

# Policy Options for Formulary Development in Middle-income Countries: Mexico Case Study



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## **EXECUTIVE SUMMARY**

In a recent work OHE developed a framework to promote efficient formulary decision making in middle-income countries (MICs).

In the present document we applied that framework to analyse the Mexican decision making process for the inclusion of a new health treatment in the positive list.

This case study was developed using primary and secondary research. The primary information consisted of interviews with stakeholders having direct experience of the Mexican health system. The secondary sources were official documents from the relevant national agencies, a selected group of peer-reviewed articles and grey literature.

The analysis shows that the Mexican formulary decision making process is a highly fragmented. This hinders the incorporation of national and local (states) priorities in the decision to incorporate new treatments in the national and institutional positive lists. Additionally, equity was identified as an important factor of the Mexican health system that is not formally considered during the process.

## 1. INTRODUCTION

A number of middle-income countries (MICs) are evolving their health systems toward universal health coverage for patient populations. Such countries have limited drug formularies and some form of an essential drugs list. *PhRMA* retained OHE Consulting to explore options and recommend methods that could help MICs efficiently and effectively identify medicines for formulary inclusion. The project main result was the creation of a framework for developing drug formularies that incorporates countries health system organization and national priorities (Hernandez-Villafuerte et al. 2016). The framework reflects what experts and the literature suggest which is the need of considering macro-level decision making factors (focusing on the health system organisation and its priority setting) and micro-level factors (looking at intervention-specific effects) to determine the overall value of medicines.

The decision-making process is broken down into four stages: (1) nomination and prioritisation; (2) assessment of selected interventions; (3) appraisal of selected interventions; and (4) financial assessment. Depending on the structure of the decision-making process, these stages could be the responsibility of a single committee or be divided among different committees or health institutions. The decisions could be taken: by a central government or decentralised between local administrations; on behalf of the single payer, in the case of a tax-funded or single insurance fund, or assigned to multiple payers or insurance funds in a pluralistic system.

Macro-level factors should be considered at prioritization stage to target the scarce resources only to assess in depth those interventions that have the highest health system intervention value, meaning interventions that are feasible (considering the WHO six building blocks (World Health Organization (WHO), 2007)) and match national priorities.

Regarding the assessment of selected interventions, the focus should be on the analysis of the micro-level factors, particularly the estimation of an aggregate measure of value of the intervention. Depending on the country's resources, this can consist of a cost-effectiveness analysis but should also include other attributes, such as the characteristics of the target population (e.g. socioeconomic status, age and gender).

Once the intervention has been assessed, the appraisal committee responsible for the final formulary decision should consider the macro-level analysis from the prioritisation stage and the micro-level analysis from the assessment stage to make formulary decisions. Finally, financial measures to make an intervention affordable should be considered. More details on the framework can be found in Hernandez-Villafuerte et al. (2016).

In the present document we applied this framework to analyse the Mexican decision making process for the inclusion of a new health treatment in the positive list. According to the OECD (2016), the Mexican health system has failed to translate the increase in health expenditures observed in the last 13 years into improvements in the health status of the population. Access, quality, efficiency and sustainability need to be significantly improved (Manatt Jones Global Strategies, 2015; Urquieta-Salomo and Villarreal, 2016; OECD, 2016). Moreover, Mexico still shows a level of health system funding that is insufficient to satisfy the health demand of the population. Therefore, our objective here is, based on the OHE framework, to propose a series of recommendations that could improve the efficiency of the Mexican decision making process in response to the need of

the population, which is in agreement with the national strategic health plan and at the same time promote the sustainability of the health system.

## **2. METHODS**

This case study was developed using primary and secondary research.

The primary information consisted of three interviews conducted during October 2015 with the following stakeholders having direct experience of the Mexican health system: (1) a pharmaceutical industry representative, (2) a representative of The National Center for Health Technology Excellence (Centro Nacional de Excelencia Tecnológica en Salud; CENETEC), and (3) an Health Economist academic.

The secondary sources were official documents from the relevant national agencies, a selected group of peer-review journals articles and grey literature, in both English and Spanish. In addition, international databases, such as World Bank data and the OECD database, were consulted to extract relevant statistics to describe the current Mexican health system.

## **3. HEALTH SYSTEM IN MEXICO**

During the past 30 years Mexico has experienced important changes in its epidemiological and demographic structure. In the period between 1984 and 2014, the Mexican population grew by almost 46 million people and life expectancy increased by more than 5.5 years (Table 1). The elderly population group has been growing steadily: the percentage of the total population older than 65 years was 6.7% in 2014 in comparison with 4.1% in 1984, and projections indicate that by 2051, 16.3% of the Mexicans will be in this age group (Secretaría de Gobernación Mexicana (SEGOB), 2015). Demographic change has brought considerable pressure to the health system, which has prompted a number of health reforms aiming to improve the health status of the population while considering both short-run and long-run affordability.

Table 1  
Evolution of selected health indicators

	1984	1994	2004	2014
Health expenditure per capita, PPP (constant 2011 international \$)	nd	388*	689	1,122
Health expenditure, public (% of total health expenditure)	nd	42.14*	45.16	51.8
Health expenditure, public (% of GDP)	nd	2.13*	2.69	3.26
Out-of-pocket health expenditure (% of total health expenditure)	nd	56.15*	51.91	44.0
Population (Thousands of persons)	73,745.9	93,055.3	105,951.6	119,713.2
% Population: 65 years old and over	4.1	4.6	5.6	6.7
% Population: 80 years old and over	0.8	0.9	1.1	1.5
Life expectancy Females at birth	72.0	75.1	75.1	77.5
Life expectancy Males at birth	66.1	68.8	68.8	72.1
Children per women aged 15 to 49 years old	4.03	3.05	2.49	2.20
Physicians (per 1,000 people)*	nd	1.5	1.5†	2.1
Number of nurses and midwives (per 1000 people)*	nd	nd	4.0	2.5‡

\*1995 data. †2003 data. ‡2011 data.

