WORLD HEALTH ORGANIZATION
Regional Office for the Eastern Mediterranean
ORGANISATION MONDIALE DE LA SANTE
Bureau régional de la Méditerranée orientale

منظمة الصحة العالمية
المكتب الإقليمي لشرق المتوسط

Regional Committee for the Eastern Mediterranean

EM/RC54/Tech.Disc.1
August 2007

Fifty-fourth Session

Original: Arabic

Agenda item 5 (a)

Technical discussion on

Medicine prices and access to medicines in the Eastern Mediterranean Region

Unaffordable medicine prices are a major barrier to access to medicines, especially for the poor and sick. WHO has formulated a four-part framework to guide action on access to essential medicines comprising: rational selection and use of medicines, affordable prices, sustainable financing and reliable medicine supply systems. This paper focuses on affordable medicine prices and draws upon findings of the 10 national medicine price surveys conducted in the Region to inform policy considerations. The Regional Committee is invited to discuss the implications of the survey findings and consider the case for action.

Contents

Executive summary

Ensured access to medicines is part of the fulfilment of the right to health. Medicine prices are a major barrier to access to medicines, especially for the poor and sick. WHO has formulated a four-part framework to guide action on access to essential medicines comprising: rational selection and use of medicines, affordable prices, sustainable financing and reliable medicine supply systems. This paper focuses on affordable medicine prices and draws upon findings of the 10 national medicine price surveys conducted in the Region, 9 of which were conducted by ministries of health using WHO/Health Action International standard survey methodology to collect prices of a pre-selected list of essential medicines. The surveys highlighted five areas for consideration: availability of medicines; public procurement prices; private sector retail prices; affordability; and price components.

Across the 10 surveys the availability of generic medicines was more frequent in the public sector than in the private sector, however there were varying degrees of availability of medicines in the public sector facilities. All the surveyed countries except three were found to be procuring at least some medicines in both generic and branded forms. In the case of generic medicines, acceptable procurement prices were observed in three countries. There was substantial variation in the prices at which countries were able to procure the same medicine. Private sector retail prices were found to be excessive generally for both generic and branded medicines. Most of the treatment courses for common acute and chronic diseases were found to be unaffordable. Some countries were still taxing medicines in different forms and mark-ups at wholesale and retail sale levels were also found to be excessive in some countries. The findings of these surveys confirm some general observations about the medicines prices, highlight some specific problems and make the case for action.

The issues of low access to essential medicines and unaffordable medicine prices cannot be effectively tackled without employing a broad health system approach. Although the medicine price surveys were not directly aimed at wider health system issues, the findings reveal the importance of broader issues related to health systems, social protection and development policies. Good governance is a critical precondition for the effective working of health systems and is key to achieving equitable health care deliverables. In the case of the pharmaceutical sector, as part of the health system, this means ensuring appropriate processes for the development, implementation and monitoring of national medicines policies, with clear objectives for ensuring: equitable access to essential medicines; appropriate institutional development; transparency and accountability in medicine procurement and pricing decisions; appropriate structure and effective functioning of national regulatory authorities; and participatory processes in monitoring and reporting problems relating to unaffordability of medicines. Adequate and equitable financing, trained human resources, service delivery and a reliable and efficient information system are also areas of concern.

Although availability of essential medicines is one of the most important objectives of national medicines policies, the unavailability of essential medicines remains a major problem. Other problems highlighted by the surveys were public sector procurement of relatively expensive brand name medicines when the generic counterparts are available at lower prices, and the buying of generic medicines at relatively high prices. Generally both branded as well as generic medicines were found to be excessively priced.

Member States are recommended to: ensure good governance in the health and pharmaceutical sector; develop an effective pharmaceutical sector as part of strengthened health system; strengthen the national regulatory authority; improve availability and the obtaining of better prices in public sector procurement of medicines; limit public sector procurement to generics; reduce medicine prices in the private sector; and rationalize tax regimes and mark-up on medicines.

1. Introduction

The quality of a public health care system, particularly in the public sector, is judged by the patients primarily on the basis of two factors: presence of appropriate medical staff and availability of needed medicines. When medicines are not available in the health care facilities, people go to private pharmacies and buy directly "out-of-pocket". WHO estimates that one-third of the population of the world does not have reliable access to medicines. In developing countries this proportion goes up to 50% [1]. Apart from this precarious access situation there are ongoing concerns about the quality of medicines, high rates of irrational prescription and incorrect use of medicines.

Access to medicines nevertheless continues to be the biggest challenge. It is a challenge that has been effectively put on the global political agenda by active civil society organizations in recent years in the context of (lack of) access to antiretroviral medicines for the care of HIV/AIDS patients. These medicines are protected by patents, resulting in very high and unaffordable prices. Goal 6 of the Millennium Development Goals also covers the agenda of improving access to medicines in developing countries [2].

Total health expenditure on medicines constitutes the second largest category of recurrent health expenditure, and some households spend a high proportion of the household health budget on buying medicines [3]. Expenditure on medicines is one of the various components of health expenditure that can result in households incurring catastrophic financial burden and further worsen the situation of the poor.[1] Understandably, this brings into focus widespread concerns about value-for-money with regard to medicines.

Little reliable information was available on what people and ministries of health actually pay for medicines until recently, when WHO and Health Action International (HAI), an international policy advocacy nongovernmental organization, joined together to work out a standard methodology for "a new approach to measuring medicine prices" and pilot tested it in nine countries. Since 2002, more than 45 national surveys on medicine prices have been conducted, including 10 in the Eastern Mediterranean Region. The objective of this paper is to discuss the findings of the surveys on medicine prices conducted in the Region, in order to highlight the major findings and the policy implications for Member States.

