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HEALTH FINANCING AND PHARMACEUTICAL POLICY REFORM IN THE COUNTRIES OF CENTRAL AND EASTERN EUROPE

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INTRODUCTION

It is now more than seven years ago that the Countries of Central and Eastern Europe (CCEE) were liberated from communism. Since then, they have embarked upon an unprecedented process of structural reform of social, cultural and economic values. At first, the focus of the reforms was on improvement of the physical infrastructure, telecommunications and utilities industries[1]. However, in view of appalling health statistics – many Eastern European countries had witnessed a drop in life expectancy in the decade prior to the downfall of communism – it was soon realised by policy makers that health care delivery is an important element of reform and that 'good health' constitutes an important economic factor[2,3].

In the meantime, in collaboration with institutional agencies such as the World Bank, the Phare (Poland and Hungary Aid for the Reconstruction of Economies) and Tacis (Technical Assistance Commonwealth of Independent States) programmes of the European Union (EU), and on the basis of bilateral support (in the UK provided by the 'Know How Fund'), many governments have adopted strategies and concrete plans of action to promote better health care delivery. These national and international efforts to reform the health care systems in the CCEE have attained a considerable scope[4,5].

The objective of this report is to provide an assessment of the reform process of the health care sector in CCEE. I shall assess the overall direction of the reforms and focus in particular on health financing and pharmaceutical policy making as two important elements of structural reform. The first part of this report provides a brief overview of the state of health of CCEE populations and the process of health care reform. The second part of the report discusses health financing and pharmaceutical policy reform. I focus on these two topics for the following reasons:

- health financing is an integral part of the health care reform process throughout CCEE. Without reform of the health financing system, it will be very difficult to embark on a sustained effort of health care reform;
- pharmaceutical policy reform has been a component of health care reform in most CCEE. The rationale for this is that the use of pharmaceuticals constitutes a straight-forward and – in comparison to the reform of other sectors such as hospital care – relatively inexpensive technology to bring about improvements in health.

This report is based on a review of the literature on health care reform in the CCEE as well as the collection of empirical data by means of a survey

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The usual disclaimers apply.

among health care policy makers of seven CCEE initiated by the Office of Health Economics in 1994*.

HEALTH CARE PROVISION UNDER COMMUNISM

Although it is now more than seven years since the communist system disbanded, it is still useful to briefly analyse health care provision during that era. In spite of major reforms, many health care systems in Central and Eastern Europe are still rudimentary, reflecting health care practice of the communist era[6].

Under communism health care services were free of charge and the state was responsible for their financing and organisation. Health care was provided according to strict planning and in principle each citizen had access to a unified system of health care on the basis of equal provision for equal need. There was an orientation towards disease prevention and citizens were encouraged to partake in the planning of health care services.

Initially, the state involvement in the health sector in the post-World War II socialist era led to significant improvements in living standards and health status in many CCEE. However, following the Brehznev era in the 1970s, health care provision in many CCEE began to stagnate[7]. One of the major causes of this was the opinion of the communist party that health care provision could be organised as an extremely hierarchical 'top-down' industry. Analogous to industry, where much responsibility was given to bureaucrats and technocrats, in health care there was much emphasis on the development of secondary and tertiary care, while primary care was neglected.** This resulted in an oversupply of specialists, while community nurses and general practitioners were largely absent[8].

The hierarchical nature of the medical system led to a lack of co-ordination between primary care and secondary care and an excessive referral of 'simple' cases to secondary care, resulting in unnecessary hospital admissions and length of stay. There were closed subsystems of health care provision and separation of services according to political parameters, employment and social status. As a result of the central planning procedure, there was chronic underfunding of the health care system in general and regional and local primary care provision suffered particularly. Although in theory every citizen had equal access to health care services, in practice high quality care in the CCEE was often only available to those associated with the political system or to patients able to pay substantial cash amounts under the table[9].

HEALTH AND DISEASE INDICATORS AND HEALTH CARE EXPENDITURES

It is no surprise that the poor health care services infrastructure in CCEE is matched by unfavourable overall patterns of health, which have significantly deteriorated over the past 15 years. In the 1960s and 1970s health indicators in CCEE generally improved, helped by relatively successful immunisation programmes[10].

However, in the 1980s, overall life expectancy decreased for both men and women. For males the decline was the larger and their life expectancy is now, for the countries reported in Table 1, between 62.8 and 70.0 years, compared with 73.1 to 76.9 years for females.

Within the European region of the World Health Organisation (WHO), all CCEE have dropped down the rankings in the life expectancy league and their relative positions continue to worsen.

In addition to poorly functioning health care systems, poor life style conditions are major factors explaining a high incidence of diseases of the circulatory system such as stroke and cardiac arrest as well as neoplasms. As Table 1 clarifies, compared to the UK, the incidence rates of circulatory diseases are 15-20 per cent higher, while neoplasms are in the same range as in the UK. Moreover, the infant mortality rate in most CCEE, ranging from 15.6 to 8.5 per 1,000 live births, is considerably higher than the UK level of 6.3 per 1,000[11,12,13].

During the period immediately following the demise of communism, the economies of the CCEE collapsed and GNP per capita declined. Macroeconomic parameters for the region showed sharp increases in the rate of unemployment (as many state employees lost their positions) and in consumer prices[14].

Seven years into the reforms, in some CCEE the economy is slowly recovering. The most notable examples are Poland, which saw a 7 per cent growth rate of the economy in 1995, and the Czech Republic, which, thanks to its central

*In early 1994, OHE conducted a survey among participants of an international congress on pharmaceuticals policies in Eastern Europe in Prague. The conference was attended by senior pharmaceutical policy makers and academicians from seven CCEE: Estonia, Lithuania, Poland, Hungary, Bulgaria, the Czech Republic and Croatia. Interviews were held with representatives from all countries on topics of health financing and social insurance, and pharmaceutical policy issues. Information gathered has been updated in 1997.

