federal funds for DECIT and resources of the Ministry of Health for the Institute for Evaluation of New Technologies. Manufacturers often contract with consultants to develop HTA dossiers for submission to the government.

In the public system, in a federal level, HTA is a formal process since 2006. However, it has a low influence in the decision-making process and the number of responses for the dossiers submitted to the government is low. The published guideline for the development of HTA dossiers for submission to CITEC is very much inspired by the guidelines from NICE. See Box 1 from Dr. Lemgruber's presentation to NICE in 2010.

**Box 1. Presentation to NICE (Lemgruber, 2010)**

### **Reimbursement Decisions**

- ❖ **The National Commission for Technology Incorporation (CITEC) is responsible for making the recommendation to the Minister of Health, who makes the final call about which technologies should be paid by the Public Health System**
- ❖ **The Commission has 5 members, 3 from the Ministry of Health and 2 from the agencies (ANVISA and the Agency that regulates the health private sector-ANS)**
- ❖ **The recommendation is based on a HTA report**
- ❖ **4 votes are needed to approve a recommendation**
- ❖ **Budget impact analysis is required**

Some initiatives by the Ministry of Health to disseminate HTA must be emphasized. The Brazilian Bulletin of Health Technology Assessment (BRATS) is published every three months to help decision-makers make more informed decisions. Ten issues have been published to date, but it is not clear if these evaluations will have links with future reviews and incorporation decisions. "Health and Economics" is a new publication coordinated by the Ministry of Health, with two issues published thus far. The Brazilian Journal of Health Economics has been also publishing Brazilian and Latin American studies as an independent journal.

## A1.5 Incorporation of New Drugs in the Brazilian Health Care System

When a new drug comes to Brazil, it must be submitted to ANVISA for registration. ANVISA evaluates the safety and efficacy of treatment based on Phase III trials, and decides whether or not to approve the indication in Brazil. After approval, the label of the drug for the approved indication is registered. There is not an official deadline for each evaluation, but it usually takes between 12 to 18 months.

After the registration of the drug, CMED, which is a branch of ANVISA, defines the price of the drug. This price is based on the category of the drug. It is considered category 1 if it has a valid patent in Brazil and brings gains to treatment (defined as higher efficacy, same efficacy with fewer adverse events, or same efficacy and safety with lower costs), and then the approved price is the lowest price from 9 reference countries. If the drug is considered as Category 2 (either without a valid patent or without gains to treatment), the maximum price is the equivalent price of the treatment already registered in Brazil that provides equivalent efficacy. For innovative products, after the initial price is set via external reference pricing, it is adjusted subsequently by SUS/CMED for inflation, affordability, etc.),

When the drug has an approved price and label in Brazil, it can be bought by patients out of pocket or reimbursed by private payers if administered in ambulatory care or in hospitalized patients. Prices of drugs are updated every year to account for inflation and the percentage of price update is defined yearly by CMED.

For a new drug, considered as high-cost, to be included in the Component of Specialized Pharmaceutical Assistance, it must be submitted to CITEC for evaluation. CITEC gives guidance in favour or against the inclusion and the Ministry of Health decides about the final incorporation. In practice, a favourable guidance is mandatory for implementation. When it is positive, there is effectively national availability of the new technology. When it is negative or when there is no answer, the access to the technology is restricted. Importantly, the government does not publish the rationale behind the recommendations given (for positive and negative guidance). Thus, it is difficult to learn from the previous recommendations, and to understand government priorities.

Since 2005, there have been 222 submissions to CITEC:

- 44 technologies incorporated by the Ministry of Health
- 24 proposals for incorporation with a negative answer
- 1 proposal for exclusion of technology with a negative answer (not excluded)
- technologies excluded from SUS reimbursement list
- 12 technologies for genetic diseases with treatment protocols under development.

- proposals considered out of the scope of CITEC

In total, there are 89 results (40%) from submissions with a result. There remain 133 technologies for evaluation.

Also, at CITEC, there are 74 studies under development supported by the Ministry of Health. Twenty-four chemotherapeutic agents are under evaluation. Currently, SUS pays a different diagnosis-related group (DRG) payment for each type of cancer but not the drugs separately. Eighty-six therapeutic protocols are under review: 53 for update and 33 being developed. Fifteen academic institutions are involved in the studies.

Manufacturers may request directly for the MS to evaluate their technologies, but unlike NICE, they cannot participate or give opinions to the process of analysis. There are public consultations about some points of the Policy for Management of Health Technologies and about the clinical protocols and therapeutic guidelines, when manufacturers can give their opinion, as well as any other institution or individual.

In practice, most of the time, manufacturers define which new technologies should be evaluated by the government since the government has not clearly defined its priorities and what will or will not be evaluated. However, public bodies, medical associations and patient groups may also request for the evaluation of new technologies.

New technologies not considered as high-cost may also be incorporated by states or municipalities in their own Lists of Essential Medicines. Besides pharmaceutical assistance, new procedures and exams may be also incorporated in the medium and high complexity program for ambulatory and inpatient care. These processes do not go through CITEC for evaluation.

In summary, the health technology assessment of medicines in Brazil is a complex process. First, marketing authorization of new drugs is tied to pricing, carried out by two separate units in ANVISA. After the first unit establishes that drug has sufficient efficacy, safety, and production quality, the pricing unit (CMED) assesses the innovative status of the drug. This assessment will normally include a submission of evidence from the manufacturer. If the new drug is deemed to be innovative (Category 1), then the price will be established based on international reference pricing.

If the drug is similar to other drugs (Category 2), then price will be based on internal reference pricing, relying on the prices of those similar drugs in Brazil. This marketing authorization puts the drug in the marketplace at that price, and there are no guarantees that private insurance (Supplementary Healthcare) will cover these drugs...

The drug will not necessarily be covered in the public system (SUS) until the drug's clinical impact, cost-effectiveness, and budget impact are reviewed by CITEC.

In the private system, the process is further complicated by different treatment of intravenous and non-intravenous drugs. The private insurance system is required to cover intravenous drugs, but important oral oncology drugs can be excluded.

In the private system, there is no formal process for the incorporation of new technologies. However, the major insurers are beginning to address this issue. There is proposed legislation for the National Agency for Supplementary Health (ANS) that would specify that if a technology submitted to CITEC (in the public system) has a negative recommendation, private insurers may opt not to pay for the technology.

## A1.6 Key Findings and Issues

In interpreting the evolution of HTA in Brazil, several key features are important to explain and identify.

First, the existence of a constitutional right to healthcare creates a need to define more explicitly what is included in healthcare, as compared to a country like the US, with decentralized control. This challenge is further heightened in a country with a substantial inequality of income and wealth. In Brazil, the discussion about which right —universal coverage vs. comprehensive coverage—should prevail has not been answered, since without enough funding, one or both of these will be affected.

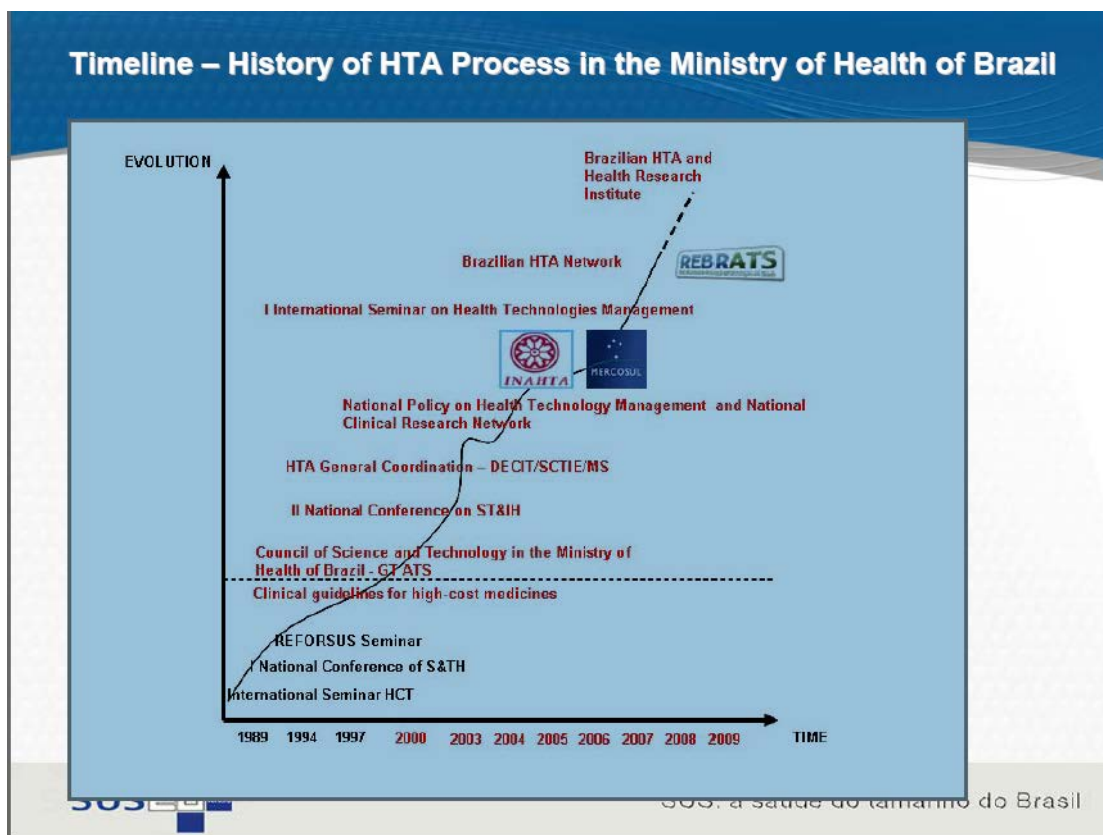
Related to this right is the costly and inefficient use of the legal system to gain access to medicines only for specific patients. This does, however, offer a potential avenue for industry to have a positive dialogue with the government about how a more transparent and effective HTA mechanism might reduce the incidence of these suits.

Second, HTA in Brazil has been tied to the broader international HTA movement. In that regard, there is recognition that health technology is broader than just pharmaceuticals. Still, in practice, the focus is on pharmaceuticals.

Third, the right to healthcare, enforced through the courts, creates a significant budget problem for affording high-cost, innovative, and life-saving medicines, such as orphan drugs.

Fourth, the long time taken in evaluation by CITEC to give recommendations either in favour or against the incorporation of a new technology acts as a barrier to the actual incorporation of the technologies. This situation, added to the lack of transparency about the recommendations given, opens space for other noneconomic factors to play into the decisions about the incorporation of new technologies in Brazil. Also, in terms of process, clear parameters for decisions have not been made transparent.

**Annex 1: From Elias (2009)**



**Annex 2: Pre-SUS History Timeline**

- Before 1900** Until the end of the 18th century the government acted only in cases of epidemic
- 1923** Creation of the National Department of Public Health, responsible for initiations in collective health (urban and rural sanitation, infant, industrial and professional hygiene, supervision, health in the harbours and combating rural endemics). For medical and dental assistance, treatment was paid out of pocket.
- 1923** Eloy Chaves Law creates the Cash of Retirement and Pension (CAPs), organized by companies considered strategic for the national economy at the time (rail, port). Financing came from employers and employees contributions. Only workers who contributed to the CAPs were entitled to receive medical assistance. What was offered in terms of medical assistance was defined by each CAP depending on the needs of each specific company and the financial resources available. The presidents of the CAPs were named by the Brazilian president, despite the government not contributing to the finance of the system.
- 1931** Creation of the Ministry of Education and Health



- 1932 CAPs were growing and 140 COPs covered almost 40.000 associates
- 1933 Creation of the first Institutes of Retirement and Pension (IAPs), which was organized by work category. In these Institutes, the government also contributed with the financing of the system, maintaining also the contribution from employers and employees. With the creation of IAPs, the government centralized health initiatives, having as primary interest the creation of a social insurance system that guaranteed the health of workers.
- 1949 Creation of the Service of Domiciliary Urgent Medical Assistance (SAMDU), which defined the right to medical assistance in case of urgencies for all citizens and was financed by all IAPs together.
- Until 1960 Predominance of IAPs, which privileged social security instead of health care
- 1960 All IAPs were centralized in a unique State institution, creating the National Institute of Social Security (INPS), which centralized health care provision for workers that contributed to the system.  
With this, there was the creation of the health care provision system, composed by three systems: proprietary (hospital network and health units property of Social Welfare, as well as professionals receiving wages from the State), accredited contractor (system of payment by service units), and “convenienced” contractor (pre-payment system).
- 1977 Creation of the National System for Pension and Social Assistance (SINPAS), which segmented actions related to pensions and to medical assistance. It was composed by the Institute of Financial Administration of Social Security (IAPAS) and by the National Institute of Medical Assistance (INAMPS). INAMPS continued to privilege “convenienced” private providers to increase the number of providers for the State. The system started to grow with private capital instead of investing in improving public providers.
- 1980 The system provides poor health care, with long waiting lists, low wages, bad work conditions, generating growing dissatisfaction of the population with the quality of medical assistance. Financial resources were mismanaged and cases of corruption started to be frequent. Besides that, the population was aging and the first contributors to the pension system were starting to retire and receive their pensions, for which there was not enough money.
- 1980’s Sanitary Movement: With political opening, movements in defence of a broader and democratic health policy are formed. In 1979 they proposed a structure for a new Unified Health System, incorporating successful initiatives from other countries, such as the universal right to health, integrity of actions, and democratization of the system.  
  
