

# Access to affordable essential medicines<sup>1</sup>

## Target

**8e** In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

Target 8e of the Millennium Development Goals acknowledges the need to improve the availability of affordable medicines for the world's poor. Several countries have made substantial progress towards increasing access to essential medicines and treatments to fight HIV/AIDS, malaria and tuberculosis, but access to essential medicines in developing countries is not adequate. In countries for which there is information, the availability of medicines in the public sector is only one third, while private sector availability is about two thirds, and the prices people pay for lowest-priced generic medicines vary from 2.5 times to 6.5 times international reference prices (IRPs) in these two sectors, respectively. Recent progress in a number of countries shows that access to essential medicines can be improved through stronger partnership among governments, pharmaceutical companies and civil society, including consumers, working together to ensure universal access to essential medicines. The role of pharmaceutical companies, ranging from multinationals to generic manufacturers to national distributors, is critical in this effort.

Target 8e is currently measured by the following indicator:

## Indicator

**8.13** Proportion of population with access to affordable, essential drugs on a sustainable basis.

Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population.<sup>2</sup> Given its complexity, an overall picture of the degree of access to essential medicines can only be generated using a range of World Health Organization (WHO) medicine access indicators that provide

<sup>1</sup> Access indicators developed by the World Health Organization are available from <http://www.un.org/esa/policy/mdggap/appendix.pdf>.

<sup>2</sup> United Nations Development Group, *Indicators for Monitoring the Millennium Development Goals* (United Nations, New York, 2003).

data on medicine availability and price in both the public and the private sectors, in combination with key policy indicators.<sup>3</sup>

## Coverage of countries with a recently updated national Essential Medicines List

Essential medicines are those that satisfy the priority health care needs of the population. They 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 at a price the individual and the community can afford. A national Essential Medicines List (EML) is a government-approved selective list of medicines that guides the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations and local medicine production. It is a cost-effective means of providing safe, effective treatment for the majority of communicable and non-communicable diseases.<sup>4</sup>

Nearly all developing countries have a published national Essential Medicines List, the majority of such lists having been updated in the last five years

Nearly all developing countries (95 per cent) have a published national EML. Of these lists, 86 per cent have been updated in the past five years. Given the importance of updating medicine selections to reflect new therapeutic options and changing therapeutic needs, all countries should ensure that their EML is updated regularly. This means that 19 per cent of developing countries need to establish an EML or update an existing one.

## Availability of essential medicines

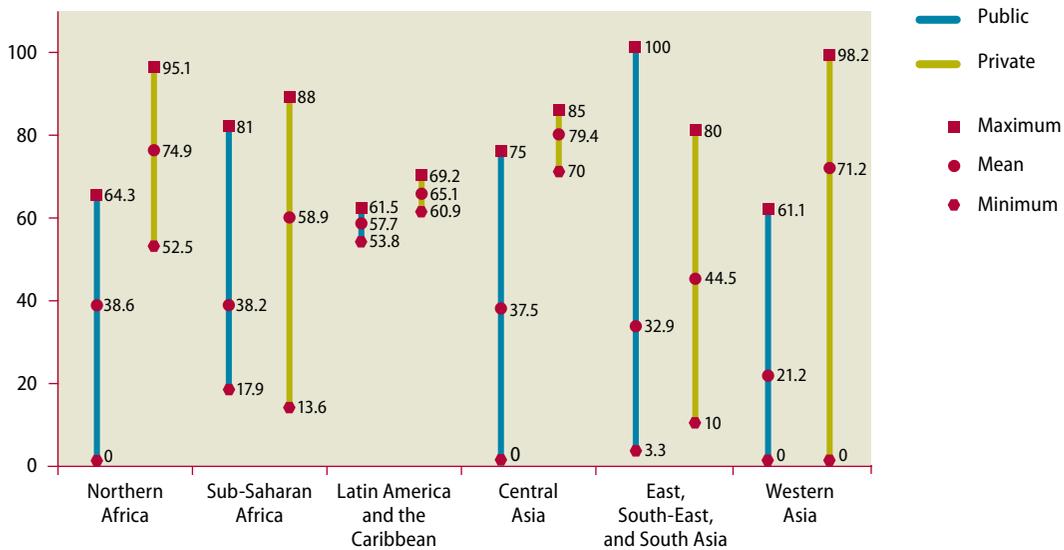
Public sector availability of medicines is low in all developing country regions, and is consistently lower than in the private sector (figure 17). In the 27 developing countries for which data are available, average public sector availability was only 34.9 per cent. When medicines are not available in the public sector, patients will have to purchase medicines from the higher-priced private sector, or forgo treatment altogether. Since health facilities in the public sector generally provide medicines at low cost or free of charge, they are especially important for providing access to medicines for the poor. In individual surveys, availability is reported as the percentage of medicine outlets in which a medicine was found on the day of data collection. Median availability is determined for the specific list of medicines in each survey and does not account for alternate dosage forms of these products or therapeutic alternatives. Public sector data may be limited by the fact that the list of survey medicines may not correspond to national EMLs—where these exist—and some public sector facilities may not be expected to stock all