Source: Data from The World Bank (2015) and OECD (2014)

The Mexican health system consists of a private and a public sector. The private sector covers around 7.3% of the population and its services are mostly provided through fee for service payment and used by those with ability to pay. The public sector provides social security to more than 92 million people and it is fragmented into different institutions (OECD, 2016). Historically, two social security institutions have led the public health sector: the Mexican Social Security Institute (Instituto Mexicano de Seguridad Social, IMSS) which covers the private formal workers and their families (around 59 million people - 48% of the population), and the Institute of Social Services, and Security for Civil Servants (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, ISSSTE) which covers government employees and their relatives (around 12 million people - 10% of the population)(OECD, 2016). In addition, there exist three smaller social insurance schemes that are linked to three state institutions (together they cover around 1% of the population): the armed forces (Secretaría de la Defensa Nacional, SEDENA), the state oil company (Petróleos Mexicanos, PEMEX), and the navy (Secretaría de Marina-Armada de México, SEMAR). As a result of a series of governmental reforms, in 2003 a new public insurance scheme was created: the System for Social Protection in Health (Sistema de Protección Social en Salud, SPSS) and its operational arm the Seguro Popular. This is a decentralized entity of the Ministry of Health (Secretaría de Salud, MoH) with functional, technical, and administrative independence that aims at providing health coverage to those that were not enrolled in any of the existing insurance schemes (self-employed, unemployed, no salaried and informal-sector employers). Currently, this scheme covers around 57 million people (46% of the population) (OECD, 2016). Finally, there are also other programs providing coverage to those outside the formal sector, such as the IMSS-Oportunidades (covering around 9% of the population) which is managed by the IMSS and financed by the government (Barraza Lloréns, 2012; Manatt Jones Global Strategies, 2015). Some



Mexicans are eligible to be covered by more than one insurance scheme, therefore the number of beneficiaries exceed the population (OECD, 2016).

The inclusion in the national scene of the Seguro Popular have increased significantly the percentage of total population coverage, in 2003 it was 48.5% and in 2014 it increased up to 91.1% (OECD, 2014). However, in 2012 18% Mexicans reported not having any health insurance (OECD, 2016). To be covered by the Seguro Popular, registration is required as well as the payment of insurance contributions. These contributions depend on the socioeconomic status of the family which is determined by the institution. When the family capacity to pay is low, the affiliation is free of charge with no insurance contributions (Gobierno del Estado de Sonora, 2009).

Not only is coverage fragmented into different social security institutions, but so also is the provision of health. The social security institutions IMSS, ISSSTE, SEDENA, PEMEX and SEMAR have their own independent networks of primary and secondary health facilities that can be accessed only by insured people of the corresponding institution. For instance, even if an IMSS beneficiary lives next to an ISSSTE hospital, he/she must travel to the closest IMSS facility to receive the needed healthcare or prescriptions. Seguro Popular is not a provider or a purchaser, its beneficiaries are attended in Ministry of Health facilities.

The Ministry of Health (MoH) is in charge of managing the national health plan. In addition, each Mexican state has its own State Ministry of Health coordinating the health system of the state. MoH facilities are normally run by each State Ministry of Health. The MoH also provides healthcare to the uninsured through a fee for services payment that depends on the payment ability of the patient.

The full costs of prescriptions for pharmaceuticals products included in the positive list are covered without co-payment for patients affiliated to one of the public social security institutions (Moise and Docteur, 2007).

The following sections describe and analyze the decision making process for the inclusion of a new health treatment in the positive list to make it accessible for those affiliated to the public insurance schemes. The analysis is structured following the framework developed and explained in the main OHE report (Hernandez-Villafuerte, 2016).

#### **4. ORGANIZATION OF THE DECISION MAKING PROCESS**

The process to list a medicament for use within the public sector has four steps as shown in Table 2. First, the Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) analyzes the safety and efficacy of the new health technology in order to issue a decision related to its introduction in the Mexican market (Table 2 step 1). After market approval, the new treatment is appraised by the General Health Council (Consejo de Salubridad General, CSG) which determines whether the new treatment should be included in the public health sector positive list (Table 2 step 2). The approval of the CSG does not guarantee that the product can be acquired by the public health sector. For the manufacturer to be able to sell to public institutions, it is necessary to apply for further assessment by each institution. For instance, only after the internal committee of the IMSS has approved the inclusion of the new treatment in its institutional positive list can the IMSS's beneficiaries access this new health technology (Table 2 step 3).

Table 2  
Process to make a new health intervention available to patients in the public sector

Steps	Responsible Institution	Main Criteria Considered	Decision
1	COFEPRIS	Safety and Effectiveness	Market Approval
2	General Health Council (CSG)	Cost-Effectiveness	Inclusion in the public positive list
3	Via separated processes: Seguro Popular, IMSS, ISSSTE, PEMEX, SEDENA and SEMAR	Affordability	Inclusion in institutional positive list
4	Commission of price negotiation CCPNM	International reference prices Information on patent status	1) Acquisition prices 2) Recommendation of cheaper or generic medicaments

Source: Authors' elaboration with information from Santa-Ana-Tellez et al. (October 19th 2014) and Gómez-Dantés et al. (2012)

The cost effective analysis submitted by the manufacturer to the CSG and the institutions committee/s includes the reference price for selling to the public health sector. In 2008 the government created a new entity with the objective of negotiating public procurement prices for patented drugs included in the institutional positive list of the main social security institutions: the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud, CCPNM). This commission allows the three main public institution, IMSS, ISSSTE, Seguro Popular and the Ministry of Health, to negotiate together a single procurement price that will be observed during one year by all public purchasers including all Mexican states and all public institutions. Between 2008 and 2010 the price of more than 150 pharmaceutical products were negotiated by the CCPNM (Gómez-Dantés et al., 2012). Additionally, according to an industry expert, new regulations will support the consideration of the CCPNM recommendations during the CSG deliberations.

According to one of the experts interviewed, the entire process, from when the manufacturer submits to the COFEPRIS to the time when patients have access to the medicament, lasts approximately 4.2 years (personal communication).

#### 4.1. Expert committee composition

The CSG membership includes a president, who is or the Minister of Health, and a vice-president (called the "Secretario"). There are also representatives of the social security institutions and other relevant Mexican institutions, such as the COFEPRIS. In addition, there are representatives from other ministries, such as the Ministry of Economics. The members are selected and removed by the President of the Republic.

The deliberations take place in sub-committees which are focused on specific health treatments that can be listed as: (1) medical devices, (2) auxiliary diagnosis services, (3) healing material, and (4) pharmaceutical products. All sub-committees have representatives from the insurance companies (IMSS, ISSSTE, PEMEX, SEDENA and SEMAR) as well as the COFEPRIS (CSG, 2015b). The representative of the National Center for Health Technology Excellence (Centro Nacional de Excelencia Tecnológica en

Salud, CENETEC), the Mexican health technology assessment agency, is part only of the committee for medical devices (CSG, 2015b; a).

The CCPNM includes representatives from the IMSS and the ISSTE as well as representatives from the finance, economics and health ministries.