**Of course, there are examples of polyclinics and other primary care facilities in CCEE of adequate quality.

Table 1 **Mortality and life expectancy: selected CCEE compared to the UK**

Country	*Malignant neoplasms per 100,000 (WHO 8-14) (0-64 years) 1994*	*Diseases of circulatory system per 100,000 (WHO 25-30) (0-64 years) 1994*	*Life expectancy at birth in years 1994*		*Infant mortality rate (per 1,000 live births) 1995*
			Males	*Females*	
Bulgaria	158	673	67.2	74.8	13.9
Croatia	200	479	67.3	74.4	8.5
Czech Republic	240	551	70.0	76.9	9.4
Estonia	156	491	63.9	73.1	15.6
Hungary	278	630	64.6	74.2	15.4
Lithuania	175	577	62.8	74.9	12.8
Poland	177	458	67.4	76.1	12.5
United Kingdom	230	400	73.7	79.2	6.3

Source: WHO 1995, UNDP 1997

location in Europe, is benefiting from many foreign investors and a boom of the tourist industry especially in the capital, Prague.

In spite of economic recovery in some CCEE, the overall economic potential of many countries of the region to finance health care services is still weak and levels of financing are generally declining. There is some evidence that health care expenditures per capita primarily depend on the economic status of a country[15]: affluent countries in Northern and Western Europe and Northern America spent between 7-14 per cent of their GNP on health care, while this percentage is much lower in Eastern and Southern Europe (3-7 per cent).

Table 2 **Health care expenditure in a selection of CCEE and the EU average***

Country	*Per capita health expenditures in US$ 1994*	*Health expenditure as percentage of GDP 1994*
Bulgaria	55	4.7
Croatia	NA	8.7
Czech Republic	262	7.5
Estonia	68	6.2
Hungary	277	6.9
Lithuania	51	4.4
Poland	102	4.6
EU	1,277 (1993)	8.3 (1993)

Source: UNDP 1997

*Figures are presented in official exchange rate US$, purchasing power parity exchange rates (PPPs) relevant to health care were not available for Eastern Europe.

**Poland, Czech Republic, Slovak Republic and Hungary.

***There is not only a close correlation between economic performance and health care expenditure but also between economic performance and health status. For instance, based on their income levels, both Northern and Southern countries of the CCEE, together with the Central Asian republics of the former USSR, appear to have attained a health status in line with their incomes.

Compared to countries of the EU, the historic health care expenditure level in CCEE was low, ranging from 3-5 per cent of GDP. However, in the more advanced CCEE economies such as Hungary and the Czech Republic, the health care expenditure level has been increasing in recent years and is now comparable to that in the middle income countries of the Southern European region[16]. In 1994, per capita expenditures on health care in the CCEE ranged from about 277 US$ in Hungary to 50-70 US$ in the Baltic states. On average, per capita expenditures on health care in real terms in the CCEE were about one sixth of the level in the EU (see Table 2).

With the exception of the Visegrad countries** and some former Yugoslav republics such as Croatia and Slovenia, it will probably take several years until the economies of the CCEE have recovered to their previous level of output and several decades to reach Western European standards. As there is a close correlation between economic performance and health care expenditures, it is a fair prognosis that the present level of health care expenditure of most CCEE will prevail for the next decade.*** Therefore, at least in the short term, improvements in health care delivery are unlikely to be achieved by higher real spending, but rather by increased efficiency of delivering care. The development of primary care is generally viewed as an appropriate instrument to provide low cost but good quality care close to the citizens[17]. When resources are shifted from expensive secondary care to inexpensive primary care, cost-efficiencies may be realised.

Government policies to reform the health care sector in the region are to be seen in the context of the many other priorities for reform of the industrial sector, the environment and other sectors such as social welfare. Nevertheless,

most governments in the region perceive health care reform as a priority, especially in areas such as health financing, the development of primary care and improving the provision of medicines.

HEALTH POLICY REFORM AND PRIORITISATION

A general problem for health policy makers in the CCEE is how to prioritise the reform effort in health care. Health care reform may easily backfire if the complexities of a health care delivery system are not well understood or if single, incremental measures are taken, which only address simple issues.

This problem is well illustrated by reference to the reform of the pharmaceutical sector. For instance, hypothetically, a country might develop a policy to ensure that prices of pharmaceuticals would be affordable for most citizens. However, if other relevant pharmaceutical reform issues were not pursued concurrently (such as improving the quality of medicines or reforming the distribution system), the result could be that drug prices are indeed affordable to patients, yet products are very difficult to find and of a low quality.

An advantage of pursuing a single, incremental reform might be that it is easy to implement at a relatively low cost. If health policy reform is pursued as a comprehensive approach, on the other hand, the process will be time consuming and costly. The WHO[18] has recently identified a rudimentary model of a comprehensive health care system, which would provide an adequate standard of health care delivery. Its basic functions are: health services, financing, production of health resources, education and training of health manpower, research and development and the management of a national health system. When health policy reform is to be carried out in a comprehensive manner, these major functions should be adjusted to meet the major health needs of a population within the context of a countries' economic, social and cultural constraints. In practice, however, in most CCEE such an adjustment is hardly possible because social structures (such as political parties, professional organisations, consumer organisations, media) to express the full dimension of need are mostly lacking, while instruments to measure expressions of need are not in place.

*It is noted that reform in the Western countries has not always been successful and that, therefore, there are limits to the transplanting of any given health care services to CCEE.

In the UK and elsewhere in Western Europe, there has been extensive health care reform in recent years[19,20,21]. Although these reforms must be seen in the context of the functioning of national health care systems, they nevertheless have a striking similarity in terms of the objectives they aim to achieve.* Generally, health care systems in Western Europe focus on the following issues.