<sup>3</sup> At the time of the development of the MDG indicators, WHO used interviews with national experts to assess the pharmaceutical situation in each country. More recently, a standard methodology for measuring medicine prices, availability, affordability and medicine price components has been developed and validated in partnership with Health Action International (HAI). To date, more than 50 surveys have been carried out in over 40 countries (see <http://www.haiweb.org/medicineprices/>). Such surveys are a significant step towards making “access” measurable with standardized, reliable indicators.

<sup>4</sup> World Health Organization, *Essential Medicines*, 2005. Available from [http://www.who.int/medicines/services/essmedicines\\_def/en/](http://www.who.int/medicines/services/essmedicines_def/en/) (accessed on 5 June 2008).

Figure 17

### Availability of selected medicines in public and private health facilities between 2001 and 2007 (percentage)



Source: Surveys of medicine prices and availability using WHO/HAI standard methodology (available from <http://www.haiweb.org/medicineprices/>).

Notes: (1) Where multiple state or provincial surveys have been conducted (China, India, the Sudan), results from individual surveys have been averaged without weighting. (2) Number of countries in the sample: among developing countries, there were 27 and 30 countries for the public and private sectors, respectively; Northern Africa, 3 countries; sub-Saharan Africa, 9; Latin America and the Caribbean, 2; Central Asia, 2 for the public sector and 4 for the private sector; East and South Asia, 7 for the public sector and 6 for the private sector; Western Asia, 5 for the public sector and 6 for the private sector.

of the survey medicines. This has been addressed in the revised edition of the survey tool, which allows public sector data to be analysed by EML status and level of care.

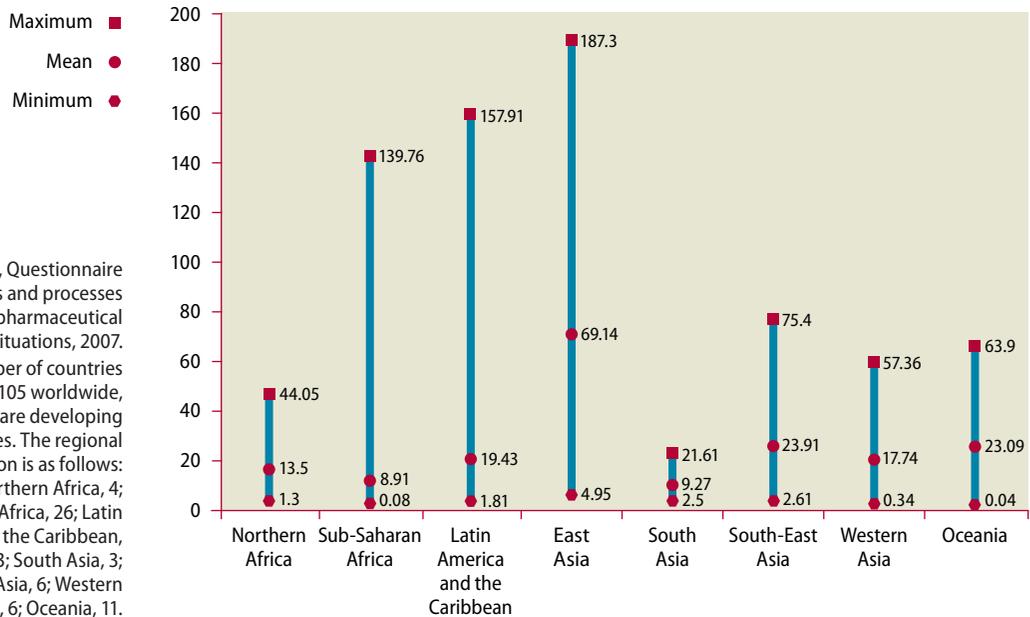
Medicine availability is not guaranteed in private health facilities either. On average, about one third (36.8 per cent) of private providers in developing countries lacked availability of essential medicines, but in a sample of six countries in East, South-East and South Asia the percentage was more than half (55.4 per cent).