2. Determinants of access to medicines

Ensured access to essential medicines is considered as part of the fulfillment of the right to health.[2] It remains a major objective of countries' national medicines policies. Access to medicines, however, is a complex subject and is perceived, defined and measured in different ways. Geographical access and financial access to medicines are the most important from a health service point of view.

WHO's working definition of access to medicines is: percentage of population who have access to a minimum list of 20 essential medicines, which are continuously available and affordable at a health facility or medicines outlet, within one hour's walk from the patient's home [2]. The Millennium Development Goals indicator for assessing access to medicines is also based on this conceptualization.

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[1] When people have to pay fees or co-payments for health care, the amount can be so high in relation to income that it results in "financial catastrophe" for the individual or the household. Such expenditure can mean that people have to cut down on necessities. WHO has proposed that health expenditure be viewed as "catastrophic" whenever it is greater than or equal to 40% of a household's non-subsistence income, i.e. income available after basic needs have been met [4].

[2] Recent work by the Committee on Economic, Social and Cultural Rights which monitors the implementation of the International Covenant on Economic, Social and Cultural Rights, which is binding to its over 150 States Parties, in its General Comment No.14 of May 2000 stated that the medical service in Article 12.2.(d) of the ICESCR includes the provision of essential drugs "as defined by the WHO Action Programme on Essential Drugs" [5].

This definition of accessibility assumes that the available medicines are effective and of consistently good quality, that there is no financial obstacle to a patient receiving it, and that required knowledge and guidance are available for proper use of these medicines.

The data from 9 national health accounts studies in the Region[3] show that medicines account for a high proportion of health expenditure; for example the mean percentage of total health expenditure on medicines in middle-income countries (Egypt, Jordan and Morocco) is around 35%. These studies also show high out-of-pocket expenditure on medicines; for example in Egypt and Morocco 54% and 75% of all medicines, respectively, are purchased directly by households.

Improving access to essential medicines is even more complex. At operational level, efforts to improve access to essential medicines need to be comprehensive, sustained and context-specific. Development of a comprehensive approach to improve access to medicines needs to take into account all the important determining factors. WHO has formulated a four-part framework to guide and coordinate collective action on access to essential medicines (Figure 1) [6]. All the four parts play an important role in efforts to improve access to medicines; they are interconnected and inseparable. Any isolated effort to improve one part may be effective for that part but it would not improve the overall situation.

Rational selection and use of medicines: limited resources should be spent on buying only most essential medicines,[4] selected on the basis of their suitability to treat prevalent diseases. The WHO essential medicines concept underpins this approach, requiring development of standard treatment guidelines for common diseases and national lists of essential medicines and their institutionalization. It is crucial to make a rational selection of medicines out of the thousands available in the market, in order to get the most effective and safest at the best prices. The WHO model list of essential medicines and national essential medicines lists serve this purpose. Another major problem is the wrong use of medicines. WHO estimates that more than half of medicines are prescribed irrationally and more than half of these are used incorrectly in the hands of patients [7].

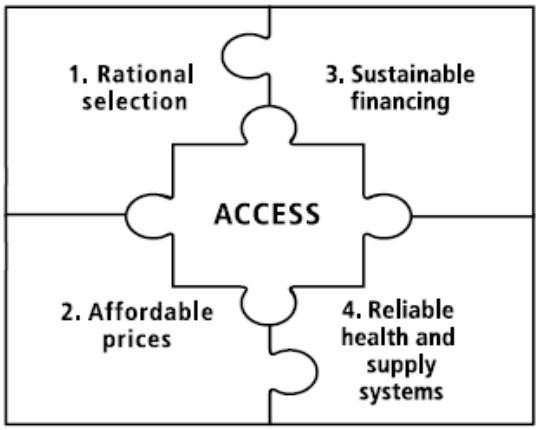

Figure 1. Improving access to essential medicines: a framework for collective action in line with Millennium Development Goals, Target 17

[3] Countries in the Region that have completed at least one round of national health accounts studies: Djibouti, Egypt, Islamic Republic of Iran, Jordan, Lebanon, Morocco, Oman, Tunisia and Yemen.

[4] "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility." [7]

Affordable prices: Pricing of medicines is the most important component of the access framework and is, at the same time, a very complicated area. Poor people and governments often cannot buy the medicines they need because they cannot afford them. From this perspective, medicine prices are a public health issue and cannot be left to the commercial considerations of manufacturers and suppliers alone. This is why, directly or indirectly, governments in most countries regulate the prices of medicines. The issue is further complicated by the fact that "high" and "low" are relative terms and whether prices are considered high or low depends upon the purchasing power parity of the buyer.

Sustainable financing: Government spending on medicines has to be seen in the context of its spending on health, the socioeconomic status of the country, its priorities and its commitment to improve the social conditions of its people. Although public spending on medicines constitutes the second largest category of recurrent health expenditure in real terms, spending on medicines in low income countries is far lower per capita than in high-income countries.

Reliable health and supply systems: An inadequate, disjointed and opaque procurement and supply system can hugely undermine other efforts in improving access to medicines. A variety of models exist for health supply systems, depending upon a multitude of local factors: central medical stores; (semi) autonomous supply organization; direct delivery system; prime distributor system; fully privatized supply system, and various combinations of these. In developing countries various channels have now been established to deliver medicines and some vertical disease programmes such as tuberculosis and HIV/AIDS have created their own systems, which sometimes results in unnecessary duplication.

