The Role of the World Health Organization on Pharmaceuticals in Europe

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ABSTRACT

The World Health Organization (WHO) is the specialized agency of the UN on public health. It gives worldwide guidance in the field of health, sets global standards for health, cooperates with governments to strengthen national health care programs, and develops and transfers appropriate health technology, information, and standards. Within the WHO European region, health status and health expenditures vary greatly. In this paper, disparities between health status, health services, and health care expenditures between countries of the WHO European region are presented. The objectives, performance, and dilemmas facing health care systems are discussed, including the recent performance ranking published by the WHO. The paper focuses particularly on access to medicines, their appropriate use, and rising drug expenditures. Strategies used by European countries to improve drug use and contain health care expenditures are outlined. Finally, the future of pharmaceuticals and public health is explored.

Keywords: drug expenditures, pharmaceuticals, pharmacoeconomics, reimbursement, World Health Organization.

Introduction

Founded in 1948, the World Health Organization (WHO) is a United Nations (UN) specialized agency that promotes technical cooperation in health care among nations, carries out programs to eradicate and eliminate disease, and strives to improve health-related quality of life. Its objective is the achievement by all people of the highest possible level of health. In support of its objective, the organization has four main functions: providing worldwide guidance in the field of health care, setting global health standards, cooperating with governments to strengthen national health care programs, and developing and transferring appropriate health care technology, information, and standards. The European region of the WHO stretches from Iceland to the Bering Strait and from Norway to Israel, comprising 51 member states, including the whole former Soviet Union. There are large variations across this region in health status and health care systems. This paper reports the WHO perspective on the goals, performance, and dilemmas of health care systems in the European region and explores future directions in pharmaceutical policy and cost containment strategies.

Health Status and Health Expenditures

Indicators of health such as life expectancy and infant mortality reflect wide variations in health status across the countries of the WHO European Region [1]. Although life expectancy has been increasing steadily in Western European countries since the 1970s, a drastic decline was observed in the countries of the former Soviet Union from the early 1990s due to the collapse of the health care system and social disruption. Now life expectancy and health status in these newly independent states is slowly improving. Similarly, infant mortality rates in the Central Asian Republics are still well higher than in Eastern European countries.

The economics of European health care systems also reflects wide disparity. The percentage of gross domestic product (GDP) spent on health care in European countries varies between more than 10% to
less than 3% (Fig. 1). While several Western European countries use about 10% of their GDP on health care, this figure is lower than 4% in most countries of the former Soviet Union. Great variations are also observed in drug expenditures (Table 1). Most Western European countries spend between US$200 and US$350 per capita on medicines while most countries of the former Soviet Union spend far less than US$100 per capita on medications. At the bottom of the scale, some Eastern European countries and certain Central Asian Republics have per capita drug expenditures of less than US$10.

There are also great disparities in the percentage of health care expenditures spent on medicines among countries worldwide (Fig. 2). Poorer countries spend a greater percentage of health care expenditures on medicines (up to 66% in some developing countries) in marked contrast with figures observed in affluent, developed countries (7–20%). In many poor Eastern European countries, coverage by social insurance or by a tax-based system is still limited, and a substantial part of the drug expenditure is in the form of out-of-pocket payment. In a number of poor countries, drug expenditures are the second largest household expenditure; this reflects the tremendous importance of the role of medicines in health care.

A growing concern from the perspective of policymakers is the rise in drug expenditures. In 1980, most Organization for Economic Cooperation and Development (OECD) countries were spending between 0.5 and 1% of their GDP on medicine; in 1996 several were spending more than 1.5% of their GDP on drugs and in some countries more than 2% (Fig. 3). Drug expenditures continue to rise, and in 1999 drug expenditure increases ranged from 5% to 15% for a number of OECD countries [3]. The biggest increase was observed in the United States, at 18% (Fig. 4). Relationships between increased drug spending, shifts in health care costs, and improved health are often difficult to analyze.

### Health Care Systems: Goals, Performance, and Dilemmas

#### Health Care System Goals

Two years ago, the ministers of health of the European region adopted the Health 21 Policy Framework, outlining health policy for European countries for the 21st century. Their goal was to achieve good health for the entire population, at the same time reducing disease incidence.