The prioritization of the government in previous years for the private capital in health care, however, created strong interests against changes in the system that bought profits to private hospitals.

1985            With a favourable political moment after the re-democratization of the country with the end of the military regimen, there's increasing social movement and discussion in relation to the future of the health care system.

## Appendix 2: Overview of the Chinese Health Care System and the Use of Health Technology Assessment for the Evaluation of Pharmaceuticals

### Key Chinese Health System Acronyms

CMS	Cooperative Medical Scheme
NRCMS/NCMS	New Rural Cooperative Medical Scheme
CHC	Community health center
EDL	Essential Drugs List
GIS	Government Insurance Scheme
LIS	Labour Insurance Scheme
MoHRSS	Ministry of Human Resources and Social Security
MoH	Ministry of Health
NDRC	National Development and Reform Committee
SFDA	State Food and Drug Administration
SOE	State Owned Enterprises
THC	Township health center
UEBMI	Urban Employment Basic Medical Insurance
URBMI	Urban Resident Basic Medical Insurance

## A2.1 Overview of the Chinese Health Care Delivery and Financing System

### Population, coverage, expenditure

China has historically been considered a 'developing country' with limited resources for healthcare:

- China's population in 2008 was 1.34bn, with 43% living in urban areas (an increase from 28% in 1990)
- Only 12% of the population are over 60
- 16% of the population are living in poverty (<\$1PPP per day)
- Life expectancy at birth is 74 years (2008) and the infant mortality rate is 18 per 1000 live births (2008)
- China's total health expenditures reached 984 billion Yuan (\$141 billion) in 2006 representing 4.7% of GDP.
- This is only 749 Yuan (\$107) per capita per year – with 1248 Yuan (\$178) for urban residents and 362 Yuan (\$52) for rural residents.
- Healthcare financing comprises of private payments (49.3%), social health insurance (32.6%) and government spending (18.1%).
- Most (over 90%) of private payments are out-of-pocket expenditure.
- Currently, there is no universal health insurance program in China; i.e., there is no single, uniform risk pool (in the sense that there is no single healthcare payer covering the general population) but rather there are separate ones.
- In 2006, it had per 1000 population 2.53 hospital/ township hospital beds, 1.54 physicians and 1.1 nurses (Chen, Banta and Tang, 2009).

## A2.2 Evolution of Population Coverage

China's health system has gone through two eras prior to initiating the current process of reform (Wagstaff, et al., 2009).

The first was command and control (starting in 1949 when Communists assumed power), notably with rural "barefoot doctors" supplying basic low tech public health and grass roots interventions. This delivered vaccination, improved neonatal mortality/maternal mortality, reduced malaria, and improved hygiene and disease prevention, in part by going door-to-door and educating people. During Chairman Mao's era, health insurance and healthcare provision was organized around the workplace. There was: (1) the Cooperative Medical Scheme (CMS) that covered members of agricultural communes (the rural population) (2) the Labour Insurance Scheme (LIS) for workers in State Owned Enterprises (SOEs) (3) a Government Insurance Scheme (GIS) that covered government officials.

The other started in 1978 when Deng Xiaoping moved China towards a market economy. Deng Xiaoping's market based reforms led to the collapse of the CMS and the LIS; insurance plummeted in the rural areas as the communes were broken up and declined in urban areas as SOEs came under

competitive pressure. Economic liberalisation also weakened the tax base and hence the ability of governments to directly subsidise hospital and other health care facilities. Such government support as did remain was directed at better off workers (on the demand side), i.e. those working for the government or the more secure SOEs, and (on the supply side) at urban hospitals. There was further geographical inequity as the poorer provinces lagged behind in income growth and interregional transfers via the central government lagged behind the growth of the economy

Hospitals/health facilities were given “financial autonomy” which meant they supplied “basic services at a loss (these were price controlled) and made profits on drugs and “high tech” care through a policy of charging for these non-basic services. Barefoot doctors who used to provide first-level [primary] care to the agricultural commune and workplace clinics, set up private village clinics as there was no longer communal funding to support them. Even utilisation of more basic health care services started to fall as health centres began charging even for public health services such as EPI and TB (outside of DOTS).

Thus economic liberalisation reduced people’s access to healthcare (measured in terms of utilisation rates) and increased the risk of them incurring large out-of-pocket expenditures when they did obtain access. Analysis seems to suggest that the main problems that emerged were:

- high out-of-pocket payments;
- high costs of health care, with inefficiencies due to long hospital stays, overuse of drugs, and overuse of interventions such as caesarean sections and MRIs scans, as providers sought to compensate for reductions in government and insurance scheme payments (and artificially low prices for those services that were paid for) by charging for additional services.

Consequences of the erosion of coverage and of public funding were that:

- Whilst China’s economic growth was high, its mortality rates were not falling in a way that reflected this. China now has heart disease, chronic lung disease, stroke, diabetes, cancer, and hypertension as a result of increased intake of fat, sugar, and calories, more smoking, accompanied by less exercise.
- health expenditures have placed a growing burden on poorer families, with evidence from 2003 indicating that out of pocket spending on health pushed an additional 19% of families below the \$1.08 poverty line, with 76% and 79% respectively of the lowest income urban and rural populations being without any insurance cover, resulting in them spending 10% and 21% of their income respectively on medical expenditures (China MOH, 2003)
- public health in terms of primary care prevention, for which China had a high reputation, began to be neglected in the 1980s and 90s, and public health surveillance declined likewise, hence HIV/AIDS, SARS and Avian Flu were not dealt with well and China has struggled to tackle TB and viral hepatitis.

## A.2.3 The initiation of health coverage reform in 2003

Major health care reform began in 2003 to rebuild the failing CMS and LIS schemes. China now has three major healthcare insurance schemes (Liu et al., 2009):

- The New Rural Cooperative Medical Scheme (NRCMS, also known as the NCMS). NRCMS is a subsidized health insurance scheme for rural populations (offering benefits covering primarily inpatient care and major outpatient expenses) with voluntary enrolment on a family basis. The intention is to move the benefit package away from insurance for expensive hospital care to one risk pool for inpatient and outpatient services; encouraging coverage for treatments for chronic conditions. The scheme involves a subsidy of RMB 80 (\$11.40) (made up of 50% each coming from central and local governments) towards an annual premium of RMB 100 (\$14.30) with individuals' contribution set at RMB20 (\$2.90). Patient co-payment is in the region of 50-60%. There is however a separate Medical Assistance Safety Net, which helps the poor pay their NRCMS premiums and reduces their co-payment rates.
- The Urban Employment Basic Medical Insurance (UEBMI) is a mandatory insurance scheme for formal sector workers in urban areas covering 200 million urban employed people. The UEBMI is, in Chen, Banta and Tang (2009), referred to as National Urban Social Medical Insurance Scheme for Employees and Retirees (USMISER). Financing of the UEBMI comes from 8% payroll tax, 6% from employers and 2% from employees for coverage for essential healthcare.
- The Urban Resident Basic Medical Insurance (URBMI). The URBMI is a voluntary subsidized insurance scheme for urban residents not in formal employment including children and students. In Chen, Banta and Tang (2009), this is referred to as the national Urban Resident Medical Insurance Scheme (URMIS).
- The role of private insurance is small and restricted to offering complementary or supplementary health insurance benefits (to that offered by the three other schemes) (Liu et al, 2009).

In addition there is a Government Insurance System for government employees, but there is an expectation that it will be integrated with the UEBMI.

## A2.4 Remaining Challenges and Other aspects of reform

### The extent of integration of the health insurance schemes

The current insurance platforms aim to cover different people at different locations, which currently still leaves a large number of people out of the insurance pool. The Ministry of Human Resources and Social Security (MoHRSS) is responsible for the UEBMI and the URBMI. The Ministry of Health (MoH) is responsible for the NRCMS. The Provinces also play an important role in the administration

of the schemes. Some Provinces are seeking to integrate the management of the different schemes, particularly the URBMI and the NRCMS, although they are still administering different benefit packages. Nationally, there is a debate as to whether the MoHRSS should take over the MoH role, becoming the purchaser for the NRCMS. The MoH would still own the hospitals and employ the doctors. But the MoH has resisted.

As a consequence of the different schemes, the insurance benefit is not standardized, and the benefits are not transferrable from one city to another. There are a large number of migrant workers whose permanent residence is in a rural area but whose workplace is in one of the cities are still unable to enjoy health benefits because of administrative rigidity. Research shows that the NRCMS scheme has reduced migration to the cities as people do not want to lose health insurance. However, this needs to be put in context. Many migrant workers are young with limited health care interests unless they are already sick. When the URBMI has been rolled out it will be possible to explore whether this has encouraged migration to the cities.

There are differences in philosophy between the MoHRSS and the MoH. The former is interested in security, i.e. in treatment once the patient is ill, whereas the MoH has more focus on health including prevention. There is also important heterogeneity of services reimbursed (for example, inpatient and outpatient, and the type of hospital covered) not only across the schemes but within them, depending on local resources. For example in the richer coastal areas the benefit package in the UEBMI is better because the enterprises can afford to pay higher wages and also to contribute more than the minimum percentage of salary.

### **The lack of autonomy for public hospitals**

The second challenge to greater integration of health insurance schemes relates to the issue of public hospitals. Currently, the public hospitals are under the control of MoH, and the operation and management suffers from low efficiency. There are more than 70 million medical staff, but they do not have the right incentives to perform well in this system, with service fees strictly under price control and heavily distorted. Hospital managers are administrators – they do not have the power to hire and fire. Doctors' wages are too low, creating disincentives to becoming a doctor at a time when more and better trained doctors are needed. Many older doctors in the rural areas are not well trained in modern medicine. The MoH appears to be reluctant to introduce reform, in part because it uses low wages to keep down health care costs. One solution to this problem could be to ease the controls on hospitals, give the hospitals their autonomous administrative rights, and let them decide how to invest and allocate the resources within the hospitals. However, this assumes that payment mechanisms provide appropriate incentives.

### **The lack of an efficient fee schedule**

Evidence from around the world indicates that fee-for-service is usually not an optimal reimbursement system. Where it is used it is important that relative fees reflect relative costs and that, overall, fee levels enable an efficient hospital to cover its costs. The existing pricing mechanism for medical services in China is perverse. Price control by National Development and Reform Committee (NDRC) prevails in this field. Many fee-for-service charges are now far below the market price level. Hospitals are unable to cover costs without other revenue sources including providing services that are not included in the insurance package, so they do not have the right incentives to provide quality care. Doctors salaries are supplemented by bonuses of up to 50% of salary, linked to

the ability of their Department to generate additional income from the sale of extra services. Given the ability to earn much-needed revenue off of the margins allowed in pharmaceutical sales, hospitals therefore tend to provide incentives to doctors to over-prescribe. Not unsurprisingly there is drug over-prescription, and inconsistent prescription has become a serious problem.