3. Global situation and response

The concerns about the high prices of medicines are global, and so are the efforts to bring prices down. Both in developed and developing countries governments continue to make efforts on behalf of affordable treatment, according to their own contexts. Direct or indirect regulation of medicine prices is, hence, almost the rule.

In recent years the difficulties relating to access to new patent-protected medicines because of their very high prices have caught public attention. For example, second-line antiretroviral medicines for treatment of HIV/AIDS or medicines for the treatment of multidrug-resistant tuberculosis in low-income countries in Africa and new intellectual property rights protection regimes in the wake of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have become important public health issues and the subject of intense discussion and debate. Existing models of intellectual property rights are being challenged, both for their impact on prices and the fact that they do not provide sufficient incentive for research and development in essential medicines for diseases which disproportionately affect developing countries and where returns on investment are either very small or uncertain [8].

In most developed countries generic medicine policies are effectively implemented. Health insurance companies and health management organizations very meticulously restrict reimbursement only to a pre-selected list of medicines, the overwhelming majority of which are generic. As a result of these policies, in 2005 63% of all the medicines dispensed in the United States of America, the largest pharmaceutical market in the world, were generic medicines. Yet the value of these generics was only US$ 22.3 billion whereas the total pharmaceutical market in the United States in the same year was US$ 252 billion. In other words, 63% of the total volume of all the medicines in the United States accounted for only about 9% of the total value of the pharmaceutical market, whereas 91% of the total value of the pharmaceutical market was for 37% of the volume (i.e. branded medicines) [9].

With the exception of Japan, almost all high-income countries now heavily promote and enforce purchase of generic medicines, resulting in phenomenal savings. Among OECD and European countries, major initiatives exist not only to further contain expenditure on medicines but also to share and harmonize medicine price information. The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is one such initiative, funded by the European Commission and co-funded by the Ministry of Health, Family and Youth, Austria, the aim of which is to establish a network to provide knowledge and information on pharmaceutical systems in the European Union with country

profiles and comparative analysis of pharmaceutical pricing and reimbursement [10]. Currently this initiative has 30 countries as participants. The comparative data on generic prices in the European Union has shown that these countries sometimes procure medicines at even lower prices than the reference prices published by Management Sciences for Health, which are considered the best international prices for developing countries. This is the case, for example, with the prices paid for generics by the United Kingdom National Health System.

Australia adopted, in 1993, a rigorous cost-effectiveness analysis system of new branded products in their Pharmaceutical Benefits Scheme. The main measure derived from the pharmaco-economic analysis is the dollar cost of achieving the desired improvement in health outcomes with the new medicine, compared with the best available existing treatment. Manufacturers are required to submit this analysis if they want to get their new medicine included in the scheme. As a result of this policy, the prices of branded medicines in Australia have become among the lowest in the world [11].

WHO has a history of working on issues of access to affordable health care including medicines [12]. The Constitution of the Organization and a number of World Health Assembly resolutions provide a strong mandate to WHO to provide guidance to its Member States on access-related issues. Ensuring access to essential medicines is one of the objectives of the national medicine policies. A number of publications have been produced by WHO headquarters as well as by the regional offices in this area. Between 2000 and 2003, a standard methodology was developed by WHO and Health Action International (HAI), a nongovernment organization, to survey medicine prices [13]. It was field tested in nine countries and then national surveys were conducted. To date more than 45 surveys have been completed, including 10 in the Eastern Mediterranean Region.

The WHO Regional Office for Africa and HAI-Africa jointly conducted surveys in 11 countries and are preparing a synthesis report for publication in 2007. Data collected on the price and availability of medicines showed that the surveyed medicines were generally expensive, hardly available in public health facilities, and, where available in private sector outlets, priced beyond the reach of the majority of the population. Prices of originator brands of medicine found in private sector outlets were found to be as much as 7 times higher than the prices of their generic equivalents. Generally, the findings of the surveys show a lack of consistency in the pricing of medicines within regions and sectors in countries, and the existence of considerable price variations across the countries surveyed. High taxes and duties were found in some of the countries surveyed.

Six surveys were also conducted in different states of India [14]. The procurement price of medicines in the public sector was found to be very efficient as compared with international reference prices. However, these medicines were inadequately available and the median availability in the public sector ranged from 0% to 30%. The median prices of medicines in the private sector were almost twice the international reference price, although a few originator brands were more expensive.

Four medicine price surveys were conducted in four central Asian states in 2004 and 2005 [15]. In these surveys the availability of branded medicines was found to be low across the region but some key medicines were also not available as generics. Prices were found to be fairly consistent across the region. Generally, prices were not affordable and data about taxes, duties and mark-ups were very hard to find; however, in Uzbekistan it was found that VAT of 20% was applied on all sorts of medicines.

Currently the WHO/HAI project is developing and testing medicine price monitoring methodology. In Kenya, for example, a quarterly monitoring exercise is ongoing following the national medicine price survey. Monitoring showed that only 8 medicines were available out of 34 surveyed medicines in more than 75% of public health facilities, although repeat monitoring has also shown that the situation is gradually improving [16]. Private sector prices were, overall, found to be 36% higher than those in the public sector. The quarterly monitoring reports and partnership between the Ministry of Health and HAI is seen to be contributing to improvement in the situation.