There are four core values serving as a base for health care systems:

- **Human rights:** Every citizen in European member states has a right to health;
- **Equity:** Individuals in European countries should have equal access to health and health care services;
- **Solidarity:** There is a responsibility of society as a whole for everyone to contribute to maintaining, protecting, and achieving health; and
- **Participation and accountability:** Health is not solely the responsibility of physicians or governments, but of a variety of sectors. Health status is also a reflection of social policy, education and environment.

Member states recognize the need to be much more outcome oriented and know what type of investments contribute the most to health. There is also an increasing need to examine integrated care, evaluating systems as a whole rather than as segments. Finally, there is a need for participation from everyone in society including government, industry, patients, and health care providers.
Role of the WHO on Pharmaceuticals in Europe

Performance

In its 2000 Annual Report, the WHO examined performance of health care systems. Three areas were identified and for each a set of performance indicators was defined:

- Health: health status of people, including life expectancy and infant mortality.
- Responsiveness: how responsive the health care system is to the needs of society and to the needs of patients, including quality of services.
- Fairness in financing: the issues of equity and solidarity. Health is a human right and the whole population should have equitable access to good health care.

A methodology was developed over a period of a year and a half to examine the performance of health care systems and relate the achievement of these indicators to investment in the health care sector (the efficiency factor). A ranking of countries based on the performance of their health care sys-

<table>
<thead>
<tr>
<th>Expenditure per capita (USD)</th>
<th>Western Europe</th>
<th>Eastern Europe</th>
<th>Newly independent states</th>
<th>Total regional population (millions)</th>
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<tbody>
<tr>
<td>&gt;$300</td>
<td>Austria, Belgium, France, Germany, Iceland, Switzerland</td>
<td>Czech Republic, Hungary, Slovenia</td>
<td></td>
<td>164</td>
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<tr>
<td>$200–$300</td>
<td>Denmark, Finland, Italy, Luxembourg, Netherlands, Norway, Portugal, Sweden, Great Britain</td>
<td>Croatia, Estonia, Latvia, Lithuania, Macedonia, Poland, Slovakia</td>
<td>Russia</td>
<td>163</td>
</tr>
<tr>
<td>$100–$200</td>
<td>Greece, Ireland, Spain</td>
<td>$100–$200</td>
<td>Poland, Slovakia</td>
<td>76</td>
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<tr>
<td>$20–$100</td>
<td>Croatia, Estonia, Latvia, Lithuania, Macedonia, Poland, Slovakia</td>
<td>Romania</td>
<td>Russia</td>
<td>206</td>
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<td>$10–$20</td>
<td>Croatia, Estonia, Latvia, Lithuania, Macedonia, Poland, Slovakia</td>
<td>Romania</td>
<td>Armenia, Bulgaria, Georgia, Kazakhstan, Ukraine</td>
<td>109</td>
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<tr>
<td>&lt;$10</td>
<td>Croatia, Estonia, Latvia, Lithuania, Macedonia, Poland, Slovakia</td>
<td>Romania</td>
<td>Armenia, Bulgaria, Georgia, Kazakhstan, Ukraine</td>
<td>54</td>
</tr>
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Figure 2 Pharmaceutical spending as a percentage of total health spending.
tem was produced and published in the 2000 WHO Annual Report [2]. Almost all Western European countries ranked among the 25 top countries in the world, but variations were identified. France was considered to have the best performing health care system (Fig. 5). This report has triggered a lot of debate; its objective was not to provide answers, but rather to initiate a discussion on how countries could better measure the results achieved in their health sector and be more creative in evaluating the performance of their health care system and in setting goals and standards. In recent discussions it was agreed that WHO, together with all member states, will continue to work toward improvement in this complex field.

Key policy transitions were one important issue in assessing performance of health care systems. As countries strive to create more outcome-oriented, better performing and more efficient health care systems, the role of government is to provide strategic stewardship (in the form of guidance and leadership) to the health care sector. Many health systems tend to pool their resources in order to increase effectiveness and increase their negotiating power. In many systems there is a split between providers and purchasers of services, and increasingly health care systems are focusing explicitly on quality development and cost-effectiveness considerations.

**Access to Medicines**

In the realm of pharmaceutical policy, four sets of goals have been set forward by the WHO [4].