The government has recognized this problem and are working to phase out mark-ups allowed on pharmaceutical sales, including on the co-pays that patients pay. This is being presented as a benefit of health care reform – lower drug prices for patients. But it creates challenges for hospital finances. The MoH is proposing to introduce a dispensing fee (an Rx service fee) to tackle the problem, i.e. replacing a 15% hospital percentage mark up with a flat rate (10 RMB or \$1.50) per-item charge which would remove the incentive to prescribe higher priced drugs but not the incentive to overprescribe. This reform is being presented as a price cut for patients (in the form of lower co-payments) and so as a benefit of health reform. Logically the fee schedule for other things could go up, but this would be seen as a price increase for patients via the co-payment so is difficult for the MoH to implement.

To expect that the NDRC can oversee thousands of medical products and services and to efficiently control their prices under a fee-for-service schedule that covers all of China seems to be unrealistic. Arguably, prices need to be decentralized in order to solve this problem. However, this presupposes the introduction of effective purchasing and incentives for quality and efficiency, which can drive reform to the delivery system that is suitable for a population with increasing chronic conditions and reduce inefficiencies. It needs to integrate prevention, primary and hospital care, and re-orient care away from hospitals to primary and community based care.

### **The need for the active purchasing of population health care.**

There is little understanding within the health care system nationally and locally of purchasing and contracting for health care services and it is unclear how improvements in delivery integration and efficiency can be brought about. There are experiments in some provinces with:

- provider payment methods linked to the use of clinical protocols for some of the most prevalent health conditions,
- the design of a benefit package to reduce financial barriers to access care and to motivate patients to use primary-based care;
- use of technology (e.g. mobile phone) to improve patient compliance;
- the conduct of patient education programmes on prevention, healthy lifestyle and best-practice care.

A note on one experiment in Ningxia province is included in an Annex to this Appendix.

There are efforts to develop clinical practice guidelines, and the MoH is seeking around 400 clinical guidelines of which around 100 have been published. These have mostly been developed over a short period by the Teaching Hospital at Beijing University and draw on relevant guidelines from other health care systems. Hospitals in the Provinces have also been asked to develop guidelines. However, it is not clear whether there is an agreed protocol for the development of national or local



guidelines designed to ensure good practice. It is also unclear how incentives will be put in place to change clinical practice.

One route currently being developed in some areas is through improvements in payment mechanisms for hospitals with the development of “case base” payments, seeking to move away from fee-for-service towards DRG type payments. These can be linked to clinical protocols derived from practice guidelines providing a “bottom up” way of paying for good clinical practice.

There is a desire to try and move to primary and community care, building a strong primary care based health delivery system with infrastructure building (township health centres (THCs)/village clinics in rural areas; community health centres (CHCs) in urban areas) with the government paying the costs of THCs and CHCs and these centres becoming “gatekeepers.” However, the costs of investing in this additional infrastructure will be high, especially as such reconfigurations are unlikely to lead to hospital closures.

There are also efforts underway to address geographical inequalities in government healthcare spending. Further exposition to the healthcare system in China will be found in Eggleston and Hsieh (2004), Han, Chen, Evans and Horton (2008), Hughes (2008), Lancet (2008) and Watts (2008).

## A2.5 Drug Purchasing

Chen, Banta and Tang (2009) note that there are more than twelve ministries or administrations governing the health sector in China: the main actors involved with pharmaceuticals are the:

- State Food and Drug Administration (SFDA). The SFDA’s focus is on the traditional hurdles of efficacy, safety and quality evaluations of the outcome of preclinical and clinical studies along with risk-based analyses. There have, however, been calls for introduction of cost-effectiveness as a possible decision-making criterion. At the moment decision makers at the SFDA do not have a good understanding of ‘technology assessment’, and they do not use technology assessment in their reviews.
- Ministry of Human Resources and Social Security (MoHRSS). The MoHRSS is responsible for the UEBMI and URBMI. The MoHRSS has three positive lists covering pharmaceuticals, services of diagnosis and treatment, and facility standards for healthcare. There is a national formulary that is composed of roughly half traditional Chinese medicines and half western medicines (Chen, Banta and Tang, 2009).
- Ministry of Health (MoH). The MoH is responsible for the NRCMS, for public hospitals and the medical workforce, and for the Essential Drugs List (EDL).
- National Development and Reform Commission (NDRC). Decisions about the maximum prices of medical drugs and devices that will be listed on formularies used by all public-funded insurance schemes are under the authority of the NDRC.

The NDRC operates two primary drug pricing regulations: (1) uniform price ceilings applicable to generics satisfying GMP standards, and (2) 'independent pricing' for imported Western branded products, mostly patented medicines, off-patent originators, and follow-on generics of superior quality (presumably in terms of convenience in dosing schedules and administration). In theory this can include Chinese manufacturers, but most Chinese manufacturers are producing generic drugs. This 'independent pricing' policy enables 'superior' drug products (in terms of safety and efficacy) to get higher prices.

The NDRC has also in place mandatory retail price cuts for 'older' drugs (the size of price cuts averaging around 20%). These mandatory price cuts failed to control pharmaceutical expenditures since less attention was given to rational use of medicines (with many hospitals and doctors having an incentive to overprescribe) and some domestic drug producers responded to these mandatory price cuts for 'older' drugs by launching 'new' drugs which were branded generic versions of the old drugs with a new name, formulation and packaging. However, the effect has been to squeeze the local Chinese generics drug industry. Experts suggest this reflects a policy objective of trying to reduce the number of suppliers to get rid of the less efficient ones and so reduce prices.

There has been a recent reform of the Essential Drug List (EDL) by the MoH (in terms of which drugs are included). The MoH is using the EDL to try to reduce costs in public hospitals, which would have to use the EDL. It has had the effect of reducing the potential for hospitals to increase the revenues from the 15% mark up by using higher priced drugs and replacing local purchasing with a regional procurement exercise to get suppliers for the EDL list. It is not at all clear how much evidence has been used to generate the EDL. It seems the EDL was comprised mostly by committees of opinion leader doctors listing what they like to prescribe.

The EDL is made up of two lists A and B. List A includes all drugs considered 'clinically necessary, widely used, safe and efficacious; and price advantageous among its class'. EDL A is the national drug list and cannot be modified by local governments. EDL B is similar except that the prices of products listed tend to be higher than similar products listed on EDL A. Local governments are only allowed to modify the national EDL by adding up to 15% to the number of drugs listed in EDL A. Although it is stated that cost-effectiveness is not a criteria for the selection of EDL drugs, recent revisions of EDL guidelines explicitly ask for the involvement of health-economists in the determination of the EDL. Some foreign drug companies already have been voluntarily submitting pharmacoeconomic data along with their conventional submissions for listing on the EDL. However, as we noted earlier, it is not clear how evidence-based EDL listing decisions are.

The MoHRSS is now trying to introduce pricing rules for the reimbursement prices it pays for the two insurance schemes (UEBMI and URBMI) for which it is responsible. It is not clear how this works in relation to the NDRC, but if NDRC sets the maximum price (or the drug qualifies for independent pricing) then MoHRSS as the payer can decide on what kind of drugs it will reimburse and at what rate, rather than the maximum price. In this selection process, it may plan to use HTA principles, but the drug cap itself is set by NDRC rather than MoHRSS. The NDRC, like other government bodies, recognise that use of pharmacoeconomics might be beneficial in the price setting process, but no official guidelines have been put forward in practice. As the independent pricing arrangement is reserved including an "innovative category" which covers the majority of imported Western patented drugs. NDRC does not set the prices for these products, although it does set the prices of generic named versions, and innovators are allowed a percentage mark up above that price.

Whilst MoHRSS does not have price setting power, which is reserved for NDRC, it can work on the drug procurement process. Traditionally, there is a 35% - 50% mark up between the manufacturer's wholesale price and the retail price, and drugs typically go through many "middle men" wholesalers before finally reaching the pharmacy department in hospitals. The EDL arrangements include Provincial procurement to replace individual hospital buying.

## A2.6 The role of HTA in China

Chen, Banta and Tang (2009) note that there has been, in China, a long interest in the adoption of HTA dating back to the 1980's when The World Bank gave strong encouragement for its adoption. However, there seems to be no clear path for the implementation of HTA in China (nor does it seem to be a priority for decision-makers).

Doherty, et al (2004) reports that HTA is rarely used in either the public or private sectors as pharmaceutical policy and medical decision-making is still based on traditional approaches of establishing efficacy, safety and quality, and then using cost-based price controls. The authors note that a survey of HTA literature on China showed that researchers in government agencies or industry did not seem to play much role in the conduct of the studies identified. Studies were conducted by independent academic groups.

Tarn, et al (2008) noted that pharmacoeconomics is a newly developed discipline in China and a systematic review of 380 pharmacoeconomics and outcome research articles relating to China showed that approaches and methods for conducting HTA are not standardized. The authors also report that pharmacoeconomic data have not been widely used in management of hospital formularies. However, whilst pharmacoeconomic data have not been used as a decision-making criterion in China, as we noted above, an increasing number of (international) pharmaceutical companies in China have started using pharmacoeconomic evaluations as supportive evidence in drug reimbursement applications, and in marketing activity.

The use of HTA is conceptually accepted in government's documents (for example documents from the NRDC, MoHRSS and MoH) but nothing has been outlined as to the specifics of HTA. Academics have been active in proposing a formal guideline, and in 2005 some general principles for HTA were put forward by the Chinese Medical Doctor Association. In 2008, a Pharmacoeconomics Specialist Committee was formed, which is charged with the task of updating the principles and pushing it into the policy making arena. More recently, in late 2010, we understand that revised guidelines developed at Peking University have been circulated, and a number of stakeholders including some government agencies and officials have been involved in discussions about them. HTA, in China, is therefore not formally conducted in a systematic fashion and therefore there is no formal arrangement for the financing of HTA. Currently HTA projects are sponsored by manufacturers on a small scale and the use of HTA is limited and based on short study horizons. Many HTA projects are organised by drug manufacturers through contracts with academia, with outputs for 'internal' company use.

The MoH considers cost-effectiveness and HTA analysis as part of its modus operatus. The MoH has signed a Memorandum of Understanding (MoU) with the UK National Institute for Health and Clinical Excellence (NICE). According to the NICE web site "with UK Department for International Development (DFID), WHO and World Bank support, NICE is looking to help the MoH build capacity (institutional and technical) and to pilot the development/adaptation of evidence informed clinical

standards for best practice, taking account of efficiency and equity considerations with the aim of supporting the Chinese government with the ongoing Rural Health Reform, a large reform initiative which emphasises quality, efficiency and access.”

(<http://www.nice.org.uk/aboutnice/niceinternational/NICESignsMemorandumOfUnderstandingWithChineseMinistryOfHealth.jsp>)

NICE’s work is linked to the development and use of clinical practice guidelines for the better management of disease rather than with technology assessment (i.e. the application of HTA to a specific drug, device or other intervention). NICE will work with the MoH over the next five years to develop a new institution responsible for promoting quality and efficiency in healthcare across China. This will build on the China Centre for Health and Development.

Within the MoH, the initial facilitator of HTA was the Department for Science and Education (DSE). Within the MoH, the Department of Hospital Administration (DHA) also has some role to play in HTA – with regards to clinical application of medical technology in ways that are consistent with the ‘principles of science, safety, effectiveness, cost-effectiveness, and ethical acceptance’. DHA requires that health technologies with ethical concerns and risks related to their use be evaluated by a third-party healthcare payer before their use.

In summary HTA has been adopted in terms of awareness and interest, by policy makers in China (albeit the definition of HTA appears to cover mainly clinical evaluation of individual technologies with little economic analysis and little consideration of treatment guidelines or of using HTA to help reform the architecture of the health care system). Such HTA as is occurring is scattered among many administrative areas. There is no coordination of or synergy between HTA activities being run by different authorities. There are different HTA mandates of different authorities (including the SFDA, MoH and MoHRSS) whose decisions affect health technology adoption in one way or the other (Chen, Banta and Tang, 2009)

## A2.7 Key Issues

There appears to be a lot of unfocussed interest in the use of HTA, primarily in the context of new technologies rather than by any system wide focus on achieving value. In this context, HTA currently seems to be seen as a “black box” with little thought given to appropriate use and to processes that will ensure the involvement of stakeholders. There are also many challenges involved in collecting economic and clinical data, not least poor infrastructure and a payment mechanism that does not reflect cost.