4. Medicine price surveys in the Eastern Mediterranean Region

4.1 About the surveys

In order to assess the regional situation in relation to medicine prices and access to medicines, national medicine price surveys were completed (see Table 1) in the past four years in 10 countries of the Region [17]. The survey findings provide information on the following important aspects of medicine prices: availability of a group of pre-selected medicines in the public and private sectors; public procurement prices for these medicines; comparison of the lowest priced generic medicines and originator brand medicines with international reference prices; originator brand medicine prices versus lowest generic medicine prices in the public sector; originator brand medicine prices versus lowest generic medicine prices in the private sector; prices of originator brand medicines and lowest priced generic medicines compared between the public and private sectors; affordability of medicine for the lowest paid unskilled government worker in terms of buying a pre-selected treatment course for nine acute and chronic conditions; analysis of the various costs, tariffs and taxes and mark-up which are added on to the ex-manufacturer[5] price in the supply chain.

The international reference prices for this survey methodology were those published annually, by Management Sciences for Health in collaboration with WHO in *The international drug price indicator guide* [18]. The Management Sciences for Health reference prices are the medians of recent procurement prices offered by not-for-profit suppliers to developing countries for multi-source generically equivalent products. The guide contains a spectrum of prices from pharmaceutical suppliers, international development organizations and government agencies. The aim of the guide is to make price information more widely available in order to improve procurement of medicines. The medicine price methodology uses these international reference prices to calculate median price ratios, i.e. how many times the recorded price of a medicine is in relation to the international reference prices of the same medicine, e.g. twice, three times, etc.

Table 1. Summary of medicine prices surveys conducted in the Eastern Mediterranean Region 2004–2006

Country	Survey year	Conducted	Medicines surveyed			Facilities surveyed		
			Core list	Local list	Total	Govt.	Private pharmacies	Total
Egypt*	2004	Ministry of Health	30	0	30	–	–	
Jordan	2004	Food and Drug Administration	23	6	29	18	20	38
Kuwait	2004	Academic	21	14	35	25	25	50
Lebanon	2004	Ministry of Health	26	6	32	20	40	60
Pakistan	2004	Nongovernmental organization	29	0	29	30	48	78
Sudan	2005	Ministry of Health	22	20	42	20	20	40
Syrian Arab Republic	2003	Ministry of Health	22	5	27	–	57	57
Tunisia	2004	Ministry of Health	20	10	30	21	42	63
United Arab Emirates*	2004	Ministry of Health	NA	NA	NA	NA	NA	
Yemen	2006	Ministry of Health	27	8	35	20	20	40

* Egypt and United Arab Emirates only collected public sector prices at central level without conducting facility surveys.

NA not available

[5] Ex-manufacturer: the point at which the medicine leaves the manufacturer.

4.2 Summary of findings

Availability of medicines

Across the 10 surveys the availability of generic medicines was more frequent in the public sector than in the private sector, however there were varying degrees of availability of medicines in the public sector facilities. Although these findings are valid only for the day of the survey and for selected dosage formulations (the most frequently used), nevertheless they are indicative of the general situation. For some countries the availability situation was found to be serious. For example, in Yemen out of 35 medicines, 16 medicines were not found in any facility and more than 29 medicines were not available in more than four public sector health facilities. A basic medicine like cotrimoxazole in generic form was only found in four public sector facilities. Some of the medicines were found in branded forms, indicating another problem—use of limited public sector resources on relatively high priced branded medicines. For a low-income country with a high proportion of poor population—more than 40% of people are not able to meet their basic needs in Yemen—the unavailability of basic medicines in public health facilities poses a serious challenge [19]. In Pakistan, on the day of the survey, 23 out of 29 medicines were not found in more than 15 public sector facilities.

Public sector procurement prices

All the surveyed countries except Egypt, Pakistan and Sudan were found to be procuring at least some medicines in both generic and branded forms. On average, procuring a branded medicine incurred a premium[6] of 3.4, i.e. if a branded medicine was procured instead of its generic equivalent. In the case of the United Arab Emirates, for example, the brand premium was 7.

For the purposes of these surveys an arbitrary benchmark was set for the analysis of the medicine prices. In the case of publicly procured generic medicines, prices are considered “acceptable” if they have a median price ratio of 1 or less than 1, which means that the price of the generic medicine is the same or less than the international reference prices of the same medicine. In the case of generic medicines, acceptable procurement prices were observed in three countries: Sudan (0.2), United Arab Emirates (0.6) and Jordan (0.6). The median price ratio for other countries varied between 1 and 2.

There was substantial variation in the prices at which countries were able to procure the same medicine. For example, the median price ratio for generic captopril varied from 0.2 to 12.8. Countries also need to examine their procurement performance for individual medicines compared to regional partners to determine those areas in which they can improve. For example, Jordan procures generic cotrimoxazole at a median price ratio of 2.4, higher than any other country. Kuwait performed well in procuring generic medicines in general. However, it performed poorly (as defined by observed median price ratio) on items such as generic glibenclamide (5.0) and diazepam (18.4) compared to other countries.