- Equitable access to needed drugs of proven quality and safety for the whole population;
- Improvement of drug use, which is closely related to outcomes;
- Ensuring value for money, making sure that in a context of constrained resources optimal value is obtained for the money spent; and
- Ensuring that national drug policies build public and professional confidence.

In the eastern part of the European region, development of pharmaceutical policies is focusing on access to essential drugs [5]; between 20% and 50% of the population in several newly independent states still does not have access to essential drugs. Four components are considered for developing access to medicines:

- Rational selection of appropriate and needed drugs;
- Affordable prices for those drugs;
- Sustainable financing, either by taxes, co-payments, or a combination of these; and
- A reliable drugs supply system, not yet available in many countries.
Role of the WHO on Pharmaceuticals in Europe

Rising Drug Expenditures

Currently, every country is facing the dilemma of rising drug expenditures and limited drug budgets. Health care systems are subjected to the growing demands of consumers and patients, pressures from doctors and pharmacists, and pressure from the pharmaceutical industry. At the same time, irrational and unnecessary drug prescribing practices are still taking place throughout European countries. Uncertainties regarding usefulness of medicines and treatment outcomes are common. Tremendous variations in clinical practice between European countries are observed which are not clearly linked to differences in health status. Underuse of new, effective treatments is of concern, while ineffective treatments continue to be used in many countries.

Numerous factors are causing a rise in drug expenditure. A variety of studies performed in different countries over the past few years point to higher volumes of drugs and higher prices, also resulting from an increased disease burden due to an aging population [6]. Concretely, this means that there is a shift to newer and often more expensive medicines in the same therapeutic class, although the extent of added benefit is not always well established; many conditions that were not managed many years ago are now being treated prophylactically; new lifestyle drugs are entering the market; new drugs are becoming available for diseases that were previously untreatable (e.g., multiple sclerosis); new diseases (e.g., AIDS) are provoking research and development of new drug treatments, and finally, the shift to ambulatory care from hospital care observed in many countries is having serious implications for drug expenditure.

Improving Drug Use and Containing Cost

Strategies employed by European countries to achieve the goals of accessibility, rational drug use, and added value for money include educational and information initiatives, managerial, administrative, and financial measures. Among educational initiatives are development of university programs, practice guidelines, prescriber information, continuing education programs, drug committees, feedback on prescription data, patient information packages implemented through Ministries of Health, health insurance institutions, professional associations, etc. Managerial and administrative measures to improve drug use and contain costs include positive and negative lists, reference pricing systems and reimbursement schemes, disease management strategies, practice guidelines and restrictions on distribution and prescription to certain parts of the health care system or certain providers. Managerial measures also include regulation of marketing and commercial information. With respect to financial measures, several countries are using fixed or directive budgets for prescribing specifically to regions or hospitals. A variety of measures have been put in place, such as price regulation, price/volume agreements, copayment schemes, financial incentives to pharmacists to improve pharmacy services, differential reimbursement rates, and promotion of generic drugs. It is a rapidly changing panorama with a number of measures switching in rapid sequence from one to another.

The effect of increased drug costs on overall health expenditures is hotly debated around the world. Price control is a very controversial subject with differing implications across Europe. Most high-income countries of Western Europe have price control systems that have been shown to contain the individual prices of drugs. However, their effect on total drug expenditure remains unclear. A number of factors are involved; low drug prices, high consumption, and high overall expenditures are observed in France, while high prices, low consumption, and relatively low expenditures dominate in Denmark. High prices, high consumption, and high expenditures are reported in Germany. For the eastern part of the European region, price control has a different function. Because many patients have to pay out of their own pocket, keeping individual drug prices down is essential to permit access to essential drugs, so prices should be based on health need and ability to pay.

On a global level, discussion regarding drug costs focuses on generic drugs, and in recent years has focused very much on access to HIV/AIDS drugs for low-income countries. Although increase in the share of generic drugs in European markets is relatively low with the exception of a few countries, major savings can be found when generic drugs are available. The other key issue is the availability of drugs needed for HIV/AIDS and treatment of tropical diseases in the poorest countries that lack the resources to pay global prices. These issues have to be tackled from a worldwide perspective, seeking partnerships with manufacturers, but also in the trade-offs in the drug market as a whole. Again, in this area, access to these drugs should be driven more by health needs than by the ability of individual patients or health care systems to pay.