## Public sector expenditure on pharmaceuticals

Low availability of medicines in the public sector may be caused by several factors. Inadequate financing or underbudgeting can result in insufficient funds to meet national needs. As shown in figure 18, there is wide variation in national per capita spending on medicines by the public sector, ranging from \$0.04 to \$187.30 among developing countries. This variation occurs even among countries of similar economic status: expenditures range from \$26.67 to \$505.46 across developed countries and from \$0.04 to \$16.30 across least developed countries. Other determinants of low public sector availability of medicines include procurement of high-priced products, such as originator brands, and inefficiencies in the supply and distribution chain.

Poor availability of medicines, particularly in the public sector, is a key barrier to access to affordable essential medicines in developing countries, especially for the poor

Figure 18  
Public per capita expenditure on medicines, 2007 (dollars)



Source: WHO, Questionnaire on structures and processes of country pharmaceutical situations, 2007.

Note: Number of countries in the sample: 105 worldwide, of which 77 are developing countries. The regional representation is as follows: Northern Africa, 4; sub-Saharan Africa, 26; Latin America and the Caribbean, 16; East Asia, 3; South Asia, 3; South-East Asia, 6; Western Asia, 6; Oceania, 11.

Addressing the root causes of low public sector availability of medicines can lead to substantial improvements. In Kenya, for example, the availability of artemether-lumefantrine 20/120 mg for treating uncomplicated falciparum malaria increased dramatically between July and October 2006 (figure 19). This corresponds to the period during which Kenya received financial support through the Global Fund to Fight AIDS, Tuberculosis and Malaria to procure and distribute artemether-lumefantrine to public health facilities.<sup>5</sup>

Adequate financing and affordable procurement prices are key determinants of medicine availability in the public sector

Kenya also benefits from a differential pricing agreement whereby the manufacturer Novartis sells this medicine at lower costs to public health systems in developing countries.<sup>6</sup> The principle behind such differential pricing is that prices should be adapted to the purchasing power of governments and households in lower-income countries so that they receive the best possible prices for life-saving medicines.

## Pricing of essential medicines

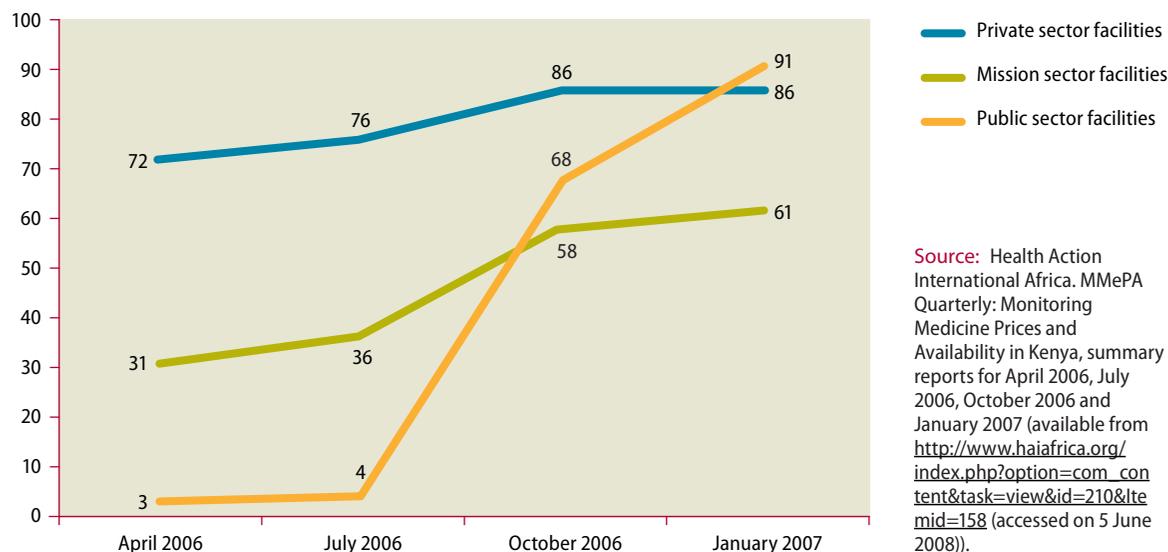
The high price of medicines, particularly in the private sector, is another key barrier to access to affordable essential medicines in developing countries