## **4.2. Stakeholders involved in developing the national drug formulary**

Different groups of stakeholders are theoretically represented in sub-committees meetings of the CSG. For instance, among the members of the CSG there are clinicians who are from the National Academy of Medicine and the Mexico National Academy of Surgery. However, according to the information collected, there are no representatives officially registered as part any sub-committee (CSG, 2015b; a; Ministry of Health, 2009). Similarly, the academic sector has officially a role in the decision making process. The regulation of the CSG mentions the need of including a representative from the National Autonomous University of Mexico (Universidad Nacional Autónoma de México, UNAM), but there is no record of any academic representative in the sub-committees (CSG, 2015b; a; Ministry of Health, 2009).

In addition, the president of the CSG has the ability to invite academic representatives as well as members of the industry who can participate in the meetings, but without voting rights (Ministry of Health, 2009). In addition, if required, the sub-committees can ask the opinion of experts for the specific health technology intervention (CSG, 2015a).

Moreover, the National System for Integral Family Development (Sistema Nacional para el Desarrollo Integral de la Familia, DIF) also has representation in all committees and has a full member on the CSG. This is a public institution that was created with the aim of ensuring the well-being of Mexican families. The current President of the DIF is the First Lady, Angelica Rivera, and the National Director is the wife of the Interior Minister (CSG, 2015b; a; Ministry of Health, 2009).

Patient associations do not have a formal role in the formulary decision making process. However, in a few cases the pressure exerted by patient groups have influenced CSG or the social security institution decisions, particularly in the case of orphan diseases.

## **5. WHICH MACRO-LEVEL FACTORS SHOULD AFFECT THE DEVELOPMENT OF A DRUG FORMULARY?**

### **5.1. Does the new intervention match one or more of the national health priorities?**

#### **National disease priorities**

Mexico is, after the USA, the country with the highest rate of obesity. Together with an unbalanced diet and other unhealthy habits this has considerably increased the prevalence of related non-communicable diseases (NCDs) such as diabetes, ischemic heart disease and hypertension (Gómez Dantés et al., 2011). The current National Development plan includes actions to reduce the morbidity and mortality related to NCDs.

In addition communicable diseases (CDs) and related diseases such as reproductive problems and malnutrition, are common amongst the poorest and most marginalized states, such as Chiapas and Oaxaca (WHO, 2006; Gómez Dantés et al., 2011). These epidemiological differences indicate that priorities have to be different for each state, which has been considered in the organization of the Mexican health system through the decentralization of the system where each state has an individual health system plan.

Despite the importance of NCDs and epidemiological challenges across the country, there is no consideration of country health priorities in the assessment of new treatments. For instance, the CSG analyses all treatment applications that it receives and that fulfill the methodological requirements for clinical and economic evidence, without consideration of the national health priorities. The sub-committees decide the order in which the applications are considered.

It is also worth noting that national disease priorities are considered by the Seguro Popular during the selection of the diseases related to its individual positive lists. This process will be discussed in more detail later in the paper.

### **Health Reforms (UHC)**

The WHO uses three dimensions to describe the concept of Universal Health Coverage (UHC) (WHO, 2013): (1) who should be covered? – the “breadth” of the system; (2) what should be covered? – the “width” of the system; and how much should it be covered? – the “depth” of the system. In this regard, the reforms that created the Seguro Popular have proved to be central in moving Mexico towards UHC in respect of the first dimension: the “breadth” of the system. Coverage has increased impressively. However, 8.9% of the population is not covered by any health insurance scheme, meaning that Mexico is still evolving along the UHC pathway.

Regarding the width of the system, the list of treatments approved for the CSG is publicly available. However, there are differences in the benefit package covered by each social security institution, which means differences in rights of accessing individual interventions. The fact that each public institution has its own network of health care facilities has produced a clear duplicity of services varying in quality and efficiency. Alongside this, there are differences between the health providers in protocols and medicaments used to deal with the same diseases. This indicates that there is not clear agreement as to what should, at a minimum, be covered by the health system.

As a response to these challenges the current government has proposed a reform that will allow patients to select a provider regardless of their social security affiliation (Manatt Jones Global Strategies, 2015). Given the duplication of facilities and the differences in treatment offered by each institutions, this reform will require a series of agreements between the institutions in terms of prices, medicaments used, healthcare protocols and sharing of information about patient’s care.

Although the government has invested in a number of initiatives aimed at achieving UHC, the formulary decision making process does not formally consider the national health system plan or the objectives of the government. It could be beneficial also in terms of efficiency in resource allocation if new treatments approved by the CSG and the social security institutions are in line with the governmental reforms.

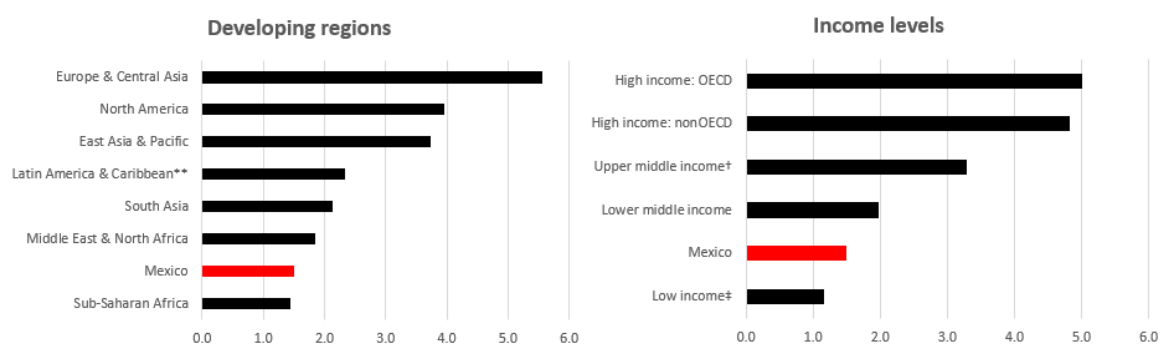
## 5.2. To what extent is the current health care system ready for the introduction of the new intervention? WHO building blocks

### Service Delivery

A possible indicator of service delivery in a country is the number of hospital beds per 1,000 people. Figure 1 shows the situation of Mexico in comparison with different regions in the world. Mexico, with only around 1.5 beds per 1,000 people, falls well below most other OECD countries and only slightly over the low income countries. Similarly, the only developing region with an average level below Mexico is Sub-Saharan Africa. In Latin America, Mexico has bed numbers per 1000 close to those of Haiti, Paraguay and Peru.