Equity of access

This principle implies that a similar set of health services should be available to all citizens. A major objective of health reform in the CCEE should be that, in spite of the deteriorating economic situation and concomitant lack of resources, the population has a basic right to an appropriate health care delivery system. Concern for equity has, however, to be understood in the complicated context of what is going on elsewhere in the economy.

Efficiency at the provider and financier level

Achieving efficiency at the provider (i.e. primary and secondary care) and financier levels (national budget) is pursued by many Western European countries by changing methods for health financing from input budgeting to output financing, and from top-down control and command to separation of financing and the provision of health care.

Improvement of health outcomes

Although many factors have an impact on health and disease, the ultimate aim of health care delivery systems should be to improve health outcomes.

Improvement of patient satisfaction and consumer choice

In Western Europe, in most countries, patients and consumers are now perceived as important partners of the government and the providers in health policy making. Patient rights and consumer choice are now considered important features of a modern health care system.

Increase of provider autonomy

In order to increase efficiency, it is necessary that health care providers are more autonomous in terms of their resource management and concomitant skills development (management capacity).

There is no fundamental objection to applying principles of health care reform in Western Europe to the CCEE. However, in maintaining and restoring health outcomes in CCEE, short

term strategies might focus on issues of equity and efficiency, while in the longer term patient satisfaction and provider autonomy might be the targets.

HEALTH CARE FINANCING

Under communism, in the CCEE the collection and allocation of funds for health care was centrally located and funding decisions were often taken by officials at the Ministry of Finance irrespective of the medical needs of the population[22]. The main source of income for funding health care was general taxation. Approved by the Ministry of Finance, funds were put at the disposal of the Ministry of Health, who disbursed them to hospitals and regions. This allocation process was facilitated by the fact that all health care institutions were state-owned and, therefore, ultimately accountable to central government.

Although in theory each citizen had a right to equal and adequate health care, in practice the system of central budget allocation resulted in inequalities and chronic underfunding. As the system was centrally organised, the funding quite often did not reach as far as the primary care level and especially to the provision of health care services at feldsher level (primary health care out-posts) which was badly funded[23,24]. In the 1970s, health care expenditures in some Central European countries such as Czechoslovakia were not dissimilar to levels in Western Europe (approximately 5 per cent of GNP). However, with increasing spending on arms and the focus on the development of heavy industry, health care expenditures in many CCEE were declining in the late 1970s and 1980s.

In reforming a country's health financing system, there are alternative methods to mobilise health revenues[25,26,27]. Methods most often used are: taxation, social insurance based on a premium system, subscription to private insurance plans or direct cash payments by consumers of health services. Today, as Table 3 illustrates, in most CCEE a model of centralised fund collection and disbursement is generally being replaced by a system of social insurance based on premium collection.

Table 3 **Proposed and implemented social insurance schemes in Central and Eastern Europe**

Country	*Introduction*	*Number of sickness funds*	*Exemptions for special groups*	*Contribution rates*	*Employer/ employee ratio*	*Contributions for pensioners, unemployed*	*Free choice of physician*
Bulgaria	implementation postponed	28 regional funds with central compensation	military, public transport	ca 9%	50:50	pension insurance, unemployment insurance	yes
Czech Republic	1993	26 regional, professional or trade funds	no	13.5%	66:33	state	yes
Estonia	1992	21 regional funds with central compensation	no	13%	100:0	state	only within district
Hungary	1994	1 sickness fund with regional offices	no	23.5%	33:66	state	yes
Latvia	1993	1 sickness fund with regional offices	no	6.1%	80:20	social security	yes
Lithuania	1993	1 sickness fund with regional offices	military	30 %	66:33	social security	yes
Poland	implementation postponed	1 sickness fund with regional offices	no	NA	NA	social security	yes

Source: BASYS information, 9. Jahrgang Nr1, Juni 1994; updated in 1997

The rationale why a majority of CCEE is opting for the adoption of social insurance systems, must be seen against the context of reforming the previous, rigid, top-down financing mechanism, which left little flexibility for financing matters of health care at provider level. The objectives of introducing social insurance by CCEE are generally perceived to be:

- to set up separate systems of health care provision and financing. Separation of these two functions presupposes a negotiating process between providers and financiers of health care. The result of these negotiations should be an agreement about prices, volume and quality of health care provision. Separation of health care provision and financing is an important element of health care reform in CCEE, as under communism these two functions were carried out by the same body: the state[23];

- more than a tax-based system, a social insurance system does leave latitude for regional and local variation, as collection, disbursement and the quality of health care provision are negotiated at this level.* The potential danger, however, could be that in a country a certain inequity in terms of providing insurance coverage and services will be introduced, as long as there is no basic statutory health insurance 'package', defined for all citizens.

On the other hand, however, there seem to be some distinct advantages of tax-based health financing systems such as:

- fund management costs of a tax based system vary between 3-5 per cent (e.g. in the UK) but are significantly higher in social insurance systems (e.g. Germany) or private health insurance schemes[15];

- coverage under tax-based systems is universal by definition, while in social insurance based systems in principle only the members of the scheme are covered. This 'weakness' of social insurance systems may be resolved by national regulation setting rules about eligibility to membership of social insurance schemes;

- social insurance systems based on employment financing by means of compulsory contributions from salaries can involve a certain degree of financial risk. This risk is particularly acute when there is an imbalance between the numbers of contributors and beneficiaries of such a scheme. In the CCEE, the number of unemployed and non-salaried workers is high and in countries such as Croatia and Lithuania this has resulted in unacceptably high premia being levied on the salaried workers[28].