Given the often low public sector availability of medicines, patients are frequently forced to purchase medicines in the private sector, where prices are higher. In the 33 developing countries for which data are available, lowest-priced generic medicines cost over six times IRPs in the private sector (figure 20). For

<sup>5</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria, Kenya Country Proposal Malaria Component, Round 4, available from [http://www.theglobalfund.org/search/docs/4KENM\\_797\\_0\\_summary.pdf](http://www.theglobalfund.org/search/docs/4KENM_797_0_summary.pdf) (accessed on 5 June 2008).

<sup>6</sup> Novartis, Coartem in Africa: Gaining momentum on the ground, available from <http://www.corporatecitizenship.novartis.com/patients/access-medicines/access-in-practice/coartem-in-africa.shtml> (accessed on 5 June 2008).

Figure 19  
**Availability of artemether/lumefantrine 20/120 mg in Kenya,**  
 April 2006–January 2007 (percentage)



Source: Health Action International Africa. MMePA Quarterly: Monitoring Medicine Prices and Availability in Kenya, summary reports for April 2006, July 2006, October 2006 and January 2007 (available from [http://www.haiafrica.org/index.php?option=com\\_content&task=view&id=210&Itemid=158](http://www.haiafrica.org/index.php?option=com_content&task=view&id=210&Itemid=158) (accessed on 5 June 2008)).

originator brand medicines, costs are generally much higher.<sup>7</sup> In public sectors in which patients pay for medicines, lowest-priced generics cost about 2.5 times more than IRPs. While national government procurement prices are usually close to or below international prices, patients pay substantially more owing to markups in the supply chain and expensive local purchases geared at addressing stockouts.

A current limitation of medicine price data in developing countries is that they do not assess the extent to which access to medicines is equitable. Such equity issues are currently being investigated using data collected in 54 world health household surveys.

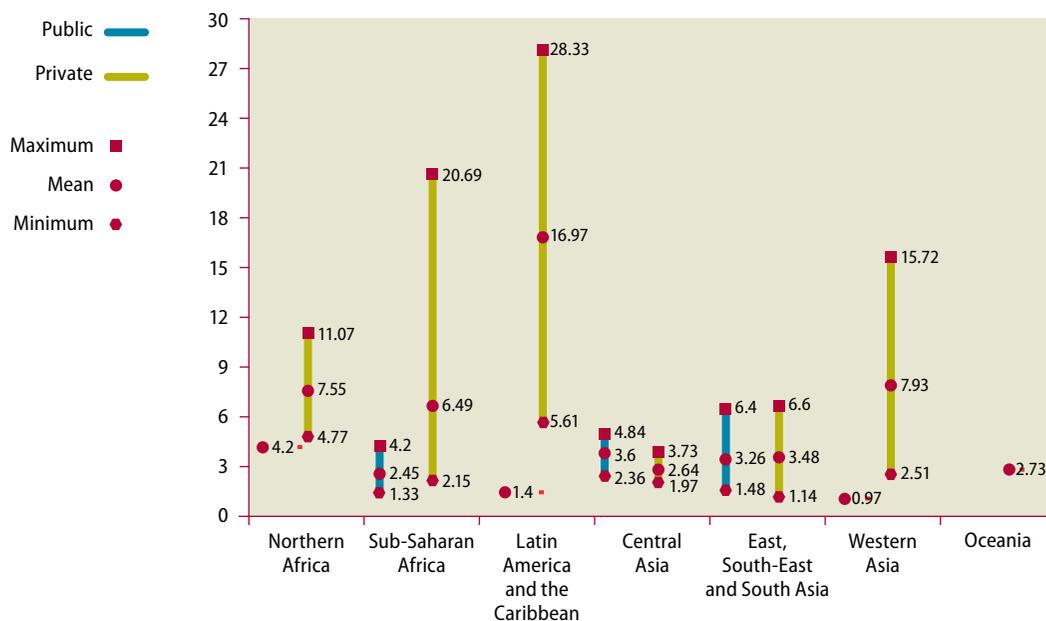
Few data are available on the markups applied to the cost of the production of medicines as they move through the supply and distribution chains. In the limited number of countries for which such data are available, results show that these add-on costs can be substantial in both the public and the private sectors (table 4). A key contributor to these add-on costs are wholesaler and retailer markups. Countries such as South Africa have attempted to make private sector markups transparent.<sup>8</sup> Other countries have regulated markups by adopting regressive schemes that allow higher markups for lower-priced products, thereby providing an incentive for retailers to sell lower-priced products. In the Syrian Arab Republic, for example, private pharmacy markups range from 30 per cent when the pharmacy procurement price is 1–40 Syrian pounds (SYP) to 8 per