Figure 1

Mexican number of hospital beds per 1,000 people in comparison with the average per region\*



\*Last data available, 2011 in the case of Mexico

\*\*Excluding Mexico and the Virgin Islands (U.S.)

†Excluding Mexico

‡Excluding the Democratic Republic of Korea

Source: Data from The World Bank (2015)

In addition, the country faces a shortage of health facilities in some areas as a result of the variation in states health system organization. Gutiérrez et al. (2014) shows that almost half of the Mexican population had no effective access to health services largely because of low/variable quality in access in many geographical regions.

Mexico has achieved a number of improvements in the last decade as a result of the Seguro Popular. The MoH has increased the health budget for building infrastructure by more than 5%, which has been used to build outpatient clinics and hospitals, including high-specialty hospitals in the poorest states (Frenk, Gómez-Dantés and Knaul, 2009).

In order to support the recent efforts increasing the number and quality of health facilities, there is a need for a formulary decision making process that considers the difficulties faced by some Mexican regions in providing new health care treatments to the population in need (Manatt Jones Global Strategies, 2015). Treatments targeting diseases affecting the most marginalised regions should have a high probability of being included in the benefit package.

### Health workforce

A direct consequence of the creation of the Seguro Popular was an increase in health workers hired by the state governments (Nigenda et al., 2015). During the first years of the Seguro Popular, some states' expenditures on human resources accounted for over 70% of the Seguro Popular resources transferred to them from the central government.

An official ceiling of a maximum of 40% of expenditures on human capital, imposed in 2007, halted this trend. Nevertheless, many states still spend over the established limit (Nigenda et al., 2015).

The Ministry of Health National Workers' Union (Sindicato Nacional de Trabajadores de la Secretaría de Salud, SNTSA) covers all the public workers in Mexico and is one of the largest labour unions in the world (Nigenda et al., 2015). The pressure of this group in the health sector decision in Mexico is particularly important and has to be considered in the application of any reform.

Despite the increased investment in human resources as a consequence of the creation of the Seguro Popular, Mexico is still showing an important deficit in skilled human capital. The rate of physicians per-capita is higher in Mexico (2.1 per 1,000 persons see Table 1) than the average rate in the Latin America and Caribbean countries (The World Bank, 2015), however, it is below the average rate in Europe, in Central Asia developing countries and in OECD members. In addition, there is a lack of nurses. The number of nurses and midwives per 1,000 people in Mexico is 2.5 compared to 4.2 of Latin America and Caribbean countries and the average for the OECD countries of 7.8 (The World Bank, 2015).

### **Information**

Giving the fragmentation of the social security system and of the provision of health, the success of a future reform allowing patients to choose treatment facilities among the public institutions will be highly dependent on the capacity to share clinical and related information (Manatt Jones Global Strategies, 2015; OECD, 2016). Otherwise, differences in coverage among the public institutions might hinder the adequate reimbursement of health care services jeopardising the efficient provision of services.

Health reforms will need to be supported by the development of an IT system that could allow sharing of information between institutions. Currently, there is not such as information system in place and any follow up of a particular condition represents a challenge. Similarly, there is a need for regulation that prevents the misuse of any shared patient information.

The need of developing an integrated IT system could also be considered during the decision making process, since a number of new treatments require a close follow up of patients which can be coordinated centrally. One way to do this is to include in the submission an analysis of whether the new treatment could be a facilitator of the development of a more integrated IT system.

### **Medical Products, Vaccine and Technologies**

It is prohibited by law for a public institution to purchase a health technology that is not included in the public health sector positive list, called the Health Care Formulary and Supply Catalogue (Cuadro Básico y Catálogo de Insumos del Sector Salud, CBCISS) (Santa-Ana-Tellez et al., October 19th 2014). CSG is responsible for the publication of the CBCISS document which includes, defines and encodes all the medical products that the public institutions are allowed to use (Rizo Ríos et al., 2014). Requests for the CBCISS can be made by different stakeholders such as public healthcare providers, scientific organization, government institutions, members of the CSG, and providers or manufacturers of the new treatments, the latter being the most common party starting the process (Rizo Ríos et al., 2014).

In addition, each one of the six institutions have their own health package including their own drugs and devices formulary. These can vary considerably between institutions. Beneficiaries of the IMSS and the ISSTE are covered without co-payment for those pharmaceutical prescriptions that are listed in the institutional positive list. There is almost no flexibility for hospitals and clinicians to prescribe medicines outside the institutional positive list. According to an industry representative, less than 10% of the drugs that are approved by the CSG are consequently approved by the social security institutions to be included in their institutional positive lists.

Drugs covered by Seguro Popular are registered in the General Health Services Catalogue (Catálogo Universal de Servicios de Salud, CAUSES). When the Seguro Popular started in 2002, a prioritization was done based on epidemiological profile of the population, equity, clinical evidence and cost effectiveness, which led to the identification of a first list of 78 health interventions. This prioritization process has continued and today CAUSES corresponds to a list of 285 interventions and their related pharmaceutical products (609 drugs) (Régimen Estatal de Protección Social en Salud México, 2015). Unlike the other social security institutions, clinicians and hospitals affiliated to the Seguro Popular have more flexibility and in particular cases can prescribe drugs that are outside of CAUSES. The clinicians working at the Ministry of Health's facilities network are entitled to prescribe all drugs that have been approved by the CSG, however, if the drug is not in CAUSES, reimbursement requires the hospital or the clinician to prove the need to use the selected drug for the particular case of the patient or patients treated. Moreover, if it is possible to demonstrate that the medicine satisfy an unmet need, it could result in the subsequent inclusion of the drug into CAUSES.

Another positive list is the Fund for Protection against Catastrophic Expenses (Fondo de Protección contra Gastos Catastróficos, FPGC). The FPGC is a fund created with the objective of covering treatments and drugs related to high cost diseases that could provoke catastrophic health expenditures for patients. Currently, a list of 49 diseases are considered high cost diseases (Régimen Estatal de Protección Social en Salud México, 2015). The insured population of the Seguro Popular are entitled to receive the services covered by this fund if they suffer from any of these diseases. The list of diseases considered high cost diseases is defined by the CSG (OECD, 2016; Lozano Ascencio et al., 2013).

Seguro Popular informs deliberations of the CSG in the process to decide the inclusion of diseases into the FPGC list. Seguro Popular conducts an analysis considering economic evaluations, burden of disease for the general population and for disadvantaged groups, and treatment options, amongst other factors. Moreover, according to a representative from CENETEC, the plan for the health system established by the government is considered to include the FPGC diseases (OECD, 2016).