As the health care system develops there is likely to be a debate about the degree of heterogeneity that is appropriate. At the moment the Government’s main concern is to ensure increased population access to a core of services. This is a political priority. However there are likely to remain very different segments of the population (in terms of income). It is not obvious that a “one size fits all” system is appropriate, given that the Government is unlikely to be able to afford a level of public health care funding over time that would make the level of access expected by middle and higher income groups available to the whole population. In this context a degree of heterogeneity in provision and financing could enable differential pricing of drugs and/or the targeting of some drugs to the increasing numbers of patients paying out-of-pocket or paying through private comprehensive or supplementary insurance. There could even be differences in the willingness to pay of public

schemes, depending on local circumstances, with more prosperous regions providing a higher level of drug benefit.

Whilst there is growing interest in the potential importance of evidence-based clinical practice guidelines in managing chronic disease, it is not clear that HTA is playing any role in the development of guidelines. The new MoU between the MoH and the UK NICE may initiate greater use of guidelines to better manage chronic disease.

The focus for the use of economics is on HTA for “micro-technologies” rather than looking at other “macro” aspects of system architecture which may yield higher gains such as reform to hospital payment systems and to the drug distribution process.

China’s current strategy is to increase the public sector share of health spending in order to provide affordable access to basic health care for its population. Once this is achieved there will then be questions as to: how the minimum package increases over time; the extent of heterogeneity of benefits offered to different population groups and geographical areas within the public schemes; and the extent to which people “top up” the public system with additional services purchased through supplementary insurance or out-of-pocket.

## Annex: Note on the Experiment in Ningxia Province

In Ningxia province there is a collaboration between the provincial government and the central government for a five year experiment 2009-2013 to structure the health care system in order to make the best use of the funds. The objective is to identify most prevalent health problems including:

- chronic (e.g. hypertension, and diabetes),
- infectious (e.g. TB, Hepatitis B, and dysentery) and
- common ailments (e.g. the common cold, UTI, and gastritis)

Improvements in delivery to tackle these health problems include:

- Developing clinical protocol;
- Defining the role and function of the three-tiered delivery system: village clinics, THCs, county hospitals;
- Designing provider payment method to incentivise providers to follow the best-practice, including referral. This raises the question as to how to re-train and/or retain qualified village doctors?
- Designing benefit package to reduce financial barrier to access care and to motivate patients to use primary-based care
- Using technology (e.g. mobile phone) to improve patient compliance.
- Conducting patient education program on prevention, healthy lifestyle and best-practice care
- Creating a purchaser who acts in the best interest of the insured population.

There are 2 intervention counties, 3 comparison counties, a total of 1.8 million people. The study design is within county: blocked randomization across townships and villages with phased in interventions. It covers five years: 2009-2013, and uses:

- Longitudinal household survey in baseline and followed up every year.
- Patient cohort study
- Provider survey
- Direct linkage to claims data for NCMS reimbursement
- Data base created by mobile phone technology

Source: Yip (2009)

## Appendix 3: Overview of the Taiwanese Health Care System and the Use of Health Technology Assessment for the Evaluation of Pharmaceuticals

### Key Taiwanese Health System Acronyms

BNHI	Bureau of National Health Insurance (中央健康保險局)
BPA	Bureau of Pharmaceutical Affairs (藥政處)
CDE	Center for Drug Evaluation (財團法人醫藥品查驗中心)
DBC	Drug Benefit Committee (健保局藥事小組)
DHTA	Division of Health Technology Assessment
DOH	Department of Health (行政院衛生署)
NHI	National Health Insurance (中央健康保險)
TFDA	Taiwanese Food and Drug Administration (食品藥物管理局)

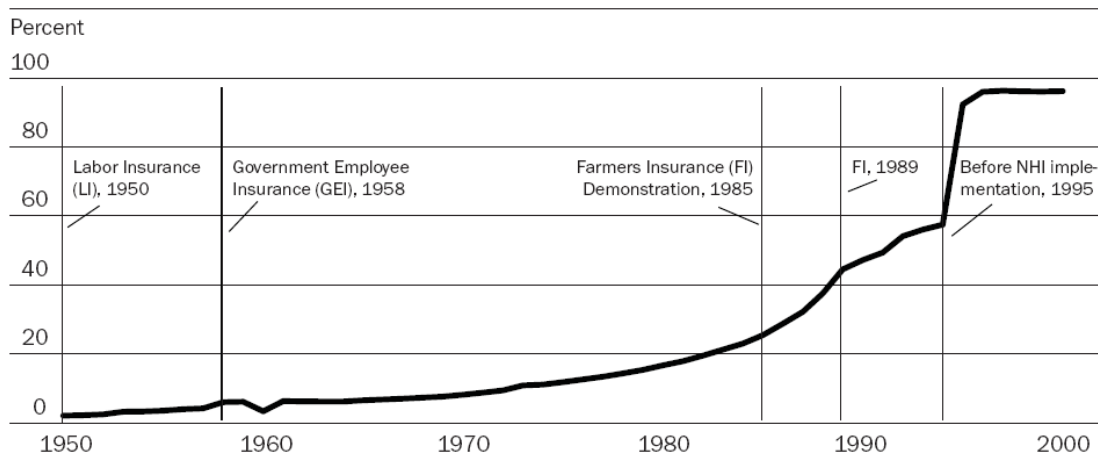
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### Taiwan Health Care System Timeline

- 1950 Establishment of Labour Insurance, the program aimed at the workers of government-run enterprises, private company employees, blue-collar employees, fishermen, skilled hands, drivers, and janitors of government agencies who were over 15 and under 60 years old.
- 1958 Establishment of Government Employees' Insurance, which covered the employees of government agencies and holders of elected public office.
- 1985 Establishment of Farmers' Insurance, which targeted members of farmer associations and individual farmers who were over 15 years old.
- 1995 Creation of NHI, a single-payer compulsory social insurance plan, which centralizes the disbursement of health-care funds.
- 1998 Establishment of CDE as a non-government, non-profit organization to support the technical evaluation of new drugs and new medical devices for regulatory requirements and offers related consultation services under the commission of DOH.
- 2007 Establishment of HTA as a pilot project within the CDE to provide unbiased assessment report to DBC of BNHI on cases of new drug submission for reimbursement.
- 2010 (January) BPA integrated into Food and Drug Administration
- 2010 (October) BNHI renews call for completion of "Second Generation NHI"

**Figure 1**

**Insurance Coverage Expansion In Taiwan, Insured People As Percentage Of Population, 1950-2000**



**SOURCES:** For 1950-1994, J.R. Lu and C.R. Hsieh, "The National Health Insurance Program in Taiwan," in *Health Economics* (Taipei: Pro-Ed Publishing Company, August 2000), chap. 14, 401; for data after 1995, Taiwan Bureau of National Health Insurance.

**NOTE:** Taiwan's National Health Insurance (NHI) was implemented in 1995.

**Source: Lu and Hsiao (2003)**



## A3.1 Overview of Taiwanese Health Care Financing, Insurance, and Delivery System

Since 1995, the health care system in Taiwan is known as National Health Insurance (NHI), which is a premium-based, single-payer, mandatory, near-universal insurance program run by the government to allocate health-care funds. The system promises access to all necessary health care for citizens with national identity cards. In 2000, the coverage already amounted to over 96% of the total eligible population, and that percentage has increased each year since NHI first began.

More than 80% of health providers are private organizations: this provides market competition for the delivery of health services to Taiwanese citizens. Given that reimbursement is on a fee-for-service basis, profit-maximizing clinics would have an incentive to provide some “unnecessary” (i.e., low-yield) services, examinations, or procedures to their patients since government is covering the bill. The Bureau of National Health Insurance (BNHI), which oversees the NHI program, has long recognized the need to prevent this type of misallocation and contain its costs. In 2002, they changed the NHI from a fee-for-service model to a global budget system.

## A3.2 Population, coverage, expenditure

- Population: 23 million people
- Coverage: 98% (in 2008)
- Total health care expenditure: 6.2% of GDP
- Health spending per capita: \$646 (US\$ PPP) [Lu and Hsiao (2003)].

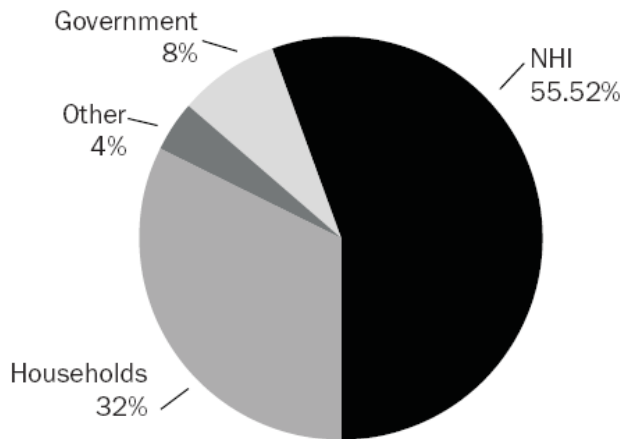
## A3.3 Financing

The healthcare market in Taiwan is financed by a single National Health Insurance (NHI) system in which revenue flows are mobilized from either by premium payments or tax contributions together with contributions from ‘employment-based financing’ and from co-payments paid by patients. Under this scheme employers pay 60%, employees 30% and government 10%. (The NHI system is governed by the Bureau of National Health Insurance [BNHI].) Healthcare providers are paid by a fee-for-service retrospective reimbursement system, and there is a list of treatments that specifies those eligible for reimbursement (Jirawattanapaisal, et al., 2009). See also Wu (2006).

In addition to spending from NHI, households and government often buy supplemental insurance or have out-of-pocket expenses. The following chart (Figure 2) shows the composition of total national health care financing in Taiwan.

**Figure 2: National Health Financing**

Source: Cheng (2003)



### A3.4 Pharmaceutical Coverage

From an interview with Taiwan’s Minister of Health, Cheng (2009) reports that NHI in Taiwan introduced forty to fifty-five new drugs every year. This has resulted in increases in spending for new drugs as a proportion of total NHI expenditure: Taiwan spends roughly 25% of the NHI budget on drugs and about one percentage of the 3-5% annual growth in spending of the NHI is on drugs. As shown in Table 1, drug fees account for 1/3 of all outpatient care expenditures.

**Table 3** Outpatient care expenditures using western medicine in Taiwan (In New Taiwan dollars [NT\$])

	1997		1998			1999			2000		
	Expenditures	%	Expenditures	%	Δ%*	Expenditures	%	Δ%	Expenditures	%	Δ%
Diagnosis fees	48,438,161,904	32.99	52,281,331,726	31.74	7.93	54,187,065,127	30.18	3.65	52,755,753,813	28.94	-2.64
Treatments and medical supply	45,322,860,492	30.87	52,007,586,248	31.57	14.75	57,545,835,248	32.05	10.65	59,761,191,988	32.78	3.85
Drug fees	48,375,623,320	32.95	54,841,394,878	33.29	13.37	61,094,298,743	34.02	11.40	62,982,417,466	34.55	3.09
Dispensing fees	4,700,703,238	3.20	5,592,111,857	3.39	18.96	6,735,153,262	3.75	20.44	6,813,726,470	3.74	1.17
Total	146,837,348,954	100.00	164,722,424,709	100.00	12.18	179,562,352,380	100.00	9.01	182,313,089,737	100.00	1.53

\*Δ%, percentage changes from last year.

**Table 1: Outpatient Expenditures**

Source: Doherty, et al. (2004)

In terms of target therapies for cancer, the NHI covers thirteen of the total seventeen drugs currently available in the world market. The NHI covers many of high-price biotechnologies but place restrictions on use, and the BNHI pays for these drugs subject to certain requirements. (It turns out that these restrictions on use and reimbursement are considered too strict and often opposed by physicians.) Despite the increasing expenditures, Taiwan still lags behind the US in the introduction

of new health technologies, often by 2 years and at times 5 years (but no longer than that). To control the rising expenditures on pharmaceuticals, the BNHI has introduced various strategies to control health expenditure including: internal reference pricing (i.e., generic grouping based on the notion of 'chemical equivalence'), external (international) reference pricing (based on prices of products in ten international reference countries), market price and volume surveys, and global budget payment for clinics and hospitals.

### **A3.5 Pharmaceutical Distribution**

Those in Taiwan can get prescription drugs from a variety of sources including private clinics, state-licensed pharmacies, and general hospitals. Doctors are the primary prescribers although pharmacists can provide over-the-counter medications. These medications range from traditional herbal remedies to modern western pharmaceuticals.