Challenges Ahead

Key Issues for the Future

The WHO has identified a number of strategic targets for future development. There is a continuous
entry of new products onto the market and a general failure to link drug development to health and health system needs. Although the pharmaceutical industry operates from a global perspective, health care systems operate from a national point of view, and this may create tension among varying perspectives and interests. Diseases such as tuberculosis, malaria, acute respiratory infections, and others continue to kill 10 million people each year. Over the last 30 years very few new, effective drugs for tropical diseases have come onto the market, while at the same time a number of lifestyle drugs have entered it. How can we make real innovation focused on worldwide health needs possible under the prevailing conditions? Criticism of “me too” drugs entering the market must be balanced by the potential benefits of therapeutic class competition, an area that requires further analysis. From the national health policy and industry perspective it is desirable to have a strong, innovative pharmaceutical industry as well as a strong, efficient generic industry. However this discord in objectives among the various sectors gives rise to considerable policy discussion.

With respect to the therapeutic value of new drugs, it is well established that when a drug enters the market, uncertainty regarding its effectiveness persists; its place and its value in the real world will be uncovered by medical practice. Several recent studies were performed in different countries to assess therapeutic value at market authorization. In Germany, of 35 new chemical entities, 12 were considered novel substances, nine were seen as an improvement, and 14 were “me too” products [7]. In the Netherlands, of the 18 new drugs that came to market in 1999, only one was classified as a possible important innovation; the other 17 were considered no better than what already existed [8]. In the United States, of 40 new medicines entering the market in 1999, 19 were classified as important contributions, many of those in very small therapeutic areas or targeted to small segments of the patient population [6]. In Spain, of 42 new substances entering the market in 1999, none was considered to be a major therapeutic breakthrough and only three were considered important improvements. All of those related to the treatment of HIV/AIDS; those remaining were considered no better than or only a minor improvement over existing drugs [6]. Clearly, a better definition of innovation and added therapeutic value is needed, and the various interpretations and judgments of what constitutes a real innovation need be worked out. This is an area that policymakers and health industries will have to examine more closely.

With regard to appropriate use of medicine, more is to be gained from using medicines better rather than examining specific intrinsic characteristics of individual products. Although it has been known for decades that significant unnecessary and inappropriate prescribing takes place, that drugs are used for the wrong indications, the wrong dosage, and the wrong duration, irrational drug use still occurs. There is tremendous potential for improvement. Reducing inappropriate and unnecessary prescribing would free up money and resources that could be used for needed innovation and for more effective treatment. Governments have a role to play in this area just as they have a role to play in promoting generic drug use.

The Future

In view of all the complex issues and the variety of stakeholders and drivers in the pharmaceutical sector and in health care as a whole, it is difficult to foresee in which precise direction the pharmaceutical panorama will further develop. It will greatly depend on the political choices that society as a whole will make, and how much money it will choose to make available for health. Science and information technology will continue to have hitherto unknown potential. To help think the process through, in 1996 in the Netherlands a scenario analysis was performed to examine how society would develop and how health and health care would be envisioned. Four scenarios were outlined:

- Modesty in wealth: currently experienced in wealthy nations. Public and private expenditure are balanced and rational and cost-effective choices have to be made to optimize the use of health resources.
- Risk avoidance: people do not wish to take risks and they seem to have an aversion to constantly being driven by technology and all types of new products on the market. This scenario includes rejecting new technology and going back to nature.
- Driven by technology: whatever technology developed by the industry is the driving force in society.
- Free market in action: people assume that a free market solves all problems; bad technology is rejected by the market and good technology finds its way through the health care system.
Demographic and political forces in society will determine future developments. The role of the WHO Regional Office for Europe is to focus on three aspects of pharmaceuticals, including distribution of information, networking of countries, and continued collaboration with individual member states to improve their drug sector. This last area particularly applies to the Eastern European countries where WHO/EURO already has a sizable number of programs assisting member states, ministries of health, and health insurance to develop and implement viable pharmaceutical policies. In the western part of the European region, WHO/EURO has an international role and serves as a platform for discussion, exchange, and dissemination of information regarding development of pharmaceutical policies, particularly those concerning pricing and reimbursement systems of drugs and those concerning rational drug use. Better information on drugs is needed, and we need to foster the ability to assess various countries’ pharmaceutical systems to apply lessons learned from past successes and failures in pharmaceutical policymaking. The WHO has taken this challenging direction over the past year, promoting international collaboration and information exchange among countries and providing direct support to countries in improving their pharmaceutical sector.