In summary, the number of different lists that exists in the Mexican decision process has created a fragmented system which hinders the standardization of health services as well as the analysis of the quality of the healthcare provided.

## **Leadership and Governance**

The Mexican constitution guarantees the right to health protection to every Mexican citizen (Mexico, 1917). However, in contrast to other Latin American countries, in Mexico the judicial system has almost no influence on the formulary decision making process or on access to new treatments. The limited influence of the Judicial Court is explained by the fact that the CSG is an institution that reports directly to the President, and there is

no other institution that could undo, affect or change its decisions. The Judicial Court can only respond to the request of, for example, a group of patients, by requiring the submitting of evidence of a new medicine for the assessment by the CSG. However, most of the submissions come from the manufacturers.

## **Financing**

According to the World Bank, between 1996 and 2010, the per-capita health expenditure in Mexico showed a steady rate of growth averaging 6.8%. In the last four years this growth has slowed down (The World Bank, 2015).

The Mexican health system has high rates of out-of-pocket health expenditure (OOP). In 1995 the OOP level was equal to 56% of the total health expenditure (Table 1). The effect of this on the well-being of Mexican families was a primary reason for the reforms that the country experienced during 2003-2004, the most significant of which is the creation of the Seguro Popular. The steady decrease in OOP observed in the past 10 years from almost 60% to 44% reflects the improvement in the financial risk protection of Mexican people as a consequence of the Seguro Popular. Although on a declining trend, Mexican's OOP is still among the highest in Latin America and is the highest among OECD countries (OECD, 2014; The World Bank, 2015). The key driver of OOP expenditure is expenditure on pharmaceuticals, which was over 85% in 2004.

It is important to note the increase in the decentralization of resources that the creation of the Seguro Popular brought to the system. The federal government allocates to each of the 32 Mexican states the financial resources to provide beneficiaries of the Seguro Popular with needed healthcare depending on the number of individuals enrolled by the Seguro Popular in the states. The states' health ministries, however, have the right to design their own strategies for the implementation of national policies.

### **5.3. Are there positive spill-overs related to the new technology?**

A final group of macro-level elements to consider in the decision process are any positive spill-overs related to the introduction of a new treatment. These could be divided into two sub-categories: (1) correlation between diseases and (2) treatment effect interaction with the health system. As mentioned in the main report, recent studies suggest that there exists a link between the decreases in prevalence of some NCDs, such as diabetes, and some CDs, such as tuberculosis. A study conducted by Jeon and Murray (2008) found that diabetes mellitus accounts for 11% of active tuberculosis cases among the Mexican population. The increase on the number of cancer cases in Mexico is a call for treatments that improve related diseases. Some cancers have been found to be linked to infections such as Human papillomavirus (HPV), Hepatitis C, HIV, and Helicobacter pylori bacteria (Pan American Health Organization, 2011). Given the epidemiological differences between states, in which some states are more affected by NCDs and other by CDs, considering links between diseases should be relevant to the decision of including a new treatment in the positive list.

## **6. WHICH MICRO-LEVEL FACTORS SHOULD BE CONSIDERED IN THE DEVELOPMENT OF DRUG FORMULARY?**

As mentioned above the CSG consists of representatives of all health public institutions: Seguro Popular, IMSS, ISSTE, PEMEX, SEDENA and SEMAR. Each institution analyses



separately, and prior to the sub-committee meetings, the information about the new health treatment to develop an internal position about coverage. The biggest institutions, IMSS and ISSTE, develop a separate full assessment of the new treatment which includes, for example, a meta-analysis of the national and international clinical and economic evidence. Individual institutional assessments and positions are discussed during the committee meeting with the aim of reaching a common agreement regarding the new treatment.

The National Center for Health Technology Excellence (CENETEC) is a MoH agency that also contributes to the CSG decisions through the development of HTA assessments and recommendations that are also considered during the appraisal of the committee. CENETEC recommendations are not binding and are only part of the documentation considered. CENETEC is responsible for assessing medical equipment, but in recent years its scope has been expanded to include medical devices, drugs and procedures (Hernández San Román, 2015).

The assessments provided by CENETEC present evidence from the manufacturer submission and also a meta-analysis of other national and international sources. This is especially useful for representatives of the smaller social security institutions that do not have the infrastructure for conducting a full assessment of the evidence. Without the support of CENETEC, small institutions could only refer to the manufacturer dossier.

In the following subsections we present the micro-level factors considered by the CSG members and compare them with our decision making framework.

### **6.1. Intervention-specific**

*Health effects/Clinical effectiveness:* this micro-level factor is considered by the CSG as well as by the assessment of individual social security institutions. Health effects are measured in life year gained (LYG) with no adjustments for health-related quality of life.

### **6.2. Disease-specific clinical outcomes**

The CSG requires that every new treatment submission includes an economic evaluation. The new intervention side effects profile has to be included in any economic submission.

Regarding the impact on existing processes of care or care pathways, there is no mechanism to consider whether the addition of a new treatment into the formulary has an impact on the current care pathway (for example with a change in the clinical guidelines of the relevant condition). Each social security institution can use very different drugs for the treatment of the same disease which leads to variation in the way a condition is treated across the country.

Each institution has the right to develop its own clinical guidelines. The CENETEC has recently taken over the role of integrating national clinical guidelines. One of its tasks is to include drugs that are available in the social security institution positive lists into national guidelines. This is a key opportunity for the CSG which might in the future be able to consider the effect of a new drug on the national clinical pathway coordinated by the CENETEC when making an inclusion decision (CENETEC, 2015).

### 6.3. Are population's values and expectations reflected in the analysis?

#### Disease-related

Mrs María Luisa González Rétiz, CENETEC director, explained during the ISPOR 5th Latin America Conference in Chile (González Rétiz, 8 september 2015), that in the case of Mexico the assessments of high-cost drugs includes not only safety and effectiveness, but also severity of the health condition and the disease burden.

#### Characteristics of the target population

*Socioeconomic status, age, ethnicity, area of residence, gender (Gini Index):* Equity considerations have been included into the submission requirements specify in the CSG guidelines (CSG, 2015b; a). This means that all submissions should include an analysis of the characteristics of the affected population as well as possible exclusion or inclusion criteria for the use of the intervention (CSG, 2015b). Although equity is considered intermittently during deliberations of the committee, there is no formal mechanism or guidelines to measure any equity dimension (i.e. socioeconomic status, age, ethnicity, area of residence, gender).