Private sector retail prices of medicines

For these surveys if the median price ratio of the medicine in retail pharmacies was found to be less than 2.5, it was considered “acceptable”. Prices above this level, especially those of generic medicines, were considered “excessive”. The surveys showed that in the case of originator brands the median price ratios were consistently excessive in relation to the benchmark 2.5 across all the countries (see Figure 2). Pakistan was the only country with a median price ratio of less than 4, while Sudan had the highest median price ratio, 18.2. In the case of lowest priced generics, Pakistan with a median price ratio of 2.3 and the Syrian Arab Republic with a median price ratio of 2.5 were the lowest and can be considered acceptable. All the other countries were found to have median prices for lowest priced generics five times those of the international reference prices.

[6] Brand premium is the difference between the brand price and the price of the lowest priced generic. A brand premium of 1 means the price of the brand and the generic medicine is the same, and a brand premium of 2 means that the price of the branded medicine is twice the price of its lowest priced generic equivalent.

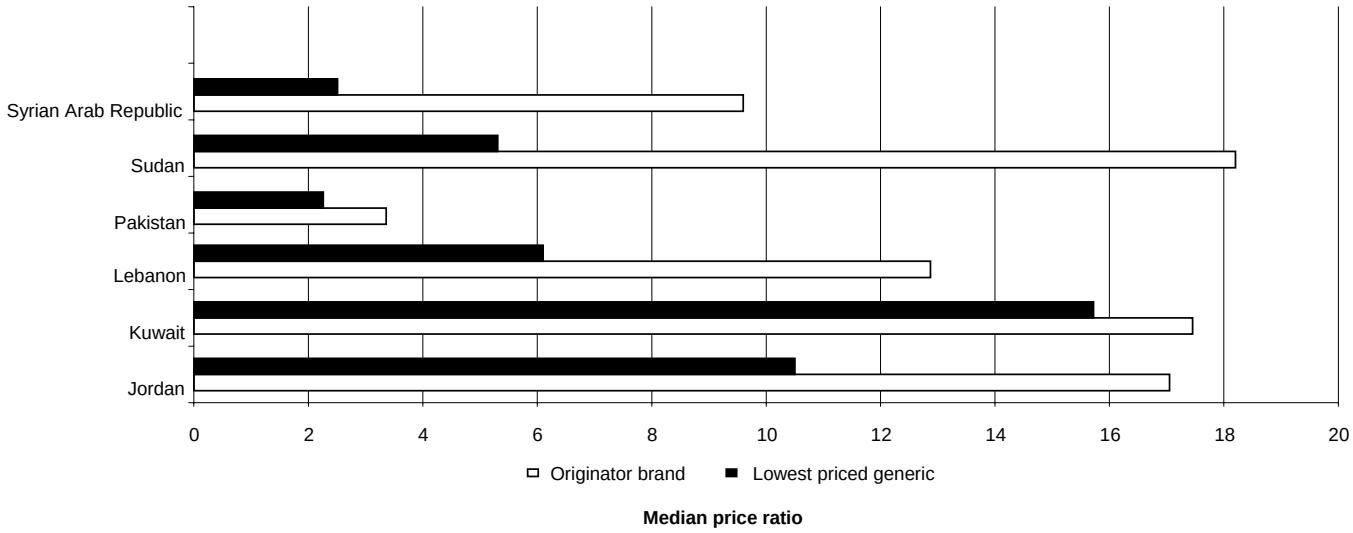

Figure 2. Median price ratios for medicines in private sector retail pharmacies

The situation in Kuwait was found to be unique. Only a small price difference was found between the prices of originator brands and the lowest priced generics in the private sector. This is in contrast with the international trends and with other countries in the Region and is considered to be the result of pricing regulations in force in Kuwait.

Brand premiums and intercountry comparison

Brand premium is the comparison between the brand and generic price of the same medicine. By comparing the price of both originator brand and its generic equivalent within the same sector, it is possible to determine how much extra the branded medicine costs. Obviously, the prices of both the originator brand and lowest priced generic of the same medicine are required for such comparison. In public sector procurement prices, only two countries had matching medicine pairs that had been procured both as originator brand and lowest priced generic—Pakistan (brand premium 7.0) and Syrian Arab Republic (brand premium 3.7).

In the private sector at retail pharmacy level, Sudan had the largest average brand premium (3.7) meaning that the originator price was more than three and a half times the generic price on average. In Kuwait, the median brand premium was only 1.1, i.e. there is only a 10% price differential between originator brand and lowest priced generic medicines. For example, the median price ratios for originator and lowest priced generic products respectively in Kuwait were 50.2 and 47.4 for atenolol, and 110.2 and 100.1 for ciprofloxacin. This provides little incentive for patients to use generic medicines. This contrasts with Lebanon, where patients can save more than 50% off the price of the originator brand by purchasing a generic, e.g. median price ratios for originator brand and lowest priced generic atenolol were 47.8 (originator brand) and 9.8 (lowest priced generic) and for ciprofloxacin were 104.1 (originator brand) and 29.3 (lowest priced generic).

Affordability

Affordability in these surveys is calculated as the number of days' wages it would take for the lowest paid unskilled government worker to purchase a selection of standard treatments. Standard treatments for nine conditions (two acute infections: acute respiratory infection and diarrhoea; and seven chronic diseases: arthritis, asthma, depression, diabetes, epilepsy, hypertension and peptic ulcer) were pre-selected. As an arbitrary threshold, a treatment requiring more than 1 day's wage was considered "unaffordable". Although the calculation for affordability was based on the income of the lowest paid government employee, it should be noted that many poor people have incomes considerably lower and less secure than this and without the accompanying social protection.