Since the acquisition cost of the medication is almost always less than the reimbursement cost (from NHI), there is an incentive for hospitals and practitioners to overprescribe medications. In fact, a patient seldom leaves a visit to a doctor without a handful of prescription drugs. Of course, cultural factors and expectations probably play a large role in this as well. As noted above in Table 1, a large share of revenue from outpatients comes from drugs. As a result, there is an overuse of drugs, resulting in health problems, such as a high rate of immunity to antibiotics to those who need it.

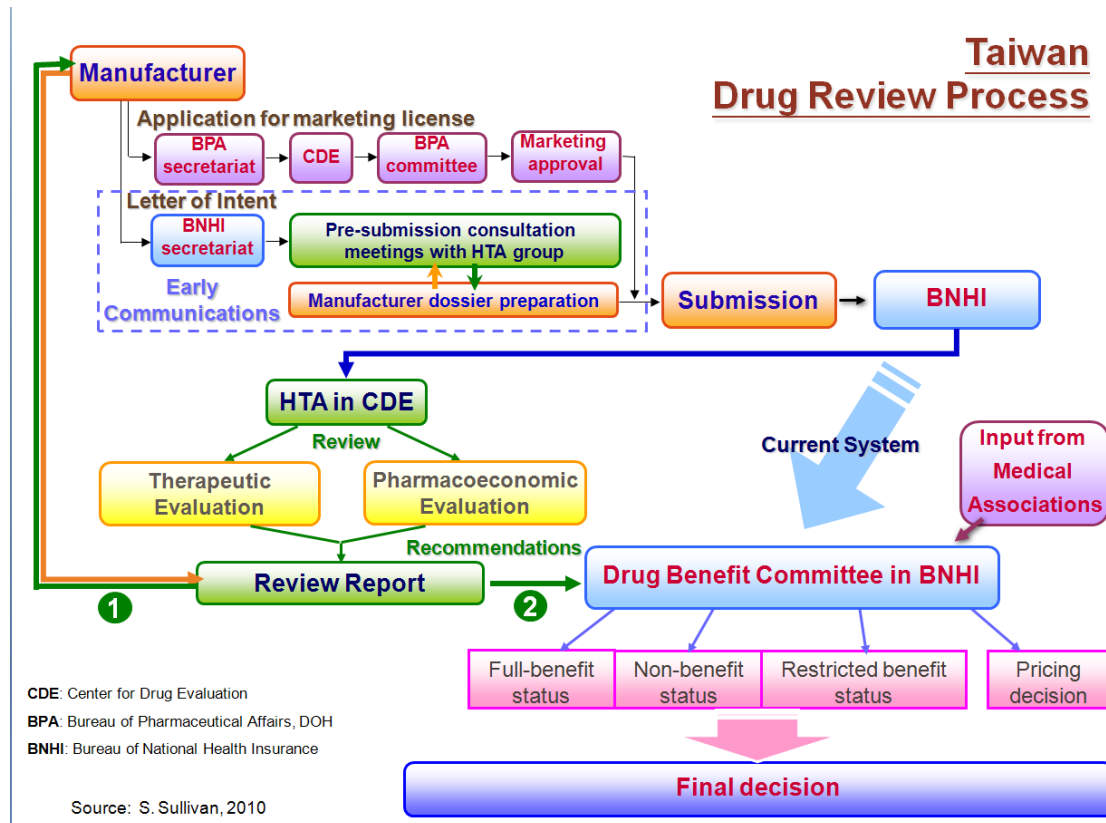
Hospitals are reimbursed by the BNH according to the price list. Each hospital is reimbursed the by same amount for the same prescription. However, each hospital has its own acquisition cost through bargaining with the drug companies. Thus, larger hospitals, such as medical centres, with strong bargaining power are able to obtain drugs at a relatively low price.

### **A3.6 Incorporation of New Drugs in the Taiwanese Health Care System**

Figure 3 represents the relationship among the government bodies involved in the drug review and HTA process (though the BPA was integrated into the TFDA in January, 2010). The process for introducing a new drug to the Taiwanese Health Care System is managed by the Drug Benefit Committee (DBC). It is comprised of experts from disciplines including physicians, pharmacists, and economists; in total, there are 24 members (5 officers and 19 medical professionals). Every month, the DBC meets to discuss applications for new drugs submitted by manufacturers, each of which is assigned to 2 of the 19 medical professionals for review. Within 2 weeks, the medical professionals assigned to the drug application submit a review for the rest of the committee to consider. The entire committee then comes together 4 to 6 months later to discuss the proposed drug.

When the Minister of Health announced the upcoming pilot program of evidence-based decision making, he stressed that it would not prolong the process. A year later in 2008, a Health Technology Assessment (HTA) program was established in probationary form and the evaluation of drugs was to be accelerated to an average of 3 months. Apparently, the HTA team completes product evaluation in about 42 days, on average, while the review by DBC still takes longer than three months.

Figure 3. Taiwan Drug Review Process



### A3.7 Pricing of New Drugs

Doherty, et al. (2004) note that there are, at least, three methods used to determine the price of new pharmaceuticals: (1) the international median price of 10 countries, (2) the international price ratio using treatment comparators and (3) the treatment course or daily cost using treatment comparators. Advantages or disadvantages of new products, along the dimensions of efficacy, dosage form and pharmacokinetic profile, are considered in decisions to increase or reduce price. Pharmaceutical companies provide evidence to experts invited by the BNHI and a drug benefit committee. Evidence from RCTs are required (with preference for head-to-head comparisons of efficacy and safety) whilst submission of pharmacoeconomic evidence is encouraged in 2008.

In 2010, a new “Pricing Principles” document was issued by the Bureau of National Health Insurance (BNHI, 2010). A distinction is made between Category I and Category II new drugs, and the reference pricing benchmarks and pricing rules are different for the two categories. For a new drug to be in Category I, drug license holders must justify a “substantial clinical improvement” via head-to-head or indirect comparison. Category 2A new drugs exhibit at “moderate improvement, while Category 2B new drugs have similar clinical outcomes as therapeutic reference class products. Category I drugs are priced (i.e., reimbursed) at the median of 10 reference countries (with a 10% premium if a Taiwanese trial of a reasonable scale has been done). The pricing of Category II drugs

uses a complicated set of rules that has the median reference price as a ceiling, including getting the lowest price among the reference countries. Interestingly, up to a 10% premium might be given for “having pharmacoeconomics results in Taiwan.”

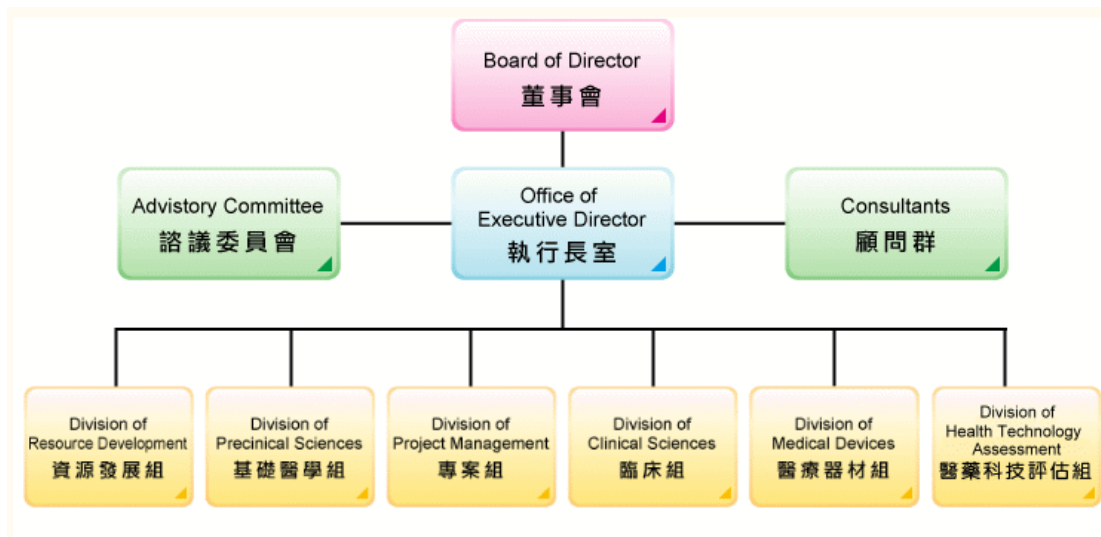
According to Doherty, et al. (2004), as of that time, if the estimated market of a new product was expected to exceed NT\$100 million per year (New Taiwan dollars), then a price-volume negotiation could be considered. The BNHI could negotiate the price of new product with the supplier for 3 years, and at the end of the third year, a pharmacoeconomic study (on Taiwanese populations) would have been conducted and the results of that study used to negotiate a price. If a new product were first introduced into the Taiwan market, the BNHI could request HTA evidence. Pharmacoeconomic evidence could be referenced from overseas literature in cases where there is lack of local data or (physician) experience. Generally speaking, it appeared that HTA, as of that time, had been well embraced by academia, industry and healthcare decision-makers in Taiwan (Doherty et al., 2004). This interest in HTA looked ever more appropriate when one considers evidence that drug (reimbursement) price is not the primary driver of increased spending in Taiwan.

More recently, however, circumstances have changed. Apparently, the BNHI never actually announced this threshold to the public, and they did not necessarily follow it. Some products with budget impact of less than NT\$100million have been required to sign a price-volume agreement to enable the drug to be reimbursed. However, BNHI has recently mentioned that they will consider setting a threshold for encouraging or requiring a price-volume agreement, maybe higher than NY\$100million, but this is not yet decided and announced. Also, with regard to the aim to conduct a pharmacoeconomic study by the end of the 3 year agreement, it is an outdated practice that has not been followed.

## A3.8 Health Technology Assessment in Taiwan

### Overview

The Division of Health Technology Assessment (DHTA) was established in 2007 as a pilot program in the CDE, a private, not-for-profit, non-governmental organization, and fully sponsored by the Department of Health. The purpose of the HTA group is to support the BNHI by providing evidence-based evaluations of the merits or drawbacks of new healthcare technologies. Currently, there are four types of new drug applications that are sent to the HTA division for review: new chemical entities, new indications, new dosage forms, and new combinations. When the HTA group receives these new drugs for review, they assign each case to 2 experts who search independently for evidence from CADTH (Canada), NICE (United Kingdom), PBAC (Australia), SMC (Scotland), the Cochrane library, PubMed, EMBASE, etc. A typical report is completed and verified within 42 days upon which it is disseminated to the BNHI for the DBC meeting.



**Figure 4: DHTA Organization Chart (Source: adapted from - <http://www.tasporg.org/wp-content/uploads/2010/04/huaxia-12.pdf>).**

Yang (2009) reports that the Taiwan Society of Pharmacoeconomics and Outcomes Research (TASPOR) has published a guideline for economic evaluation of health technologies but unlike the KPEG ('Guidelines for Economic Evaluation of Pharmaceuticals in Korea'), which is the equivalent set of HTA guidelines employed in South Korea, it is not an official guideline.

### A3.9 Role of HTA

At the moment (2010), the BNHI does not mandatorily require evidence for pharmacoeconomic results from new drug submission; however, it provides an incentive for a manufacturer to conduct local PE study by giving a 10% mark-up of the reimbursement price. It is entirely voluntary for manufacturers of health technologies to provide this information. The HTA assessment report will contain the international evidence from the literature or other HTA agencies. If the BNHI needs economic evidence, it asks the CDE. This means under the voluntary HTA scheme run by Taiwan, there is an incentive for manufacturers to submit locally conducted economic evidence to justify a higher reimbursement price.

Also, there is a trend toward having HTA play a larger role in the drug review process. In 2010, HTA/CDE held an educational seminar on HTA methodology and asked pharmaceutical companies to conduct systematic reviews. The main driver behind this push toward HTA has been the introduction of new drugs into the NHI formulary: the more important issue is allocative efficiency of health technology adoption decisions (Hsieh and Sloan, 2008). However, Hsieh and Sloan (2008) note that, although adoption of new health technologies puts pressure on healthcare budgets, the estimated benefits (this includes quantified health benefits) far exceed the costs. In a strict economic sense, the adoption of expensive, new health technologies is not necessarily 'costly'. The issue is not so much about the absolute level of spending on health technologies but on what the money buys.