Although the Mexican system offers the same opportunities of accessing public health insurance regardless the socioeconomic status of the patient, inequalities in access to healthcare continue to exist. Urquieta-Salomo and Villarreal (2016) found socioeconomic inequalities in access to prenatal care and breast examinations, and significant gaps in the use of healthcare services between insured and uninsured. They also pointed out differences in population health status between geographical locations. There is also variation in healthcare quality among states.

One of the objectives of the Seguro Popular was to decrease those disparities (i.e. geographical inequalities in health status and the quality and availability of healthcare provision). Although progress in this direction has been observed, there is still a gap in access, quality and health coverage between geographical regions. Moreover, some studies suggest that the positive effects due to the introduction of Seguro Popular are greater in urban areas than in rural areas (Grogger, Leon and Ome, 2013). This is partly due to the decentralised system where the Seguro Popular funds and health care provision are managed separately by each State Ministry of Health (Nigenda et al., 2015).

The split of public expenditure on health between the Seguro Popular and the other social security institutions raises equity considerations. The highest proportion of public health expenditures are for the social security of workers in formal employment. These are covered by IMSS, ISSTE or other social insurance schemes.

*Impact on non-health factors (e.g. social stigma):* The drug decision making process does not consider non-health factors during the appraisal of a new intervention. However, the document providing a guide to methods by CENETEC includes a chapter on ethical and societal factors exploring whether a new health technology affects society in general or affects an specific group of individuals. CENETEC considers that a new health technology should prove to be in agreement with the cultural values of the population and that the assessment of any new technology should consider factors such as distributive justice, efficiency and equity. CENETEC guidelines regulate only the

assessments produced by this institution. A separate document regulates the CSG's procedures and the submissions for new technologies.

The specific mention of ethical and societal factors in CENETEC guidelines could be considered a signal that there exists an interest to explore these factors during the appraisal process (CENETEC, 2010). However, CENETEC does not offer a concrete description of how these factors should be measured or the relative importance that should be assigned to them during decision process.

#### **6.4. Non-health factors**

Patient convenience and patient opinions are not considered during the process.

### **7. FINANCIAL FACTORS**

#### **7.1. Is the new treatment good value for money?**

##### **Cost effectiveness**

As mentioned above, the CSG requires that every new treatment submission includes an economic evaluation. This should take the form of cost effectiveness analysis, where health effects are measured in life years gained.

Cost utility analysis, where health effects are measured in QALYs, can also be included but it is not required. If this analysis is incorporated, it should preferably incorporate quality of life outcomes of the Mexican population (CSG, 2015b). Although the use of QALYs is mentioned in the CSG guideline one of our interviewees noted that the common practice is to use life years gained. There is an official cost effectiveness threshold which is set at one Mexican GDP per-capita (around 10,000 dollars) per life year gained (Rizo Ríos (2013) and personal communication).

In addition, only direct medical costs should be included in any economic evaluation, which are those incurred by the healthcare institution when providing the treatment. Nevertheless, when indirect costs (e.g. impact on non-health public sectors, productivity gains, care for others, etc.) are considered important they can also be included. It is also worth mentioning that cost offset (per patient) to the health care system is not included in the CSG guideline (CSG, 2015b).

Cost effectiveness analysis submitted by the manufacturer is reviewed by the social security institutions and CENETEC. The latter is responsible for the examination of the model, its assumptions, the quality of the data used, and the overall value for money of the treatment (defined by comparing the cost effectiveness ratio with the CSG threshold).

Economic evaluations are also considered during the deliberations to include a new drug in the institutional positive lists. Factors such as relevance of the comparators used and strength of the efficacy and effectiveness assumptions are considered in greater detail (OECD, 2016).

## **7.2. Is it the treatment affordable for the health system?**

56% of public health expenditures on pharmaceuticals accounts for patented products. Despite policies to promote the use of generics, including use of tenders, the use of generics in the public sector is still limited (Gómez-Dantés et al., 2012).

### **Budget impact**

CSG does not assign a high importance to budget impact which can be explained by the fact that the CSG is not responsible for the budget of the public institutions. However, it is required as part of the submission to the CGS for treatments used in low-incidence diseases with high social impact (Rizo Ríos et al., 2014; CSG, 2015a). In addition, the CSG recommends to include a budget impact for those drugs that could represent a significantly high financial impact for the national health system (CSG, 2015a). The budget impact calculation should consider epidemiological data that reflects the Mexican situation in an analysis of the expected demand.

Budget impact analysis is particularly important during the evaluation by individual social security institutions. It has a key role in the decision about inclusion of a new treatment in the institutional list (Manatt Jones Global Strategies, 2015; OECD, 2016).

### **Affordability measures**

The use of tenders increases the use of generics which can generate savings which in turn can be used to fund new / cost increasing interventions. The potential savings related to the tenders depends on the number of suppliers and the bargaining power of the public institution. In this regards, the IMSS is considered one of the largest insurance providers of the Western Hemisphere which impacts on its negotiating capacity (Manatt Jones Global Strategies, 2015). During 2014 one of the biggest public tenders in the world related to the health sector took place in Mexico, with the participation of all the federal institutions and 17 state health ministries. Around 90 million Mexicans were covered by the public institution participants in this bid. The negotiating power of the public sector increased with the creation of the CCPNM. The latter issues, among other things, recommendations on the substitution of expensive patented drug with cheaper pharmaceutical products or generic (Gómez-Dantés et al., 2012).

International reference pricing, in addition to the normally accepted distributional margins, has a central role in the definition of the maximum prices that the new drugs can be sold for in the market (Secretaría de Economía Mexico, 2007). During the negotiating process for patented drugs the CCPNM considers different factors, one of the most important being international reference prices. Some of the countries selected as comparators are USA, Brazil, Colombia and Costa Rica.

Measures mentioned in our framework targeted either volumes or prices of the new products such as:

- Sub-group of the patient population/"Appropriate use" rules
- Rebate schemes involving volume caps
- Managed entry agreements (MEAs)

However, we did not find evidence of use of any of them in the Mexican context.

## **Transferability**

CSG guidelines explicitly mention transferability. It states that the results and information presented in submissions should be transparent and clear such that it could be possible to consider the application of the information in other contexts (CSG, 2015b).

Regarding the transferability of evidence from other contexts to the formulary decision making process in Mexico, it is worth mentioning that CENETEC's reports include a section on contextual elements where the information on national and international clinical guidelines, as well as the evidence presented in the reports of other HTA agencies inside and outside Mexico, is considered. Some examples of other countries HTA reports considered are those from NICE (the UK), IQWiG (Germany), IECS (Argentina) and agencies in Spain and Australia. The biggest social security institutions, IMSS and ISSTE, also consider the analysis done by agencies in other countries during their own assessment.