Western European countries typically rely on several funding sources for their health care system and alternative methods are used in varying proportions. A dual system combining both taxation and social insurance may be considered, rather than treating them as two opposite alternatives for raising funds for health care provision. On the contrary, in order to enhance the balance of risk mix and the equity of health care delivery, from a policy perspective it can be quite attractive to implement the two methods together to provide a mixture of funding sources. Irrespective of the introduction of tax-based or social insurance methods for health financing, there will be a continued role for government to meet income redistribution and equity considerations[29].

EXPERIENCE WITH THE INTRODUCTION OF SOCIAL INSURANCE IN SELECTED CCEE

Estonia was one of the first countries to introduce a social insurance system in 1992[30]. The population coverage of the insurance is approximately 95 per cent. Primary and secondary care, as well as a range of pharmaceuticals according to a national formulary, are covered by the scheme. In terms of actual flows of resources, health care is financed 85 per cent by social insurance, 10 per cent by general taxation and 5 per cent by other sources (Table 4).

In Bulgaria, 70 per cent of health care expenditure is covered by general taxation and 30 per cent by out-of-pocket payments. Out-of-pocket payments consist of two major components:

1. Cash-payments to get preferential treatment and 'jump the queue' of waiting lists which exist for many surgical procedures.

2. Co-payments in line with reimbursement policies.

The central fund collection and disbursement scheme of general taxation has a population coverage of 100 per cent. The annual national budget is allocated by the Ministry of Finance, according to the Budget Law to fund specific health care institutions such as teaching hospitals, hospitals operated by the Ministry of Health and regional hospitals operated by Municipalities[31]. In Bulgaria, a major health care reform is being discussed, and a compulsory National Health Insurance system based on a social insurance model is likely to be

*There are, of course, examples of systems based on local taxation and negotiation, such as Sweden.

Table 4 **Sources of health care financing**

State	*Health care financing*				
	General taxation	*Social insurance*	*Private insurance*	*Out-of-pocket payments*	*Other sources*
Bulgaria	70%	–	–	30%	–
Croatia	–	95%	–	5%	–
Czech Republic	–	82%	5%	3%	10% insurance (railway/miners)
Estonia	10%	80%	–	5%	Loans, etc: 5%
Hungary	–	85%	–	15%	–
Lithuania	85%	5%	–	10%	Charity
Poland	98%	–	–	2%	–

Source: OHE survey, 1994, updated in 1997

introduced[16]. However, due to the economic crisis of 1997, the implementation of the model has been postponed.

In Croatia, 95 per cent of health care is paid for by social insurance and the remainder by out-of-pocket payments. Croatia inherited the insurance system set up in 1945 in Yugoslavia[28]. The population coverage is 100 per cent and benefits include both primary and secondary care. Patients pay a health care provider directly, and receive ex-post reimbursement from their insurance agency. The Croatian insurance system provides an adequate example of the contribution burden on salaried workers. To cover the health care cost of the Croatian population the average worker is now charged about 23 per cent of average pay in contributions, which is hardly sustainable[5].

As of January 1993, the Czech Republic introduced a social insurance scheme[32,33,34,35] with a population coverage of 100 per cent. Both primary and secondary care are covered. The employers pay two thirds and the employees one third of the total insurance premium. When the system was introduced, all services were accorded a certain number of points, and these are the basis for settling claims between the regional health insurance accounting offices, hospitals, physicians and other providers. The point system is in need of revision as the number of points initially accorded to services is not always representative of the amount of work or cost involved and total outlays depend on the total amount of premium income rather than on the number of points. As a result, the Czech health insurance branch prefers to keep certain procedures outside the point value system and directly reimburses certain items such as the supply of drugs and medical supplies. The total of these direct payments exceeded 30 billion Czech crowns in 1993, as compared to 19 billion crowns reimbursed under the point system. At present, public insurance pays 82 per cent, private insurance 5 per cent and a specialised insurance for, among others, railway workers and miners pays 10 per cent of the health care bill. The railway workers and miners insurance is governed by the same regulation as the general insurance fund.*

The present social insurance system has been in operation in Hungary since 1994[22]. The population coverage of the scheme is approximately 98 per cent. Primary and secondary care are both covered. Hospital and primary outpatient health care are funded 100 per cent but some out-patient services must be paid for by the patient. The insurance scheme reimburses the health care provider directly. The funding of the system is largely based on contributions from employer and employee and out-of-pocket payments. It is interesting to note that in Hungary (and also in Slovakia), the collection of premia and the administration of funds have been devolved from the Ministry of Welfare to the National Institute of Health Insurance.

Recently, Lithuania introduced a social security system through which pension and other premiums are collected by a statutory agency (SODRA) charged as a percentage of gross salary (currently about 30 per cent of an average salary, which is high by any standard)[24]. SODRA is currently paying for a restricted number of pharmaceutical prescriptions, but the brunt of expenditures in health is still met by general taxation: the SODRA scheme is supporting about 5 per cent of the health care bill, whereas 10 per cent is paid out-of-pocket and 85 per cent through general taxation. As premia are relatively high and the range of services reimbursable through the insurance scheme limited (i.e. patients will have to pay out-of-pocket in many instances), in

*Act 589/1992, Act 592/1992, Act 550/1991.

Lithuania, there is a fundamental discussion underway about the relationship between the service and premium level.

In Poland, the financing scheme of health care has not fundamentally changed and health care is still paid for 98 per cent through general taxation[36]. Poland is in the process of strengthening regional health services in the 48 districts (voivoiships). These will be given a much more pivotal role in the allocation of health care funds. There is a plan to introduce a comprehensive insurance scheme.

PITFALLS IN IMPLEMENTING HEALTH CARE FINANCING SYSTEMS

In spite of substantial social insurance premiums in Lithuania (30 per cent of average pay), there is criticism in that country that the number of benefits to which citizens are entitled is small and that there is an imbalance between the premium paid and the benefits received. The provision of pharmaceuticals in the country is a good example of this. For the average Lithuanian citizen, who pays a premium, most medicines still have to be paid out-of-pocket.