HTA would therefore be helpful in determining adoption of health technologies, for which the marginal/incremental health benefits (in monetary terms), exceeds the marginal/incremental costs.

### **A3.10 Future of HTA in Taiwan: Findings and Issues**

Despite its increased importance in the drug review process, HTA is still currently a pilot project. There are about ten employees to conduct synthesis of evidence and analysis of new drugs. All projects done by DHTA are currently delegated by BNHI, so they are subordinate to the DOH and BNHI. It is, however, financially independent from the BNHI, and aims to make an unbiased, independent assessment of the evidence.

According to Jirawattanapisal, et al. (2009), there is no legislative instrument backing the use of HTA in pharmaceutical reimbursement decisions in Taiwan although some progress has been made. In 2007, the Minister of Health established an HTA system under the Centre for Drug Evaluation (CDE). The CDE acts as an adviser to the BNHI – which is the single payer for all beneficiaries – in all matters relating to HTA. The BNHI (specifically the Drug Benefit Committee (DBC) of BNHI) takes consideration of HTA evidence as part of the information arsenal for pharmaceutical reimbursement decision-making. The CDE is thus not a healthcare payer as in the case of HIRA (the National Health Insurance Review and Assessment, which is agency within the NHI) in South Korea: it is an independent evaluator.

This independence, however, doesn't guarantee complete lack of bias: HTA deliberations and discussions are not made public in Taiwan. Few people outside of the BNHI and DBC members have access to their reports. (It is the BNHI's decision not to disclose the assessment report, not the HTA group.)

Currently, the new law regarding the "second generation" of NHI is under review in the legislative Yuan, and is expected to be completed in early December of 2010. There are two clauses related to HTA. First, it states that BNHI "can" conduct HTA analysis in appraising new drug as opposed to stating that they "should"; this clause has not yet been approved, which means that HTA's function or role is still not specified in the new law. The second clause was approved and stipulates the following: if the BNHI cannot complete HTA analysis on a new drug within 90 days of the submission, the BNHI has to directly accept the inclusion of new drug in the reimbursement list. There can be no delay in the approval process due to tardiness from an HTA report.

It is noteworthy that the HTA assessment report for BNHI has been completed within 42 days since the beginning, and has never been delayed. The decision on reimbursement and pricing is by DBC, so that is the reason for any delay. The HTA assessment report does not recommend the listing and pricing: it is given to the appraisal committee members to review before the DBC meeting, and they make the recommendation.

The BNHI spends about 25% of its budget on drugs. However, this important statistic is somewhat misleading. The fact that the reimbursement level is higher than the acquisition cost means that providers are paid more by government than the amount they pay to purchase the drugs. This gives them an incentive to prescribe more.

Understanding the role that HTA will, can, or should play in Taiwan requires an appreciation of the fact that a centralized health care system can behave as a monopsony buyer, negotiating in the case of innovative branded drugs with a monopoly seller--the manufacturer. The price outcome of such a "bilateral monopoly" negotiation is indeterminate (in terms of its relation to marginal cost),

according to economic theory. The sellers are, in fact, concerned the government has the upper hand, and that this will push down prices in face-to-face negotiation. Hence, the idea of international reference pricing becomes appealing, because it also reduces the costs of negotiation. And if international prices are related to “value” to the customer based on willingness to pay for health gain (reflecting also ability to pay, i.e., income levels), then the reference price could roughly be based on value.

Thus, the reference price used to set the reimbursement level acts a ceiling on what manufacturers can obtain in their negotiation with hospitals, clinics, and other providers. Without knowledge of these discounts, it will not be possible to assess the actual cost-effectiveness of drugs in real-world practice. However, once a health care system is operating in a “second-best world”, where some prices differ substantially from opportunity costs, economic theory suggests that it will not be straightforward to determine optimal prices.

Smaller high-income countries like Taiwan have substantial segments of well-off individuals who expect access to the latest innovative medicines. If the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have approved a drug, there is usually little reason to question access or spend substantial resources re-reviewing it. Basically, the Taiwanese government and NHI will provide access, but try to balance cost containment and access in order to maintain citizen support.

Similarly, if the price is in alignment with similar countries, the government will have limited need to do a formal or very sophisticated HTA analysis. “Free-riding” or “piggy-backing” on other, similar countries’ assessments is the efficient and logical thing to do. Furthermore, when price is established by negotiation rather than by rule and transparency, then there is a greater potential for side deals and corruption. Nonetheless, if the international reference prices were too low (i.e., suboptimal) to support global R&D efforts, then the result would be dynamically inefficient (in the long run for all countries).

On the other hand, the lack of a tight linkage between the government-established reimbursement level for new drugs and the acquisition cost (i.e., what manufacturers receive) means that Taiwan’s contribution to global R&D will be less than would be expected from the reference price. In a recent review of four European nations, Drummond, et al. (2010) reach a conclusion of potential relevance to Taiwan.

Compared with HTA, reference pricing is a relatively blunt instrument for obtaining value for money from pharmaceuticals. Thus, its role in making reimbursement decisions should be limited to drugs which are therapeutically equivalent. HTA is a superior strategy for obtaining value for money because it addresses not only price but also the appropriate indications for the use of the drug and the relation between additional value and additional costs. However, given the relatively higher costs of conducting HTAs, the most efficient approach might be a combination of both policies.



## Appendix 4: Interview scope for the three emerging markets

### A4.1 HTA and your healthcare system

- a. What role does HTA currently play in the healthcare system of China/Brazil/Taiwan? Is there a written guideline or established process for HTA in China/Brazil/Taiwan?
- b. What role should HTA play in the healthcare system of China/Brazil/Taiwan?
- c. Do manufacturers have role in the current HTA process?
- d. What role should they play?
- e. Do you expect that HTA in your country will be able to adapt accordingly, if not why?
- f. How is HTA financed within your country?
- g. What status (for example advisory, mandatory etc.) does current guidance take, and do you expect this to change within the next 5 years?

### A4.2 Dissemination of information

- a. How are the outputs of any HTA processes disseminated?
- b. How are the outputs of HTA implemented and enforced?

### A4.3 Topic selection

- a. How are health technologies (topics) selected and prioritised for clinical and economic evaluation under the HTA system in your country?

### A4.4 Coverage of HTA in China/Brazil/Taiwan

- a. Should HTA in China/Brazil/Taiwan cover drugs, public health, surgery, other etc., which should have the greatest priority and why?

#### **A4.5 Information use (ability to learn with/from other countries also developing or having developed HTA and use of information from internal organisations)**

- a. Which other country/countries do you think have relevant or useful HTA approaches—that China/Brazil/Taiwan might want to follow or learn from—and why?
- b. What are the key links between the HTA body/bodies and academic/research institutions?

#### **A4.6 Challenges**

- a. What are the three main challenges which the healthcare system in China/Brazil/Taiwan has recently faced or is currently encountering?
- b. Did HTA have a role to play in addressing any of these?
- c. Looking forward, what are the three main challenges the healthcare system in China/Brazil/Taiwan is likely to face in the next five years?
- d. Does HTA have a role to play in addressing any of these?

#### **A4.7 Stakeholders and the policy debate**

- a. Is there an active debate or discussion about the form and evolution of HTA in China/Brazil/Taiwan?
- b. If so, who are the key stakeholders in the policy discussion, and what are their positions?

#### **A4.8 Literature**

- a. What do you feel are the most relevant reports and material which outline HTA in your country, including published and unpublished, peer-reviewed and grey literature?

## Appendix 5: Interview Programme

The Table below represents local experts identified as potential targets to interview for each country. In total 19 experts were interviewed from this list across the three countries. For China the names highlighted in bold represent those whom were interviewed. For Brazil the interviews were conducted on the basis of non-disclosure of their names. Similarly for Taiwan, those names represent those determined as potential targets for interview, but the specific subset who was interviewed has not been disclosed.

	Academic	Government	Industry	Other
China	<ul style="list-style-type: none"> <li>● <b>Dr. Gordon Liu</b>, Professor of Economics, Guanghua School of Management, Peking University.</li> <li>● <b>Dr. Shanlian Hu</b>, Professor of Epidemiology and Health Management, School of Public Health, Fudan University</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Dr. Zhenzhong Zhang</b>, Director of China Health Economics Institute, Ministry of Health.</li> <li>● Lu Fengxia, Chairman, Drug Price Evaluation Center, NDRC</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Dr. Vivian Chen</b>, Director of Healthcare Economics, R&amp;D-based Pharmaceutical Association Committee</li> <li>● <b>Dr. Chuan Chen</b>, Director of Government Affairs, Xian-Janssen Pharmaceutical Ltd.</li> <li>● <b>Dr. JiuHong Wu</b>, Director of Pharmacy Department, the 306th Hospital of PLA.</li> <li>● Ashoke Bhattacharjya within JnJ. He is within the Health Policy team</li> <li>● Manny Papadimitropoulos (Regional Director of Health Outcomes for Lilly in Emerging</li> <li>● Bill Montgomery and / or Narayan Rajan (works out of Australia for Manny and also has great technical knowledge of these developing markets)</li> <li>● Guang Zhiqiang, GAD, Pfizer</li> </ul>	<ul style="list-style-type: none"> <li>● David Banta – although not based in China, helped establish HTA in China</li> </ul>

Brazil	<ul style="list-style-type: none"> <li>• Denizar Vianna – Adjunct Professor at the State University of Rio de Janeiro; Coordinator of the Excellence Centre of Economic Evaluation and Decision Analysis of ProVac Network - Pan American Health Organization (PAHO);</li> <li>• Marcos Bosi Ferraz – Adjunct Professor at the Federal University of São Paulo (Unifesp) and Director of Centro Paulista de Economia da Saúde (CPES)</li> <li>• Carisi Polanczyk – Professor at the Federal University of Rio Grande do Sul (UFRGS) and Adjunct Coordinator of the Institute of HTA (IATS).</li> </ul>	<p>The local expert will organize an interview with an experts listed below, if feasible:</p> <ul style="list-style-type: none"> <li>• Claudio Maierovitch - Coordinator of the Commission for Incorporation of New Technologies (CITEC) -</li> <li>• Alexandre Lemgruber - Office Of Economic Evaluation of New Technologies - Brazilian Health Surveillance Agency (ANVISA)</li> <li>• Mauricio Vianna – Former Executive of CITEC when it was subordinate to SAS (Secretariat for Health Attention)</li> <li>• Flavia Elias – Member of the Health Technology Assessment General Coordination (CGATS-DECIT)</li> <li>• Augusto Guerra – Superintendent for Pharmaceutical Assistance of the Minas Gerais Health Secretariat</li> </ul>	<ul style="list-style-type: none"> <li>• Inge Duchesne - Director for HE in Janssen LA</li> <li>• Allan Finkel - Lilly Corporate Affairs Director in Brazil</li> <li>• Mario Saggia - Health Economics Senior Manager at Johnson &amp; Johnson Brazil</li> <li>• Wilson Follador - Health Economics and Market Access Manager at Sanofi-Aventis Brazil</li> <li>• Alexandre Schiola - Head of Regional Market Access - Latin America at Bayer HealthCare</li> <li>• Marcelo Canella - Market Access Manager GSK Brazil</li> </ul>	<ul style="list-style-type: none"> <li>• Stefen Stefani (HTA expert and auditor at Unimed; one of the big HMOs) – as the private market is important in Brazil, good to interview someone from private sector</li> <li>• Isabela Sores Santos (ANS)</li> </ul>
Taiwan	<ul style="list-style-type: none"> <li>• Dr. Huang, Weng-Foung, Professor at National Yang-Ming University.</li> <li>• Gau-Tzu Chen, Director, Pharmacy Department, Koo Foundation Sun Yat-San Cancer Center also acts as the chairman in the committee of approving new drug in NHI list.</li> <li>• Prof. Lan Chung-fu, director of the Institute of Health and Welfare Policy, National Yang-Ming Univ., who is leading TaiwanSPOR.</li> </ul>	<ul style="list-style-type: none"> <li>• Ms Jasmine Raoh-Fang Pwu, PhD, Director</li> <li>• Sheen Mao-ting, general manager of the Department of Medical Affairs under the BNHI - He is a senior officer in the Bureau of National Health insurance and in charge of medicine and technology reimbursement .</li> </ul>	<ul style="list-style-type: none"> <li>• Carol Cheng, IRPMA’s, (International Research-Based Pharmaceutical Manufacturers Association) Chief Operating Officer</li> <li>• Samuel Wang, Vice President of TAIWAN GENERIC PHARMACEUTICAL ASSOCIATION</li> <li>• Ashoke Bhattacharjya within JnJ. He is within the Health Policy team</li> <li>• Manny Papadimitropoulos (Regional Director of Health Outcomes for Lilly in Emerging Markets</li> <li>• Bill Montgomery and / or Narayan Rajan</li> </ul>	<ul style="list-style-type: none"> <li>• Serena Chow, GAD of Taiwan Janssen, who leads HE/HTA function.</li> <li>• Mingliang Zhang,</li> </ul>

## Appendix 6: Interview Summaries

The following summaries are based on feedback received from the local team members on the interviews which have been conducted. The key points which can be drawn from the interviews are outlined below. Where appropriate this material has been incorporated into the market summaries in Appendices 1 – 3.