In relation to transferability in the Latin America region, Mexico, represented by CENETEC, is part of the Health Technology Assessment Network of the Americas (Red de Evaluación de Tecnologías en Salud de las Américas, RedETSA). RedETSA consists of Canada and 13 Latin American countries represented by their Ministries and 28 institutions. Promoted by the Pan American Health Organization (PAHO), RedETSA aims at supporting and strengthening the appraisal and assessment of health technologies in the region by facilitating the exchange of information and the creation of regional resolutions and documents. Currently, RedETSA does not perform any joint assessment of new medicaments but aims at supporting the development of the necessary capacity to conduct HTA in Latin America (RedETSA, 2015).

In 2012, the Inter-American Development Bank (Banco Interamericano de Desarrollo, BID) created a regional collaboration called Regional Public Goods Initiative (Iniciativa de Bienes Públicos Regionales, "Iniciativa BPR"). This aims at offering relevant information to the decision makers regarding high cost medicaments. "Iniciativa BPR" started as an alliance between institutions representing Colombia, Ecuador and Mexico (the CSG) to assess high cost medicaments. The result of the assessments was a List of Essential Medicines that comprises 20 drugs, including Bevacizumab for colorectal cancer, Imatinib for leukaemia, Sorafenib for renal cancer and hepatocellular carcinoma, Bortezomib for multiple myeloma, Infliximab for arthritis rheumatoid, psoriasis, ulcerative colitis (IFARMA, 2015). According to one of the experts we interviewed, the recommendations under the "Iniciativa BPR" are of a non-binding nature. Currently, there is a plan to incorporate HTA agencies from other Latin American countries. However, this has been hindered by concerns about the generalizability of those results and by political disagreements with regard to having a second HTA network in Latin America, in addition to RedETSA.

Such collaborative initiatives are useful if they encourage evidence sharing which can be transferred from one country to the other (e.g. clinical outcomes). However, caution needs to be used when interpreting results of cost effectiveness/cost utility analysis in different contexts. As explained earlier, the consideration of macro-factors related to the stage of development the national health care system as well as local micro contextual factors should play a role, in addition to evidence transferable intervention-specific effects, in formulary decision making.

## **8. SUMMAY AND CONCLUSION**

The health system in Mexico is organised into six public social security institutions that operate independently and do not compete directly with each other. As a result, the health system is fragmented and shows significant inefficiencies with duplication of facilities, effort for the assessment of new health technologies, and development of clinical guidelines. This is accentuated by the decentralization of the resources of the Seguro Popular to the Mexican states, resulting in geographic variability in the organizational capacity and quality of healthcare provision.

Seguro Popular has had a key role in pushing the Mexican system along the UHC pathway. This is reflected in the significant increase in the percentage of the population covered by an insurance scheme in the last 10 years, from around 50% in 2003 to 91% in 2014. However, as mentioned by Li et al. (2015), to understand the current position of the country in the UHC pathway, it is also important examine the actual use of services, such as the effective cervical cancer screening coverage. This stands at only 66% (for women aged 25–64). The fraction of women who have never had a pelvic exam is 17% (Gakidou, Nordhagen and Obermeyer, 2008). All of the above-mentioned indicators show that the country needs to make further progress to achieve UHC along all three dimensions (breadth, width and depth).

Regarding the second dimension of the UHC, i.e., the “width”, there are significant inequalities in the Mexican health system. The Seguro Popular and the FPGC, responsible for covering those Mexicans who are not entitled to any other insurance schemes, cover only a limited number of interventions, while the ISSSTE and IMSS cover almost all health needs of their insured populations. The CSG has identified 62 diseases that can potentially generate catastrophic health expenditures: however, these diseases have only been gradually incorporated in the FPCG list, and a number of diseases are still not included. Even more important is the fact that some diseases included in the FPCG are not fully covered, including HIV, for which the treatment of opportunistic infections and the prevention of infections are not covered (Juan et al., 2013).

The process to identify new medicines to be included in the public sector positive list is also highly fragmented, with a different positive lists for each social security institution. Decisions of the General Health Council (CSG) have national impact but are generally followed by further assessments conducted by each institution via a non-transparent process. We note that many interventions which were accepted for inclusion by the CSG were subsequently rejected by individual social security institutions.

It is difficult to explain the rejection rate and the variability in the institutional positive lists when we consider that the CSG takes into account the clinical evidence and the cost-effectiveness to exclude or include a new treatment of the public positive list. Prior to the CSG meeting, the evidence is assessed by each of the main social security institutions which also have the opportunity to discuss their perspective during the CSG’s deliberative process. Therefore, it could be assumed that all the main factors considered important by the social security institutions are discussed during the CSG deliberations. The one factor that does appear to be central in the CSG discussions is the affordability of the new health technology which may be key. Another possible explanation is differences in the epidemiological profiles of the insured populations among the social security institutions. However, the main epidemiological differences are across regions and the institutions work in parallel over all Mexican regions, so they attend similar divergent populations. Moreover, the evidence suggests that the CSG internal

deliberations do not include individual Mexican states epidemiological profile or disease priorities.

As we have mentioned above, providing patients access to a new drugs in the Mexican health system requires the assessment and approval of the CSG as well as the assessment and approval of each public insurance fund separately. This is inevitably leads to dissimilarities in the medicines covered by insurance funds as well as an unclear process and duplicative process that implies additional costs for the health system. The Mexican health system could benefit from the experience of other countries such as Germany.

The Mexican and the German health systems share some similarities, both have more than one public insurance fund and there exists an institution that represents all public insurance schemes. Most of the German population (86%) is covered by the public statutory health insurance scheme (SHI) which is operated by more than 140 competing sickness funds (Blümel, 2013). In the German system the benefit package is determined by one institution— the Federal Joint Committee (G-BA)—whose decisions consider patient interests as well as the interests of the sickness funds. Although these sickness funds compete between each other to capture the highest number of enrollees, this competition is not based on the benefit package, which is the same for each sickness fund (Green and Irvine, 2013). Central assessment of new treatments allows the sickness funds to save evaluation resources and avoid inequalities. In order to improve efficiency in the Mexican decision making process, an integrated approach would make sense, with a more conclusive role for the CSG in the definition of the actual list of medicines that the insurance schemes offer to their insured populations. Moreover, this would promote equality among the institutional positive lists, decreasing inequalities in the health system.