Most of the surveyed countries in the Region provide medicines free of charge in the government health facilities. Jordan and Sudan, however, charge a fee in public sector facilities which covers part of the price of medicines. In Sudan, for example, treatment of type 2 diabetes mellitus with metformin for a lowest paid government worker or family member in a government hospital would cost of 4.1 days' wages. Since diabetes is a chronic disease, 4.1 days of income would go towards buying this medicine every month.

In the private sector, most of the medicines were found to be unaffordable by the poor. One example is the case of amoxicillin to treat acute respiratory infection, a common problem in developing countries. While in most countries the lowest priced generic of amoxicillin was found to be affordable, the originator brand version was not affordable in Jordan and in Kuwait, where 2.4 and 2.3 days wages, respectively, had to be paid for one week's supply to treat an episode of acute respiratory infection in adults. A low-wage government worker prescribed fluoxetine would need to work for between 1.6 (Syrian Arab Republic) and 8.6 (Jordan) days to afford a month's treatment with the generic version. The originator brand was found to be extremely unaffordable in all countries. Even the low priced generic of fluoxetine in Pakistan was highly unaffordable, i.e. 7.7 days of wages. One month's treatment with omeprazole for the treatment of peptic ulcer was found to be very unaffordable for a low-wage earner, whether purchased as the generic (2.9 days' wages in Sudan and 19.3 days' wages in Jordan) or the originator brand (23.7 days' wages in Pakistan).

Price components of medicines in the private sector

Whether a medicine is imported or produced locally, from the point of its departure from the importer or manufacturer to the point at which it is purchased at a retail pharmacy, many costs are added on in the supply chain. These additional costs can be divided into three categories: tariffs and taxes; mark-ups at the wholesale and retail levels; and service charges. The final retail price that patients pay was found to be substantially increased because of these additions.

For imported medicines, import tariffs were not levied by most of the surveyed countries in the Region except Lebanon, which adds a substantial percentage, and Sudan and Pakistan, which place an import tariff on medicines with the exception of a few key medicines of public health importance (Table 2). For locally produced medicines, various fees, duties and/or taxes are levied in Sudan which add up to 10% on the final retail price. Other countries do not put any direct taxes or duties on locally produced medicines.

Wholesale margins varied from 2% in Pakistan to 35% in Kuwait while retail margins usually exceeded wholesale margins, ranging from 8% to 30%. In Kuwait, the wholesale mark-up, 35%, was more than the mark-up at the retail level, 26%. The price of imported beclomethasone inhaler, used in the treatment of asthma, was 70% more than the price at which it landed in the country, because of high mark-ups.

Table 2. Price component summary for medicines in the private sector

Country	Port and clearance	Other fees/duties	Tax	Import/ Wholesale mark-up (%)	Retail mark-up (%)	Total cumulative mark-up
Kuwait	–	–	–	35%	26%	70.1%
Lebanon (imported)	11.5%	–	–	10%	30%	59.5%
Lebanon (local)	–	–	–	10%	30%	–
Pakistan (local)	–	11%	–	2%	15%	35%
Sudan (imported)	11.5%	8%	–	15%	20%	66.70%
Syrian Arab Republic (local)	–	–	–	(36%)	8%–30% sliding scale	

The mark-up on medicines in Sudan includes a levy for the Ministry of Defence (wound tax). Atenolol tablets, for example, incur a cumulative mark-up of 67% in Sudan. In Lebanon a levy for the Lebanese Orders of Pharmacists and Physicians is also payable by importers. Where wholesale and retail mark-ups are a fixed percentage of the medicine price, a larger profit is made on higher value items. This creates an incentive to sell more expensive products, including selling originator brands rather than generic equivalents where there is a significant price difference. The sliding scale system used for retail margins in the Syrian Arab Republic reduces the profit made on higher priced products and thereby reduces the overall cost of these products to the patient.

5. Key issues requiring policy interventions

There is no doubt that the determinants of medicine prices are multifold and, depending upon the national context, various combinations of these come into play. The surveys quoted in this paper are not methodologically perfect; they present the situation with regard to prices at a single point in time for selected essential medicines recorded from a randomly selected number of public health facilities and private pharmacies. However, it is also clear that the findings of these surveys confirm some general observations about the medicines prices, highlight some specific problems and make the case for action. A number of key issues requiring intervention emerge from the findings.

1. Need for a health system approach in improving access to medicines

The issues of low access to essential medicines and unaffordable medicine prices cannot be effectively tackled without employing a broad health system approach. Without such a comprehensive approach, efforts to improve access to medicines will remain uncoordinated and unsustainable. To achieve equitable and efficient health care, the health system has to respond as a whole. Although the medicine price surveys were not directly aimed at wider health system issues, the findings reveal the importance of broader issues related to health systems, social protection and development policies.

Good governance is the overarching and most critical precondition for the effective working of health systems and is key to achieving equitable health care deliverables. In the case of the pharmaceutical sector, as part of the health system, this means ensuring appropriate processes for the development, implementation and monitoring of national medicines policies, with clear objectives for ensuring: equitable access to essential medicines; appropriate institutional development; transparency and accountability in medicine procurement and pricing decisions; appropriate structure and effective functioning of national regulatory authorities; and participatory processes in monitoring and reporting problems relating to unaffordability of medicines. Without good governance and respect for the rule of law, the best of policies will remain ineffective.