In Lithuania and some other CCEE, such as Croatia, the employed are contributing significant shares of their income as social insurance payments to finance the level of benefits. In these countries, this situation has resulted in a societal discussion, the employed protesting that they should not be the only sources of funding the treatment cost of the disease 'burden' of society.

The implication of this discussion touches upon a more fundamental mechanism of the functioning of a social insurance system in the CCEE: dismantling a system of universal welfare coverage to replace it with an occupation-based system in the contemporary social and economic environment (with rising unemployment) could be disastrous in both financial and social terms.

OUT-OF-POCKET PAYMENTS

In view of the haphazard nature of public sector health care finance and corresponding budget constraints, in a majority of CCEE patients are increasingly paying for health care services themselves, either as a co-payment for existing services offered through the public sector or as a cash payment for services obtained through private channels.

There are no precise estimates of the scale of out-of-pocket payments. However, in this context, two general points can be made. The first is that the scale of out-of-pocket payments is inversely proportional to the state of the public health care system. The second is that probably in some CCEE, the scale of out-of-pocket payments is extensive, constituting a significant percentage of overall expenditures on health care.

This point is well illustrated by Table 5, which presents estimates of out-of-pocket payments at primary and secondary care level and for pharmaceuticals. The data were collected in the framework of an OHE survey carried out in 1994 and represent the views of senior health policy makers in a number of CCEE.

In general, a patient's contribution towards the cost of medicines is significant in most CCEE. In some countries, such as Estonia and Lithuania, out-of-pocket payments for medicines represent half or more of the total expenditures on drugs. This high percentage of private payment can be explained in several ways:

- many CCEE operate formulary listings, which only allow a limited range of pharmaceuticals to be reimbursed;
- even when products are reimbursed, patients often still have to contribute a significant co-payment;
- medicines available through state channels sometimes have a low quality and consequently, patients have an incentive to purchase higher quality products in the private sector.

Table 5 **The contribution of out-of-pocket payments**

Country	*Co- and cash payments*		
	Hospital care (as % of hospital care)	*Doctor consultations (as per cent of consultations)*	*Medicines (as % of total cost of medicines)*
Bulgaria	not available	not available	30%
Croatia	5%	5%	5%
Czech Republic	no	dentist only	27%
Estonia	no	<5%	50%
Hungary	no	not available	15-20%
Lithuania	3%	10%	60%
Poland	no	no	–20-30% for domestic medicines –100% for imports

Source: OHE survey, 1994, updated in 1997

In primary and secondary care, the relative level of co-payments is generally lower than in the pharmaceutical sector. It must be borne in mind, however, that in addition to 'official' co-payments, there is a significant amount of 'under the table' payments. Especially as regards the provision of care in a hospital, there are usually long waiting lists. The purpose of 'under the table' payments is to jump the queue and receive immediate treatment, as well as to improve the quality of services received.

According to government economists' views, there is an economic rationale for using co-payments as a policy instrument. It is argued that co-payments constitute an incentive to limit health care consumption, the assumption being that patients, having to contribute to the cost of their own treatment, will request less health care in the spirit of saving money from their own pocket. In addition, government economists purport that co-payments can potentially alleviate the public sector health care financing burden.

On the other hand, co-payments are demand-driven and the implementation of such policy instruments can introduce problems of lack of access to health care for certain groups in society such as the elderly. The consequence of this is that, whenever co-payment schemes are proposed, an analysis should be made of the societal impact of such policies so that groups may be defined who should be exempt from paying. If such exempt policies are not defined, the net effect of governmental co-payment policies could be a decrease of solidarity in providing health care.

PHARMACEUTICAL POLICY MAKING

It is not a coincidence that in many CCEE, the reform of the health care system has initially focused on the pharmaceutical sector. The reason for this is probably that through the introduction of modern medicines, significant improvements in health care status can be brought about without having to set up complex health care infrastructures such as modern hospitals[37,38].

Compared to Western European countries, the CCEE generally spend a much higher percentage of their total health care expenditures on medicines. In the UK and Germany this figure is about 11 per cent, whereas the average for CCEE approximates to 40 per cent (see Table 6). In real terms, however, per capita expenditures on medicines in the CCEE are much lower compared to Western European levels[39,40]. The fact that a rather large percentage of total health care expenditure is spent on pharmaceuticals can be explained by the relatively inelastic demand for pharmaceuticals.

Pharmaceutical policy reform needs to be as comprehensive in nature as health policy should be in general. The following sections briefly analyse to what extent the CCEE have begun a comprehensive reform of the pharmaceutical sector. I shall focus mainly on three major issues of reform: pricing and reimbursement policies, distribution and privatisation, and drug regulatory control systems.

PRICING AND REIMBURSEMENT POLICIES

In most CCEE today, governments increasingly resort to demand- and supply-oriented policies to limit pharmaceutical expenditures. An example of a supply-oriented policy is direct price control, whereas a demand-oriented policy could be the introduction of a patient part payment system in connection with the implementation of a limited list of reimbursable products (i.e. a formulary). There does not seem to be any systematic or dogmatic approach by the CCEE governments in selecting policies to curb the cost of pharmaceuticals. Many governments opt for limiting the demand for, as well as the supply of,

Table 6 **Pharmaceutical expenditures 1996**

Country	*Pharmaceuticals budget in million US$*	*Population in millions**	*Per capita expenditure on pharmaceuticals in US$*	*Percentage of pharmaceuticals/ total health care*
Croatia	432	4.4	90	NA
Czech Republic	1,040	10.2	101	39
Estonia	45	1.5	29	43
Hungary	1,058	10.1	104	38
Lithuania	47	3.7	13	25
Poland	2,357	38.8	61	60
UK	7,875	58.3	139	11.6

**Source:* WHO June 1997, Budapest

pharmaceuticals available under public reimbursement schemes[41,42,43,44]. For reasons of clarity we distinguish between supply- and demand-oriented policies.