By comparing the current organisation of the decision making process in Mexico with our assessment framework, we outline a list of initial recommendations that could improve the efficiency and the predictability of HTA decision making in the Mexican health sector:

- *Macro-level factors.* Although the government invested in a number of initiatives aimed at achieving UHC, the formulary decision making process does not formally consider macro-factors in reaching a decision, such as the national health system plan, planned reforms, and the objectives of the government. Macro-level factors are not currently and directly considered in any stage of decision making. In the Mexican case, some of the main factors that could be considered in the decision making process are:
  - a) *Disease priorities:* A process of prioritization of the drugs to be assessed that considers the disease priorities of the country would allow a more efficient allocation of resources. The CSG could develop a process that requests the submissions to support new treatments that are related to the priority diseases, but which have not been submitted yet.
  - b) *National health priorities and governmental reforms:* It could be beneficial in terms of efficiency in allocation of resources for new treatments approved by the CSG and the social security institutions to be in line with governmental reforms and national health system priorities.
  - c) *Differences in the epidemiologic profiles of states:* Differences in the epidemiologic profiles of states should be considered when identifying the “priority” interventions. In a formal and structured process, the states should be

able to request the assessment of treatments that match their specific needs. Based on this the CSG could invite the manufacturer to submit products for consideration that address the specific needs of particular states.

- d) **Service Delivery:** In order to support the recent efforts to increase the number and quality of the health facilities, there is a need for a formulary decision making process that considers the difficulties faced by some Mexican regions in providing new health care treatments to the populations in need.
- e) **Health workforce and stakeholder involvement:** Many reforms and policies are delayed or stopped by the union of workers (SNTSA) which has a significant power in almost every Mexican state. We note that the institutional and the CSG processes could benefit from limiting the role of the union (for example, by allowing it to participate in the deliberations without voting rights). However, we recognize that the political and cultural environment might hinder those changes.
- **Equity:** Although the CSG method guidelines mention equity as one of the factors to be discussed, our interviewees suggested that equity is rarely considered. A more formalised and systematic approach to measure and consider equity is necessary given the high importance of this factor for the Mexican health system. One of the objectives of the creation of the Seguro Popular was to the decrease of geographical inequalities in health status and healthcare. Therefore, treatments targeting diseases affecting the most marginalised regions should have a higher probability of being included in the benefit package.
- **Impact on existing processes of care or care pathways:** A more centralised system to develop clinical guidelines could allow the CSG to consider the effect of a new drug into the national clinical pathways. This could support the governmental objective of encouraging resources sharing between social security institutions and decrease the fragmentation of the system.
- **Reduce duplication of assessments:** There could be efficiency gains from limiting proliferation of assessment processes. Currently, the CSG considers the assessments carried out by the CENETEC as well as the assessments conducted by each individual institution represented in the CSG. A more centralised assessment process would avoid the duplication of work. This could eliminate the asymmetry of information among the social security institutions, and centralise resources in an agency with the human and infrastructure capacity to not only evaluate the submitted manufacturer information, but also conduct full assessments that consider the case of the Mexican population.
- **Health gain measurement:** Health effects are measured in life years gained with no adjustment to health-related quality of life. This could be too limiting and disadvantage treatments for long term/chronic conditions with significant benefits on patients' quality of life and overall well-being rather than on survival. It would helpful to better understand the rationale for the choice of this methodological approach, e.g. whether is driven by lack of country-specific data, such as an EQ 5D tariff.

Table 3 shows a summary of our comparison between the Mexican decision making process and our framework, alongside our recommendations for improvements of each stage of the formulary decision making process.



Table 3  
Decision making stages: Mexican case study

Decision making stages		Breath of factors	Value assessed	Mexico	Decision on:		Recommendations
OHE Framework	Mexico	OHE Framew.	OHE framework	Breath of Factors + Value assessed	OHE Framework	Mexico	per decision making stage
Nomination and prioritisation	<i>There is not prioritisation: Manufacturers initiate the CSG assessment process</i>	Macro-level factors	Health system intervention value (HSIV)	<i>No consideration of macro-factors, therefore, the HSIV is not taken into account</i>	Interventions to be assessed and appraised	<i>No decision related to this stage</i>	<ul style="list-style-type: none"> <li>- The CSG should be more proactive and request the submission of those new treatments that are related to the priority diseases of the country</li> <li>- Consideration of regional differences</li> </ul>
Assessment of the intervention	<p><i>Each social security institution does an assessment: Ministry of Health, IMSS, ISSTE, PEMEX, SEDENA and SEMAR.</i></p> <p><i>- An additional assessment from CENETEC feeds into the CSG process.</i></p>	Micro-level factors	Aggregate intervention value and value for money	<i>Main analysis is the cost-effectiveness for the public sector</i>	Recommendation for inclusion (or exclusion)	<i>CENETEC gives a non-binding opinion. The other institutions prepare a position to be discussed at the CSG committee</i>	<ul style="list-style-type: none"> <li>- Reduce duplication of assessments</li> <li>- More systematic consideration of equity issues</li> <li>- More systematic consideration of the impact on existing processes of care or care pathways, and on government reforms</li> </ul>
Appraisal of the intervention	<p><i>1) General Health Council (CSG): This committee has representatives from the six institutions.</i></p>	Micro-level factors and Macro-level factors	HSIV; Aggregate intervention value; Value for money	<p><i>1.1) Cost-effectiveness for the public sector</i></p> <p><i>1.2) Budget impact: for those treatments linked to low-incidence diseases with social consequences</i></p> <p><i>1.3) Other factors not systematically considered</i></p>	Decision of inclusion (or exclusion)	<p><i>1) Inclusion in the public sector positive list (CBCISS)</i></p>	<ul style="list-style-type: none"> <li>- Formal consideration of equity</li> <li>- Formal consideration of the impact on existing processes of care or care pathways</li> <li>- SNTSA participation in the deliberation process but without voting rights.</li> <li>- Formal consideration of regional differences</li> <li>- Inclusion of health-related quality of life</li> </ul>
	<p><i>2) Appraisal in each institution.</i></p>			<p><i>2.1) Budget impact</i></p> <p><i>2.2) Affordability</i></p> <p><i>2.3) Other factors not systematically considered</i></p>		<p><i>2) Inclusion in the institution positive list (e.g. CAUSES in the Seguro Popular)</i></p>	
Financial assessment	<i>The six institutions consider this separately in their individual assessments. The price of new medicament is negotiated by the CCPNM</i>	Budget Impact analysis	Financial sustainability	<i>Affordability of the health technologies International Prices</i>	Affordability measure/s	<i>Price for the patented drugs that are going to be acquired by most of the public sector</i>	

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