Adequate and equitable financing is another vital component of the health system. Although financing for essential medicines is relatively high in developing countries as a proportion of recurrent health expenditure, in real terms it is far from what is required to meet the basic medicine needs of the people. In most of the countries in the Region, the absence of pre-payment schemes, based upon the concept of risk-pooling, renders the poor and sick socially unprotected and vulnerable to health and pharmaceutical market failures.

The lack of sufficient trained human resources in the pharmaceutical sector for development and implementation of medicines policies is also a health system-related issue. For example, insufficient numbers of pharmacists result in inadequate pharmaceutical regulation, inspection and market surveillance. Service delivery is also important, and in the case of medicines this means ensuring robust and appropriate medicine supply systems. Finally, a reliable and efficient information system, another cross-cutting function of the health system, needs to include a regular flow of information about the availability and prices of medicines.

2. Non-availability of essential medicines

Although availability of essential medicines is one of the most important objectives of national medicines policies, the unavailability of essential medicines remains a major problem which takes many forms and is underpinned by many causative factors. It is ironic in these surveys that although

most public sector procurement systems were found to obtain good prices by virtue of their economies of scale, the medicines were either not available in the system because of non-price related factors, or they were not being purchased as low priced generic medicines.

3. Relatively high public sector procurement prices in some countries

Although the surveys showed that low public sector prices were being obtained overall, important problems require further analysis and policy intervention. The first is the problem of procurement of relatively expensive brand name medicines when the generic counterparts are available at lower prices. Eight out of ten countries were found to be buying at least a few brand name medicines in the public health care system. The reasons for this need to be looked at more closely and solutions identified. The second problem for some countries is the buying of generic medicines at relatively high prices. Why, for example, are three countries (Jordan, Sudan and United Arab Emirates) able to buy generic medicines so efficiently, i.e. at a median price ratio of 1 or less, when other countries are buying the same generics at double the international reference price? In the case of the United Arab Emirates, it may be due to benefit from the Gulf Cooperation Council pooled procurement programme.

4. Excessive medicine prices in the private sector

Using the cut-off point (median price ratio 2.5), generally both branded as well as generic medicines were found to be excessively priced. In the case of originator brands, these excessive prices are despite the fact that multinational pharmaceutical companies practise differential pricing policies.[7] For the poor even these prices remain unaffordable. This raises the question of what price differential is acceptable between a branded medicine relative to its generic version and what action should therefore be taken to lower these prices. It also indicates the need to strengthen social protection mechanisms, including ensured access to essential medicines, for those who do not have the ability to pay for even the lowest priced medicines.

The surveys showed that more branded medicines are sold in the private sector, and that in many countries of the Region poor people have to buy out-of-pocket because of the inadequacy of the public sector and the absence of any social health insurance. It is imperative therefore that governments effectively regulate the prices of the medicines in the private sector in order to keep them as affordable as possible for the lower–middle and low-income groups. The affordability data generated by these surveys show that the situation is indeed bleak for the poor in many countries of the Region. The fact that the same medicines were found to be drastically different in price in the private sector of different countries also calls for more in-depth analysis and monitoring.

5. Issues emerging from analysis of price components in the supply chain

Little is known about how medicine prices are determined by the manufacturers but what is and can be known is how much gets added on to ex-manufacturer prices in the supply chain in the private sector. In those countries where the surveys included the price component analysis, it was found that there was an additional 35%–70% on top of the manufacturer price accounted for by taxes and duties, wholesale and retail mark-up and service charges of various kinds. There is a case for rationalizing these additional costs in order to bring down the retail price of medicines as much as possible.

Various questions can be raised even on the basis of the data available from five countries. For example, in Sudan, which has to import an overwhelming majority of its medicines, removal of 11.5% port and clearance charges and 8% other taxes on medicines would result in almost 20% reduction in the prices of medicines. Similarly, removal of levies for development of professional associations (Lebanon) or defence (Sudan) would not only reduce the burden on the poor but also remove the

[7] Differential pricing policies: when multinational companies make the same branded medicine available at different prices in different countries based on the purchasing capacity of the local population. Thus, a company will market a medicine at a lower price in developing countries than in the industrialized countries. This practice is also known as “tiered” pricing.

associated ethical problem. Wholesale mark-up ranged from as low as 2% to as high as 35% and retail mark-up from 15% to 30%. Since high fixed mark-ups are a direct incentive to wholesalers and retailers to sell expensive brands, revision and rationalization would reduce prices and further benefit patients, especially the poor.

6. Conclusions

The surveys undertaken so far in the Eastern Mediterranean Region and elsewhere have convincingly highlighted issues relating to access to medicines, including unaffordability of median prices. At the same time, they have also indicated the ways to reduce these prices to make them relatively more affordable to the population, especially the poor. Most of the issues highlighted in this paper can be effectively dealt with, provided a coherent medicine pricing policy is developed and implemented as part of the national medicines policy. As a result of undertaking these surveys, a few countries around the world have already taken effective measures to overcome certain issues and have been able to lower prices, including at least two countries in the Region.