### A6.1 Brazil

#### Industry View

Although HTA has been a formal process at the federal level since 2006, it has low influence on the decision-making process and there have been few responses for the dossiers submitted to the government. In the private system there is no formal process for the incorporation of new technologies, though industry leaders may get organized.

There is a published guideline for the development of HTA dossiers for submission to CITEC, very much inspired in the guidelines from NICE. However, despite this guideline and the associated formal process, the results from CITEC are not clear. Patients can get access to treatments without the formal approval of CITEC because states can create their own formularies.

In theory, recommendations from CITEC could be also used by the private payers to deny reimbursement for new technologies (Technologies with a negative recommendation from CITEC can be denied for reimbursement also by private payers). This influence from HTA in the private sector is still not clear.

In terms of role that HTA could play, the government should identify and evaluate the technologies that add value to the health system. But the timelines need to be defined and the whole process made more transparent. Also, there should be more participation of the society in the decision process, involving citizens, physicians and providers.

#### Academic view

HTA is an integral and relevant part of a Policy for Management of Health Technologies created by the Secretary for Science and Technology of the MS in 2003.

As in the case of NICE-UK, manufacturers and other health organizations (Medical Specialty Societies, Patient Organizations, etc.) could have a seat in the council of CITEC (Commission for Incorporation of Health Technologies) to state their points of view and possible counter-parts in the process, for example proposing risk-sharing programmes, transfer of scientific knowledge, among others.

If HTA is to make a difference, it will be important to gain legitimacy with all the actors involved in the process of HTA.

## Private sector payer view

HTA is not well organized, and the process is unclear. It is still an isolated initiative from some private and public payers that incorporate some new technologies. However, the situation is, however, better than five years ago.

To improve HTA, it will be important to define objective criteria for the incorporation of new technologies, and not let adoption depend on pressure and political influences. From the political point of view, the incorporation of new technology should be stricter. There is a big difference between the public and private sector (due to inequality of wealth). There is no sense in incorporating technology to the public system without enough resources to pay for it. In the end patients don't get access to treatments. The private system has been faster in the incorporation of new technologies.

HTA in Brazil will improve, but it will take longer than what would be desirable. The big challenge is the difference between the public and private systems, because it is hard to imagine how the public system will reach the same level of technology access as the private system. Also, there must be coordination for the price of new technologies to achieve a level that brings return to investments from manufacturers but is still affordable for payers. And there should be a revision of the price of a technology if it gets a new indication.

## A6.2 China

### Academic perspective

Academic interviewees saw HTA as very 'rudimentary' in China and there are no formal guidelines for conducting HTA reviews. At the moment, drug manufacturers play a more important role by providing technical and financial supports to HTA projects (they are the main customers for HTA outputs). Manufacturers will therefore be the driving force behind HTA developments (especially for innovative drugs) as the government is not proactive in the field and academia lacks financial resources to perform such analyses. (Domestic pharmaceutical companies are, however, lagging behind international ones in this area.) HTA is thus only performed on a case-by-case basis. It is currently voluntary and will not be changed into a mandatory requirement in the next 5 years.

If there were to be an official HTA review body like NICE then arguably the reviews and studies could be performed by various stakeholders with government's role being that of providing guidance and standards for analysis. The HTA system would also need to provide adequate incentives for manufacturers to put their products through the review process. The general view of the academic community is that HTA should not be centralised by the government.

## Industry perspective

Industry has argued that HTA should serve as a reference tool rather than a mandatory process: it can only play a meaningful role when several critical conditions are met, including availability of -sufficient data and evaluation standards. In the short-run, China is unlikely to roll out HTA. The recent negotiations between the government and the pharmaceutical industry indicate that the government is not well prepared for such negotiations. Experience with the Essential Drug List reform shows how inefficient it can be if a policy is put forward without sufficient information.

Ideally, an HTA organisation should be independent to avoid bias even if it is affiliated with government institutions. HTA should take the role of balancing patient access and cost-containment for the government and should not be used as a cost-saving tool only. HTA should take a broad view of value, and should not just look at drugs.

There are problems in conducting studies in China. Most hospitals are state-owned with hospital charges tightly controlled below cost. The data developed from this kind of system will not be suitable for a rigorous HTA analysis, which assumes prices reflect resource use. Currently, the Chinese government has its eyes on the Australian and Korean systems but these countries have very different healthcare systems to China.

## A6.3 Taiwan

### Industry View

In industry interviewees commented that the current role of HTA in Taiwan is very limited. It is not actually used and may not be needed for cost control given the other constraints, especially the global budget. HTA is not currently used in drug pricing. HTA (i.e., cost-effectiveness) is only used as an argument when a drug is rejected. In its appraisal, the Drug Benefit Committee will read the HTA report produced by the Division of HTA (DHTA) in the Center for Drug Evaluation (CDE).

Currently, the BNHI is the sole payer, and there are no clear rules or policies for applying HTA. They decide who can participate in the discussion. Furthermore, current HTA is only a systematic review of other developed countries' reports: no local Taiwanese analysis or model is required or provided. The HTA information is not disseminated though it should be—as part of a transparent process.

The CDE-HTA pilot project (the DHTA) is beginning to ask companies to make a submission. Some in industry have asked: Why should companies participate in this if it is eventually going to be used in pricing—but not in a well-defined way—it is just creating another hurdle for companies? This comment may be in response to the new drug reimbursement application form which was announced by BNHI to become effective on Nov 1, 2010. This form was revised by CDE-HTA team at the request of the BNHI.

From a historical perspective, HTA in Taiwan could be described as the one-off brain-child of an ex-CEO of the BNHI that resulted in this pilot project. The project was headed by a scholar who aimed

to implement systems similar to other countries. The project has not really gained much traction because the government already has tools—reference pricing and price surveillance—for controlling drug prices.

It would be good if HTA could be used to establish efficient disease management or guidelines. But Taiwan needs more time to develop a consensus on how to use HTA. There are ongoing hearings on a new public law. The patient stakeholder group seems to support HTA as a rational process; however, they don't seem to realize that it is more likely that it will be used to reduce access to new expensive, but innovative drugs.

The generic drug industry is robust in Taiwan and doubts that the research-based industry will support HTA. This is because there is pressure on the BNHI to provide access to new breakthrough drugs, and the current median-based external reference pricing (with a basket of 10 countries) provides a reasonable price (from their perspective) for these drugs. The generic industry would favour HTA for these drugs because it is likely to reduce prices on branded drugs and allow more money for generics. They would also favour creating greater independence of the HTA unit from the CDE.

The use of drugs is driven by the profit margin—the difference between what the NHI reimburses and what the acquisition cost from wholesalers. The generic industry is concerned about opening the market to generics made in China.

## Academic View

Academic interviewees commented that, currently, Taiwan does not really have HTA. The only guideline is from ISPOR in Taiwan: there is no official government guideline. Neither the BNHI nor the DHTA unit in the CDE is lobbying strongly for a greater role for HTA. They do not really seem to want to be accountable to the public.

DHTA currently conducts literature review and summarizes the evidence from other countries as outlined above; it does not do a local pharmacoeconomic analysis. Knowledge about this process is very limited and manufacturers have no access to this report and no opportunity to challenge it. If properly set up, HTA could help to provide a better, efficient resource allocation of health care resources. The BNHI currently exploits its monopsony power.

HTA is a rational policy, and should be applied to all drugs, not just new ones. But BNHI only worries about the financial costs, and does not pay much attention to efficiency, i.e., health gain for the money spent.

Reform of the NHI is under discussion but the focus is on finance and the insurance premium, not HTA. The current working on HTA is vague: the BNHI could apply it in the appraisal and pricing of new drugs. The public representatives support it as a rational and scientific approach that would also help to combat bureaucracy and corruption.



## Government View

Government interviewees commented that the CDE will not rely heavily on the HTA review report. Indeed, the pilot HTA project (the DHTA) will be folded into the BNHI in the future. BNHI has other strategies for cost control, and this HTA appraisal is not necessary for that. Budget impact is the major concern.

Approval and price negotiation are separate steps, and the latter step can take significant time, and drugs sometimes fail to be approved for reimbursement list. CDE is an independent assessment body and is not heavily influenced by the BNHI. Access to expensive life-saving drugs is supported in many cases. CDE is, however, not free to disseminate the HTA report, and sometimes CDE members question the quality of these reports, according to interviewees.

Manufacturers and patient groups both have a one-time opportunity to participate in a DBC, but for appealed cases only, not for the first review. DBC finds time consuming to have a presentation from the manufacturers at the meeting, even for 10 minutes presentation only. Presenters get many questions from the committee members, and this ends up taking longer.

Although the DOH currently funds the DHTA, they respond to requests from the BNHI. They have been internalized by the BNHI, playing a constructive role in the communication between BNHI and the industry on the submission of new drugs for listing. Comprehensive HTA in Taiwan seems unlikely in the future since the current pilot is operating quite well. Also, it would be difficult to spin off as an independent agency.

Although HTA may eventually cover more than new drugs, there is little reason to review devices that are covered by virtue by being embedded in DRG payments. BNHI recently decided to make HTA summaries available to the public. Neither the government nor the companies are in favour of full public dissemination of the HTA review. Manufacturers know the information sources and processes, and can ask the CDE if they have a question.

The HTA review is based on the reviews in three other countries and other database searches and focuses on indications that the company applied for. DHTA has produced meta-analysis guidelines and is asking manufacturers to conduct them and make a submission.

## References

- Augustovski, A., Iglesias, C., Manca, A., Drummound, M., Rubinstein, A. and Garcia Marti, S. (2009) Barriers to generalizability of health economic evaluations in Latin America and the Caribbean region. *Pharmacoeconomics*. 27(11), 919-929.
- Banta, D. and Almeida, R. (2009) The development of health technology assessment in Brazil. *International Journal of Technology Assessment in Health Care*. 25(Suppl 1), 255-259.
- Battista, R.N. and Hodge, M.J. (2009) The “natural” history of health technology assessment. *International Journal of Technology Assessment in Health Care*. 25(Suppl.1), 281-284.
- Bureau of National Health Insurance. (2010) *NHI New Drug Listing and Pricing Principles*. 22 January.
- Byrkjeflot, H. and Neby, S. (2008) The end of the decentralised model of healthcare governance. *Journal of Health Organization and Management*. 22(4), 331-349.
- Chalkidou, K., Levine, R. and Dillon, A. (2010) Helping poorer countries make locally informed decisions. *British Medical Journal*. 241, 3651.
- Chen, C.L., Chen, L. and Yang, W.C. (2008) The influences of Taiwan's generic grouping price policy on drug prices and expenditures: Evidence from analysing the consumption of the three most-used classes of cardiovascular drugs. *BMC Public Health*. 8, 118.
- Chen, H.F., Lee, C.H. and Chang, R.E. (2010) Workload of attending physicians at an academic center in Taiwan. *Journal of the Chinese Medical Association*. 73(8), 425-430.
- Chen, L. C., Schafheutle, E.I. and Noyce, P. R. (2009) The impact of nonreferral outpatient co-payment on medical care utilization and expenditures in Taiwan. *Research in Social and Administrative Pharmacy*. 5(3), 211-224.
- Cheng, L. J. and Wang, J. D. (2006) Is cost-effectiveness analysis necessary for national health insurance? *Journal of the Formosa Medical Association*. 105(12), 1031- 1035.
- Cheng, S.H., Chen, C.C. and Chang, W.L. (2009) Hospital response to a global budget program under universal health insurance in Taiwan. *Health Policy*. 92(2-3), 158-164.
- Cheng, T.M. (2003) Taiwan's new national health insurance program: Genesis and experience so far. *Health Affairs (Millwood)*. 22(3), 61-76.
- Cheng, T-S. (2009) Lessons from Taiwan's universal national health insurance: A conversation with Taiwan's health minister Ching-Chuan Yeh. *Health Affairs*. 28(4), 1035-1044.
- Chen, Y., Banta, D. and Tang, Z. (2009) Health technology assessment development in China. *International Journal of Technology Assessment in Health Care*. 25(suppl.1), 202-209.