Supply-oriented policies

Although under communism prices of most goods and services were strictly controlled by the Ministry of Finance, in most CCEE there is little experience with direct price control of pharmaceuticals. Imported products from Western countries constitute a particular problem as the importation of these products is a new phenomenon and the question is legitimate what benchmark price these products should have.

Direct price control of pharmaceuticals has been established in the Czech Republic, Croatia, Estonia, Lithuania and Poland; whereas Bulgaria and Hungary have a more liberal pricing environment (Table 7). Countries which have imposed direct price control generally use a cost-plus method to calculate prices. For domestic producers, this means that prices will be set at a cost of production level plus an additional mark-up for distribution. With the exception of Croatia, the price granted to foreign imported medicines is usually calculated according to the price level in the country of origin – often in Western Europe – if the manufacturer is able to produce reasonable original documentation. This is important as, in the past, some countries in the region have granted prices to wholesalers which were not based on original documentation.

In Western Europe, there is increasing evidence that price control systems of pharmaceuticals are generally difficult to operate, especially in view of price comparisons of medicines with a similar therapeutic activity. It is, therefore, remarkable to note that most CCEE have introduced policies of direct price control of pharmaceuticals. A plausible reason is that with the general liberalisation of pharmaceutical markets and the introduction of new, expensive medicines, governments feel the need to constrain the cost of pharmaceuticals. There is evidence that the introduction of too liberal policies has resulted in chaos in the market. In Bulgaria, for instance, during the period 1991-1992 there was neither drug price control nor a system of fixed prices for medicaments. This resulted in a situation of price instability, with the price of similar medicines varying widely from one pharmacy to another, because of different wholesale prices[42].

Other policies which affect the level of consumer prices of pharmaceuticals are the fixing of wholesale and retail margins and the imposition of a Value Added Tax (VAT). Countries of the region have introduced an array of wholesale, retail and VAT margins, which are presented in Table 7. The wholesale margin (as a percentage

Table 7 **Supply-oriented policies: pricing formulae and distribution margins**

Country	*Price control*	*Formulae domestic: cost of production + mark-up*	*Formulae foreign: manufacturer's home country price of origin*	*Wholesale (wh) / retail (ret) margin*	*Value Added Tax (VAT)*
Bulgaria	no	yes	yes	25% wh+ret	to be introduced
Croatia	yes	yes	no	wh: 10% ret: 30%	15%
Czech Republic	yes	no, Ministry of Finance sets maximum price	yes	wh: 0 to 12% ret: 26 to 38% wh+ret: 38%	5% (only for wholesale)
Estonia	yes	yes, wholesale and retail margins depend on type of product, i.e. proprietary or generic	yes, but difficult to implement due to competition	wh: 5 to 25% ret: 15 to 80%	18% (not imposed at present)
Hungary	no	no	yes	wh: 6 to 10% ret; 15 to 20%	no
Lithuania	yes	yes	yes, but the prices should be authorised by the Lithuanian Ministry of Health	wh: 15% ret: 40%	18% in general, but drugs are sold without VAT
Poland	yes	yes	yes	wh: 10% ret: 20 to 25%	0 to 7%

Source: OHE 1994, updated in 1997

mark-up ex factory) in the reported countries ranges from 5 to 25 per cent. The retail margin (as a percentage mark-up ex factory or ex-wholesale) varies between 15 and 80 per cent.

In view of the wish of many countries to become members of the EU, the VAT and distribution margin systems will in due course have to be harmonised with EU countries'. In some CCEE (Poland, Czech Republic, Hungary, Slovakia) this process has already started.

Demand-oriented policies

In most of the CCEE, the government is aware that a proper assessment of the pharmaceutical needs of the population should be the basis of pharmaceutical health policy, and that policies to curb demand are not very effective if demand is not known and utilisation patterns are not regularly monitored.

In Poland and Hungary[43] wholesaler-based information systems are being developed, while in the Czech Republic and Bulgaria occasional data have been collected concerning the demands for certain medicines such as antibiotics and tranquillisers.

In several CCEE, demand-oriented policies are being implemented in combination with strict drug selection criteria and reimbursement conditions. The Czech Republic is probably one of the first Central European countries which has introduced a comprehensive demand-oriented reimbursement policy[44]. The Czech model has the following components:

- a National Formulary has been composed. The formulary lists a number of domestic and foreign products. The products are grouped according to chemical structure and the reimbursement level depends on whether a product falls in one of the following four categories: essential drugs (fully reimbursed), complementary drugs (partly reimbursed), supporting drugs and others. Reports indicate – surprisingly – that price was not a major consideration in the compilation of the list, since the aim was to ensure a complete range of treatments. The list is revised twice a year;
- a price reference system has been introduced for medicines reimbursable under the public social insurance scheme. The cheapest product with a similar chemical structure has been chosen as the reference product. This is in most cases a Czech domestic product, if available. The price advantage of domestic producers in comparison to foreign imports has been estimated to be in the region of 15-20 per cent[10];
- if a reference-priced product is prescribed, the patient has the option either to receive a Czech product for free (if the product is regarded as essential) or to have a foreign import and pay the difference between reference reimbursement level and foreign price out-of-pocket.

In general, the effects of demand-oriented policies can be enhanced when governments link the overall reimbursement level of pharmaceuticals to the state of the economy. If an economy is expanding, governments may decide:

- to increase the number of reimbursed products;
- to increase the minimum reference reimbursement level per product group;
- to upgrade products from part reimbursement to full reimbursement.