At a regional level the Regional Office is planning a number of initiatives.

a) On-line availability of public procurement prices. The Regional Office will create a web-based medicine prices hub where the annual tender/procurement prices, achieved by countries, including those achieved by the GCC pooled procurement programme, can be posted. This information will provide good guidance for countries on the best prices available and achieved by other countries in the neighbourhood and in the Region.

b) On-line availability of international reference prices. Medicine price surveys and follow-up work and discussions have revealed that ministries of health either do not use or make relatively little use of international reference prices, or that they use inappropriate reference prices. WHO already produces international reference prices in collaboration with other agencies and these can also be made available on the e-hub.

c) Medicine price surveys and monitoring of medicine prices. Experience has shown that using standardized methodology to conduct medicine price surveys is a useful strategy for understanding the various aspects of medicines prices and affordability and WHO will continue to support such surveys. Five more countries in the Region are planning such surveys. Those countries that have already done surveys may consider repeating them as and when required. A new methodology for monitoring of prices is being field tested under the same project and will provide information about prices and availability of medicines in countries on an ongoing basis. The findings of the surveys highlight a number of areas for further in-depth inquiry, and countries can also look at any one particular area either through further study or secondary analysis of the data.

d) In-depth studies on medicine price components. There is a need to study further the various components of medicine prices and see where they can be reduced and where the benefits of reduced prices can be passed on to consumers. WHO can support such studies.

e) Development of medicine pricing policy packages for Member States. WHO can work with the Member States to undertake proper analysis of medicine pricing policies in their entirety. Such policies need to be coherent within themselves, in order to achieve the necessary balance between meeting the public health and the economic development objectives; they must also be nested in national medicine polices which, in turn, should be an integral part of the national health policy and vision. Initial work in this area has shown deficiencies on all these accounts. Medicine pricing policies in most of the countries have developed over a period of time and lack coordination and explicit linkages with overarching national health and development policies. At the same time, a single uniform approach cannot be employed although the principles, objectives and priorities for developing or reforming such policies are clear.

7. Recommendations to Member States

1. Ensure good governance in the health and pharmaceutical sector through: developing/strengthening, implementing and monitoring national medicines policy based upon the essential drugs concept as part of the national health policy and strategy, with the clear objective of improving access to medicines; ensuring transparency and accountability in pharmaceutical policy and management, especially in public sector procurement and medicine pricing decisions; and ensuring a monitoring system is in place for availability and prices of essential medicines.
2. Develop an effective pharmaceutical sector as part of strengthened health system through: increasing financing for essential medicines to ensure universal coverage; ensuring that pre-payment schemes cover provision of essential medicines; planning human resource development in the pharmaceutical sector; investing in reform of the medicine supply system to ensure efficiency and coordination with other health programmes in the health system, taking into account the local context in relation to decentralization; and ensuring information about the performance of the pharmaceutical sector, including availability of essential medicines and their prices, is included in the national health information management system.
3. Strengthen the national regulatory authority through: investing in institutional development to ensure the comprehensive coverage of health products and the availability of appropriate financial, human and technical resources, including expertise and infrastructure for medicine price regulation and monitoring; ensuring its independence, both financially and in decision-making; ensuring transparency and accountability in its work; and developing collaborative links with other well developed national regulatory authorities in the Region.
4. Improve availability and the obtaining of better prices in public sector procurement of medicines through: realistic and systematic quantification of essential medicine needs in the government health system following the national essential medicines list; purchasing generic medicines only; pooling procurement of medicines to create economies of scale; using appropriate international reference prices to make better informed procurement decisions; and comparing public procurement prices in the region to make better informed procurement decisions.
5. Reduce medicine prices in the private sector through systematic review and reform of national medicine pricing policies and effective regulation.
6. Rationalize tax regimes and mark-up on medicines through in-depth analysis of the components added on to ex-manufacturer prices and implementation of appropriate policy changes, including exemption of essential medicines from taxes and duties, rationalization of mark-ups and development of a sliding scale model for pricing.

References

1. *The world medicines situation.* Geneva, World Health Organization, 2004.
2. UN Millennium Project. *Prescription for healthy development: increasing access to medicines,* Report of the Taskforce on HIV/AIDS, Malaria, TB and Access to Essential Medicines. Sterling VA, Earthscan, 2005.
3. *World development report 1993: investing in health.* Washington DC, World Bank, 1993.
4. *Technical briefs for policy makers,* No. 2. Geneva, World Health Organization, 2005.
5. Hogerzeil H et al. Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? *Lancet,* 2006, 368:305–11.
6. *Equitable access to essential medicines: a framework for collective action.* WHO policy perspectives on medicines no. 8. Geneva, World Health Organization, 2004.

7. *WHO medicines strategy 2004–2007: countries at the core.* Geneva, World Health Organization, 2004.

8. *Public health, innovation an intellectual property rights.* Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, World Health Organization, 2006.

9. Ross-Degnan D, Waning B. Unpublished data 2007.

10. *Pharmaceutical pricing and reimbursement information*. http://ppri.oebig.at

11. Birkett DJ, Mitchell AS, McManus P. A cost-effectiveness approach to drugs subsidy and pricing in Australia. *Health affairs*, 2001, 20(3): 104–14.

12. *Public–private roles in the pharmaceutical sector*. Geneva, World Health Organization, 1997.

13. *Medicine prices: a new approach to measurement.* Geneva, Health Action International and World Health Organization, 2003.

14. Kotwani A et al. Prices and availability of common medicines at six sites in India using a standard methodology. *Indian journal of medical research*, 2007, 125:645–54.

15. Waning B. Unpublished data, 2007.

16. Mbindyo R. Unpublished data, 2007.

17. *National medicine price survey reports.* Available at www.haiweb.org/medicine prices.

18. *The international drug price indicator guide*. Arlington VA, Management Sciences for Health and the World Health Organization, 2006.

19. Poverty Reduction Strategy Paper 2003–2005, Republic of Yemen. Available at www.imf.org/External/NP/prsp/2002/yem/01/index.htm.