Question and Answer Period

Josephine Mauskopf, RTI Health Solutions, Research Triangle Park, NC

Do you have any specific ideas about how one might encourage a pharmaceutical company to develop a drug for tuberculosis or malaria?

de Joncheere

For the last one and a half years, under the leadership of Dr Brundtland, our new director in Geneva and former Prime Minister of Norway, discussion has been taking place on this subject. Currently, there is a bi-annual round table discussion involving the WHO, the pharmaceutical industry, European member states, and nongovernmental organizations and consumer groups, to examine these issues. There is also increased interest from the European Parliament and the European Union. It is obviously a complex issue. Until now, the industry was not interested in developing new drugs for malaria. They were concerned that even if drugs were available, there would be no one to pay for them. It was concluded that we need enticements, a sort of global trade-off for pharmaceutical prices, or agreements could be reached between the industry and governing bodies that include commitment to research these underserved therapeutic areas. In addition, international funds are being set up, such as those at the World Bank and the Bill Gates Foundation, to provide funding and guarantees that medicines developed by a pharmaceutical company will be bought.

Stephen Chapman, Keele University, Keele, Staffordshire, UK

The main problem with the free market taking care of the needs of populations is that it is very difficult to determine need in some developing countries and the former Soviet Union countries, principally due to the lack of good public health data and the very small markets. As a state fragment with a population of five million, the market in Georgia becomes less competitive and less attractive to international pharmaceutical companies.

Unidentified Speaker #1

Does the WHO have any plans for collaborative work with pharmaceutical companies to deal with markets that are not commercially attractive?

de Joncheere

Scenario analysis is a science in itself, we must consider the different options that society may follow and map the possible routes. Based on available evidence, the free market scenario is clearly not the best approach, particularly in transitional countries, to achieve equitable access to essential drugs. In many of the more affluent countries, there is friction concerning the development of health care systems and industrial interests. The health care system of every country is a combination of those forces in society. WHO has ongoing discussions with the industry, because we believe that it should not be part of the problem but rather part of the solution. Clearly, trying to understand all the different points of view, of consumers, industry, and national government, is necessary for a better understanding of the conflicts and their solution.

François Schubert, Glaxo Wellcome R & D, Greenford, Middlesex, UK

Based on the experience we have from the International Conference on Harmonization (ICH), please comment on international harmonization from a
regulatory point of view. Do you foresee from the members internationally or in Europe the same movement for pharmacoeconomics requirements, or not?

de Joncheere

WHO is an observer to the ICH process, and we are close observers because of the implications it has worldwide. From an official point of view, I do not know whether or when there will be something happening in the area of pharmacoeconomics. From the scientific point of view, as the science of pharmacoeconomics is evolving, there will be core issues identified. Countries that will get increasingly involved in those issues will start using those core approaches. Through scientific developments and exchange of information, some convergence should take place among the different countries that are examining pharmacoeconomic data. From the point of view of policy decisions, it is necessary to have the data available regarding pharmacoeconomic evaluations. From an overall public health perspective and regarding affordability issues, available data to be used may be different from one country to another. In that respect, scientific development should take us further.

John Parkinson, University of Dundee, Dundee, Scotland

You mentioned closing the gap between efficacy, effectiveness, and outcomes and directive 75–318 says “normal conditions of use.” Could you comment on the fact that phase three trials are clearly necessary but many are not performed under normal conditions of use?

de Joncheere

A major issue here is the real gap between approved indications and what is happening when a drug reaches the market in terms of clinical practice and real-world outcomes. There is a tremendous scientific challenge there that needs to be tackled, which should be facilitated and accelerated by the information technology available nowadays. It should also be possible to ensure that information actually produced is being used in decision making rather than considered interesting but not applied.

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References

7 Scrip 2001; Various issues.