If an economy deteriorates and government funds deplete, opposite measures could be taken. To illustrate this point, the Czech government is, in fact, planning to extend the list of non-reimbursable products and to increase the number of products for which a co-payment is due.

From a government policy perspective, the advantages of a comprehensive, demand-oriented reimbursement policy may be:

- a price reference system does not constitute an infringement of prescribing freedom as it gives physicians the option to prescribe cheap (i.e. no co-payment by the patient) or expensive products (for which a co-payment is due);
- a price reference system does not constitute an inhibition of the principle of free trade of goods: a pharmacist has the option to dispense expensive medicines if the patient is willing to make a co-payment;
- a comprehensive reimbursement policy leaves the government sufficient options for intervention on the basis of general performance indicators of the economy.

From the point of view of the policy maker, a disadvantage of a price reference system could be that it may sometimes be difficult to cluster products and compose lists of medicines with similar therapeutic effects. It is interesting to note that some CCEE (i.e. Poland, Lithuania) are contemplating price reference systems comparable in design, but differing in detail from the Czech price reference system.

Co-payments for pharmaceuticals by patients are an example of demand-driven policies. Most CCEE have introduced co-payment systems for pharmaceuticals (see Table 8). These systems are

Table 8 **Demand-oriented policies: patient part payment systems for pharmaceuticals**

Country	*Patient part payment system for pharmaceuticals*	*Main exemption*
Bulgaria	• Essential drug list for 114 products for chronic diseases (part payment: 25%, 50%, 75%, 100%). • Reimbursement for 2 special groups: 1. 100% for people with low income and people in social care establishments; 2. 50% for people with income less than 130% of the minimum income agreed.	Chronically ill, pensioners, children, young mothers, 'socially disadvantaged'
Croatia	Flat rate/script	Diabetics, pensioners, children
Czech Republic	Three categories: • fully covered: essential drugs, drugs for chronic diseases; • partly covered (various per cent, depending on the therapeutic value); • not covered.	Pensioners, children, 'socially disadvantaged'
Estonia	• List of reimbursed drugs for outpatients. • For people >70 years, children <4 years and disabled, all drugs are reimbursed, exceeding a co-payment of $0.38 per drug.	$0.38 flat charge per item per prescription with no exemptions
Hungary	100%, essential drugs. • 95%, complementary drugs. • 80%, supplementary drugs. • 0-50%, remainder, depending on therapeutic value.	Army personnel, accidents, low incomes, chronically ill (36 diseases)
Lithuania	• From 3-7 and >65 years co-payment: 20%. • Other groups pay 100%.	Mentally ill, diabetics, children <3 years
Poland	• Basic, flat rate, WHO essential drug list (30 per cent co-payment). • Hospital list (100% reimbursed).	Chronically ill, pensioners of railway system, police, army

Source: OHE survey 1994, updated in 1997

fairly uniform in terms of setting levels of co-payment related to the medical necessity of a medicine. Usually, some categories of people identified who are exempt from the co-payment, such as: the chronically ill, pensioners, children, army personnel, railway workers or police. However, to reach the government target of savings on public expenditures, there is a trend to limit the number of people exempt from co-payments. Although the evidence is only anecdotal, as a result of these policies certain patient groups in the CCEE (e.g. some of the elderly) may, de facto, be without proper access to pharmaceuticals.

PRIVATISATION OF THE DISTRIBUTION CHAIN

When markets were liberalised, private enterprises rapidly emerged in many CCEE in the sector of retail shops, restaurants and bars. In many countries of the region, state retail pharmacies have been privatised or private activities started. This often without the establishment of a specific regulatory framework, determining the general and specific modes of operation of private enterprise in the pharmaceutical sector.

Motivated by high price levels and corresponding margins at the pharmaceutical wholesale level, private operators started to import foreign medicines, even though local registration of such medicines had often not taken place. Governments have generally not been able to hold back these developments as private pharmacies and wholesalers are often perceived as among the first symbols or signs of the benefits of the developing market economy.

Following market developments, many governments of the CCEE countries have now adopted a strategy to privatise the pharmaceutical distribution chain. The role of the government is to facilitate this process, determining the general conditions of privatisation.

As Table 9 indicates, the privatisation process of the pharmaceutical distribution chain has been almost completed in some countries of the region, and in most countries private wholesaling has overtaken public. In fact, since the privatisation of the distribution chain started, a process of consolidation has set in. In Poland, for instance, there is already significant maturation of the wholesale chain, since it was liberalised in 1989 and the number of private wholesalers is down from about 2,000 in 1989 to about 300 now. This

reduction has mainly come about by a natural process of competition, mergers and market forces.

With the emergence of private distribution channels, it should be noted that there is a real danger that there will not be equal access to pharmaceuticals all over the territory of a country. Private wholesalers and retailers will have a propensity to operate in the cities and more affluent areas of a country, as they are primarily interested in realising a high margin on expensive medicines. With the often decrepit state distribution system in disarray, the provision of pharmaceuticals to rural areas may become critical.

REGISTRATION AND PHARMACEUTICAL CONTROL SYSTEMS

Most CCEE did inherit a system of drug registration from the previous era, and this system can be regarded as quite adequate in countries such as Hungary and former Czechoslovakia. These registration systems were designed to limit the availability of western medicines.

However, with the liberalisation of the CCEE economies, there were no longer fundamental reasons to block the influx of medicines from Western Europe. Many western medicines are now available in CCEE markets, usually at a similar price or even at a higher price than in the West and often without appropriate documentation. Concurrently, many eastern markets were faced with the availability on their markets of products from former communist countries, without appropriate documentation and often of a doubtful quality.