Danzon, P., Towse, A. and Mulcahy, A. (2011) Setting cost-effectiveness thresholds as a means to achieve appropriate drug prices in rich and poor countries. *Health Affairs*. 30(8), 1529-1538.

Doherty, J., Kamae, I., Lee, K.K.C., Li, H., Li, S.-C., Liu, G.G., Tarn, Y-H. and Yang, B-M. (2004) What is next for pharmacoconomics and outcomes research in Asia? *Value in Health*. 7(2), 118-132.

Dos Santos, N.R. (2008) Public healthcare policy in Brazil: Crossroads and choices. *Cien Saude Colet*. 13(Suppl.2), 2009-2018.

Drummond, M., Jönsson, B., Rutten, F. and Stargardt, T. (2010) Reimbursement of pharmaceuticals: Reference pricing versus health technology assessment. *European Journal of Health Economics*. 12(3), 263-271.

Drummond, M., Schwartz, J., Jönsson, B., Luce, B., Neumann, P., Siebert, U. and Sullivan, S. (2008) Key principles for the improved conduct of health technology assessments for resource allocation decisions. *International Journal of Assessment in Health Care*. 24(3), 244-258.

EFPIA. (2005) *The use of health technology assessments (HTA) to evaluate medicines*. Key Principles. Brussels: European Federation of Pharmaceutical Industries and Associations.

Eggleston, K. and Hsieh, C-R. (2004) Healthcare payment incentives: A comparative analysis of reforms in Taiwan, South Korea and China. *Applied Health Economics and Health Policy*. 3(1), 47-56.

Elias, P.E.M. and Cohn, A. (2003) Health reform in Brazil: Lessons to consider. *American Journal of Public Health*. 93(1), 44-48.

EUnetHTA. (2008) *EUnetHTA handbook on HTA capacity building*. European Network for Health Technology Assessment. Work package 8.

Fernandes, E., Pires, H.M., Ignacio, A.A.V. and Sampaio, L.M.D. (2007) An analysis of the supplementary health sector in Brazil. *Health Policy*. 81, 242-257.

Garrido, M.V., Gerhardus, A., Rottingen, J-A. and Busse, R. (2010) Developing health technology assessment to address health care system needs. *Health Policy*. 94(3), 196-202.

Gerschman, S. (2008) Compared supplementary healthcare policies in the context of public health systems: European Union and Brazil. *Cien Saude Colet*. 13(5), 1441-1451.

Gottret, P. and Schieber, G. (2006) *Health financing revisited: A practitioner's guide*. Washington, DC: The World Bank.

Hailey, D. and Juszwishin, D. (2006) Managing external risks to health technology assessment programs. *International Journal of Technology Assessment in Health Care*. 22(4), 429-435.

Han, Q., Chen, L., Evans, T. And Horton, R. (2008) China and global health. *The Lancet*. 372, 1439-1441.

- Hsieh, C-R. and Sloan, F. (2008) Adoption of pharmaceutical innovation and the growth of drug expenditures in Taiwan: Is it cost-effective? *Value in Health*. 11(2), 334-344.
- Hughes, V (2008) China takes first steps toward healthcare and drug reforms. *Nature Medicine*. 14(11), 1132.
- IBGE. (Brazilian Institute of Geography and Statistics). (nd) *Projection for year 2010*. Available at [www.ibge.gov.br](http://www.ibge.gov.br).
- IFPMA. (no date) *Health technology assessment and the value of medicines*. IFPMA Position Statement. Geneva: International Association of Pharmaceutical Manufacturers and Associations.
- Institute of Medicine. (2009) *Initial national priorities for comparative effectiveness research*. Washington, DC: National Academies Press.
- Jakubowski, E. and Busse, R. (2001) What is “best practice” in health care? State of the art and perspectives in improving the effectiveness and efficiency of the European health care systems. *Health Policy*. 56, 235-250.
- Jirawattanapaisal, T., Kingkaew, P., Lee, T-J. and Yang, M-C. (2009) Evidence-based decision-making in Asia-Pacific with rapidly changing health-care systems: Thailand, South Korea and Taiwan. *Value in Health*. 12(Suppl.3), S4-S11.
- Jurberg, C. (2008) Flawed but fair: Brazil’s health system reaches out to the poor. *Bulletin of World Health Organization*. 86(4), 248-249.
- Kutzin, J. (2001) A descriptive framework for country-level analysis of health care financing arrangements. *Health Policy*. 56, 171-204.
- Lancet. (2008) Health-system reform in China. *The Lancet*. 372(9648), 1437.
- In Lee, S-Y., Chun, C-B., Lee, Y-G and Seo, NK. That (2008) The national health insurance as one type of new typology: The case of South Korea and Taiwan. *Health Policy*. 85, 105-113.
- Lee, Y.C., Huang, K.H. and Huang, Y.T. (2007) Adverse pharmaceutical payment incentives and providers' behaviour: The emergence of GP-owned gateway pharmacies in Taiwan. *Health Policy and Planning*. 22(6), 427- 435.
- Liu, G., Fukuda, T., Lee, C.E., Chen, V., Zheng, Q. and Kamae, I. D2009) Evidence-based decision-making in China, Japan and Singapore. *Value in Health*. 12(Suppl.3), S12-S17.
- Liu, Y.M., Yang, Y.H. and Hsieh, CR. (2009) Financial incentives and physicians' prescription decisions on the choice between brand-name and generic drugs: Evidence from Taiwan. *Journal of Health Economics*. 28(2), 341-349
- Lu, J.F. and Hsiao, W.C. (2003) Does universal health insurance make health care unaffordable? Lessons from Taiwan. *Health Affairs (Millwood)*. 22(3), 77-88.

Mossialos, E., Dixon, A., Figueras, J. Kutzin, J. (2002) Funding health care: Options for Europe. *European Observatory on Health Care Systems*. Policy Brief No. 4. Copenhagen: World Health Organization Regional Office for Europe.

Murray, J.L.C. and Frenk, J. (2000) A framework for assessing the performance of health systems. *Bulletin of the World Health Organization*. 78(6), 717-731.

China MOH. (2003) National Health Services Survey.

Neumann, P., Drummond, M, Jönsson, B., Luce, B., Schwartz, J. Siebert, U. and Sullivan, S. (2010) Are Key Principles for improved health technology assessment supported and used by HTA organisations? *Journal of Health Technology Assessment in Health Care*. 26(1), 71-78.

Perleth, M.E., Jakubowski, E. and Busse, R. (2001) What is “best practice” in health care? State of the art and perspectives in improving the effectiveness and efficiency of the European health care systems. *Health Policy*. 56, 235-250.

NICE. (2010) NICE signs memorandum of understanding with the Ministry of Health of China. Available online at <http://www.nice.org.uk/aboutnice/niceinternational/NICESignsMemorandumOfUnderstandingWithChineseMinistryOfHealth.jsp>.

OECD Health Data. (2010) Available online at <http://www.oecd.org.uk>.

Pan-American Health Organization/World Health Organization. (2008) *Health systems and services profile: Brazil*. Monitoring and analysis of health systems change/reform. Washington, DC: PAHO. Available at [www.lachealthsys.org](http://www.lachealthsys.org).

PhRMA. (nd) *Health outcomes research: Principles for government supported health outcomes research and medical technologies and services*. Washington, DC: Pharmaceutical Research and Manufacturers of America. Available at <http://www.phrma.org/about/principles-guidelines/health-outcomes-research>.

PhRMA. (nd) *Principles for use of evidence-based medicine: Advancing patient care and health care value*. Washington, DC: Pharmaceutical Research and Manufacturers of America.

PNAD. (2008) *Pesquisa Nacional por Amostra de Domicílios*. Available at [www.ibge.org](http://www.ibge.org).

Shih, S.F., Lew-Ting, C.Y., Chang, H.Y. and Kuo, K.N. (2008) Insurance covered and non-covered complementary and alternative medicine utilisation among adults in Taiwan. *Social Science & Medicine*. 67(7), 1183- 1189.

Shih, Y-C.T., Pan, I-W. and Tsai, Y-W. (2009) Information technology facilitates cost-effectiveness analysis in developing countries: An observational study of breast cancer chemotherapy in Taiwan. *Pharmacoeconomics*. 27(11), 947-961.

Shillcutt, S.D., Walker, D.G., Goodman, C.A. and Mills, A.J. (2009) Cost effectiveness in low and middle-income countries: A review of debates surrounding decision rules. *Pharmacoeconomics*. 27(1), 903-917.

Sivalal, S. (2009) History of health technology assessment: A commentary. *International Journal of Technology Assessment in Health Care*. 25(Suppl.1), 285-287.

Sorenson, C., Drummond, M. and Kanavos, P. (2008) *Ensuring the value for money in healthcare: The role of health technology assessment in the European Union*. Observatory Studies series No. 11. Copenhagen: World Health Organization Regional Office for Europe.

Sun, Q., Santoro, M.A., Meng, Q., Liu, C. and Eggleston, K. (2009) Pharmaceutical policy in China. *Health Affairs*. 27(4), 1042-1050.

Tantivess, S., Teerawattananon, Y. and Mills, A. (2009) Strengthening cost-effectiveness analysis in Thailand through the establishment of the health intervention and technology assessment program. *Pharmacoeconomics*. 27(11), 931-945.

Tarn, Y-H., Hu, S., Kamae, I., Yang, B.M., Li, S-C., Tangcharonensathien, V. Teerawattananon, Y., Limwattananon, S., Hameed, A., Aljunid, S.M. Bapna, J.S. (2008) Healthcare systems and pharmaco-economic research in Asia-Pacific region. *Value in Health*. 11(Suppl.1): S137-S155.

Wagstaff, A., Yip, W., Lindelow, M. and Hsiao, W. (2009) China's health system and its reform: A review of recent studies. *Health Economics*. 18, S7-S23.

Watts, J. (2008) Chen Zhu: From barefoot doctor to China's Minister of Health. *The Lancet*. 372, 1455.

Wendt, C., Lorraine, F., Rothgang, H. (2009) Healthcare system types: A conceptual framework for comparison. *Social Policy & Administration*. 43(1), 70-90.

WHO. (2010) *Global Health Indicators: Part II*. Geneva: World Health Organization. Available at [http://www.who.int/whosis/whostat/EN\\_WHS10\\_Part2.pdf](http://www.who.int/whosis/whostat/EN_WHS10_Part2.pdf).

WHO. (2000) *The World Health Report 2000 – Health systems: Improving performance*. Geneva: World Health Organization. Available at <http://www.who.int/whr/2000/en/index.html>.

WHO. (2003) *Health systems performance assessment: Debates, methods and empiricism*. Geneva: World Health Organization.

WHO. (2007) *Everybody's business, strengthening health systems to improve health outcomes: WHO's Framework for Action*. Geneva: World Health Organization. Available at [www.who.int/healthsystems/strategy/everybodys\\_business.pdf](http://www.who.int/healthsystems/strategy/everybodys_business.pdf).

Wu, D. (2006) The healthcare system in Taiwan. *World Hospitals and Health Services*. 42(1), 14-17.

Yan, Y.H., Hsu, S., Yang, C.W. and Fang, S.C. (2010) Agency problems in hospitals participating in self-management project under global budget system in Taiwan. *Health Policy*. 94(2), 135-143.

Yang, B.M. (2009) The future of health technology assessment in healthcare decision making in Asia. *Pharmacoeconomics*. 27(11), 891-901.

Yip, W. (2009) China's health care reform: Opportunities and challenges. Presentation at the Office of Health Economics. London. June.