In view of these problems, many CCEE have opted for the following registration procedure[38]:

- products from Western Europe can usually be registered against appropriate documentation. This is usually constituted by a marketing license from a western country. In view of the high cost of western medicines, some governments of the CCEE have imposed reimbursement restrictions;
- products from former communist countries can register until a certain date. If a certain date has passed without a notification, these products are considered illegal.

CONCLUSIONS

Countries of Central and Eastern Europe are now more than seven years into the reform process of their societies. The health care sector has been a constituent part of this transformation. In the beginning the focus was on development of strategies and policies of health care reform. However, by now the implementation of such policies has become an urgent priority.

With few exceptions, the CCEE have opted to reform their health financing systems by the

Table 9 **Privatisation of the pharmaceutical distribution system**

Country	*Privatisation status*	*Wholesalers*	*Pharmacies*
Bulgaria	Privatisation without appropriate regulatory framework	Public: 30 Private: 350	Public: 900 Private: 1,000
Croatia	Wholesalers, pharmacies will be privatised, 15 are private already	Public: data not available Private: >40	Public: data not available Private: 15
Czech Republic	State owned pharmacies have been privatised step by step. Owners are private persons or hospitals	Private: 327	Public: 930 Private: 70
Estonia	Completed	Public: 1 Private: 36 3 production units are private	Public: 39 Private: 221
Hungary	Pharmacies will be 100 per cent privatised. Only fully licensed pharmacists can open a pharmacy	Public: 25 Private: 12	Public: 1,400 Private: 300
Lithuania	Partial privatisation of wholesalers and about 80 per cent of pharmacies. Owners of pharmacies must be local pharmacists. Restrictions of business profile	Public: 5 Private: 200	Public: 360 Private: 120
Poland	Privatisation without regulatory framework	Public: 16 Private: 300	Public: 800 Private: 5,000

Source: OHE survey 1994, updated in 1997

introduction of social health insurance. However, extra funds cannot be generated by this new way of financing health care. Ultimately, extra funds for health care provision can only be made available when the economies of the CCEE start to expand.

At present, in the CCEE, the only option for improved health services delivery is rationalisation of existing facilities. Rationalisation can be achieved by developing community based primary care services. Perhaps as much as 90 per cent of community-based health care problems can be resolved by a family practitioner without referral to more expensive secondary care. If a system of community-based primary care is developed and the family practitioner is made the gatekeeper of the health care system, a significant number of referrals to secondary care may be rendered unnecessary.

This, in turn, might lead to the closure of expensive hospital beds. The resources, which are thus saved, can be ploughed back into the development of basic health care services and preventive care. The number of referrals could be further reduced and even more savings could be reinvested in the system. To many Eastern European policy makers, it is sometimes difficult to explain that reform of a health care system does not necessarily mean that more resources are to be put in the system. In a system of constrained government budgets, such as is the case in most CCEE, improvements of health care delivery can only be realised when rationalising health care delivery by increasing efficiency.

Two additional points need to be made in relation to the implementation of social insurance systems by the CCEE:

- the fundamental separation of the functions of health care provision and health financing. This should be the first deliverable, when social health insurance schemes are initiated. The separation of the two functions will allow negotiations at a regional level, resulting in an optimal mix of cost effective and quality services. The potential danger, however, could be that in a country a certain inequity in terms of providing insurance coverage and services will be introduced, as long as there is no basic statutory health insurance 'package', defined for all citizens;

- irrespective of the choice of tax-based or social insurance as methods for health financing, there will be a continued role for the government to meet income redistribution and equity considerations.

In the present stage of the reform process of the health care systems of the CCEE, the provision of pharmaceutical care is very important, as pharmaceuticals represent relatively inexpensive health technologies, which are much easier to introduce and adopt than reform of hospital care or care demanding a great deal of training and attitudinal change. Examples of the last category would be the introduction of new types of care, such as community care, which were unknown to the communist system.

The expectation will be that once CCEE economies start to expand and the health care reform in these countries reaches an advanced stage, the proportional use of pharmaceuticals will decrease until levels of use may be reached comparable to those in Western Europe.

However, with the liberalisation of the pharmaceutical markets in many CCEE, a real danger has emerged: if the liberalisation process is not buttressed by a system of just regulation and control of the pharmaceutical market, ultimately the availability of pharmaceuticals in a society may not be guaranteed. There is more than anecdotal evidence that in many CCEE, in the absence of a regulated social safety network, weak societal groups such as the elderly are paying the price of liberalisation, which de facto leaves them without appropriate access to pharmaceuticals. Referring to the importance of maintaining adequate standards of public health, governments of CCEE have the fundamental right to control the pharmaceutical market place.

In their attempt to reform the pharmaceutical markets of their countries, CCEE are advised to take a comprehensive approach. Many countries have tried to limit the impact of pharmaceutical expenditures on the public budget. However, liberalising the pharmaceutical distribution channel and limiting the range of pharmaceuticals to be reimbursed through the state system potentially introduces a great amount of inequity in the system. This inequity is reinforced when, at a national level, an appropriate regulatory mechanism is not in place, which would allow the government to step in when necessary for the sake of maintaining and protecting appropriate standards of public health.

The Visegrad countries, which seek membership of the European Union by the turn of the century, have already launched an impressive campaign, to overhaul the pharmaceutical regulation of their territories and bring them into line with EU standards of medicines regulation and control.

Finally, it is not in the interest of the multinational pharmaceutical industry to operate in a poorly regulated environment, as this can give rise to demands for unreasonable discounts

and bribes by domestic producers and traders who are able to escape the eyes of effective regulatory scrutiny.

It is, therefore, in the interest of the multinational pharmaceutical industry to continue to support the process of comprehensive reform of the pharmaceutical markets of the CCEE. Only then will a situation occur which can be mutually beneficial for governments and patients in the CCEE, as well as the industry itself.

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