The final price of medicines can be strongly determined by the high add-on costs in the supply chain

<sup>7</sup> Surveys of medicine prices and availability using WHO/HAI standard methodology, available from <http://www.haiweb.org/medicineprices/>.

<sup>8</sup> National Medicine Policy for South Africa, available from <http://www.doh.gov.za/docs/policy/medicinesjan1996.pdf> (accessed on 5 June 2008).

Figure 20

**Ratio of consumer prices to international reference prices (consumer price ratio) for selected generic medicines in public and private health facilities**


Source: Surveys of medicine prices and availability using WHO/HAI standard methodology (available from <http://www.haiweb.org/medicineprices/>).

Notes: (1) In each survey, median consumer price ratios are obtained for the relevant basket of medicines found in at least four medicine outlets. As baskets of medicines differ by individual country, results are not exactly comparable across countries. However, data on specific medicines are publicly available on the Health Action International (HAI) website (<http://www.haiweb.org/medicineprices/>). (2) Data correspond to the most recent survey available for countries in the region taken over the period 2001-2006.

(3) Number of countries in the sample for the public and private sectors, respectively: Northern Africa, 1 and 3; sub-Saharan Africa, 9 and 10; Latin America and the Caribbean, 1 and 2; Central Asia, 2 and 4; East and South Asia, 4 and 7; Western Asia, 2 and 7; Oceania, 1.

Table 4

**Margins between producer and consumer prices in the public and private sectors (percentage)**

| Country                     | Public sector markup | Private sector markup |
|-----------------------------|----------------------|-----------------------|
| China                       | 24-35                | 11-33                 |
| El Salvador                 |                      | 165-6 894             |
| Ethiopia                    | 79-83                | 76-148                |
| India                       |                      | 29-694                |
| Malaysia                    | 19-46                | 65-149                |
| Mali                        | 77-84                | 87-118                |
| Mongolia                    | 32                   | 68-98                 |
| Morocco                     |                      | 53-93                 |
| Pakistan                    |                      | 28-35                 |
| Uganda                      | 30-66                | 100-358               |
| United Republic of Tanzania | 17                   | 56                    |

Source: Surveys of medicine prices and availability using WHO/HAI standard methodology (available from <http://www.haiweb.org/medicineprices/>).

cent when the procurement price is 501 SYP or higher.<sup>9</sup> Taxes and duties are other contributors to add-on costs in the supply chain. Medicine prices can be reduced by eliminating duties and taxes on medicines,<sup>10</sup> a policy measure which has already been implemented in many countries.

While affordable prices are a key determinant in improving access to medicines, adequate, sustainable and equitable financing of medicines is also required. UNITAID and Advance Market Commitments for vaccines (AMC) are two examples of innovative financing mechanisms that have recently been put in place. UNITAID uses the proceeds of a solidarity tax on airline tickets to purchase drugs and diagnostics for HIV/AIDS, malaria and tuberculosis, while AMC uses donor commitments to provide incentives to vaccine makers to produce vaccines for developing countries.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief (PEPFAR), and UNITAID have generated substantial funding for the treatment of HIV/AIDS, tuberculosis and malaria. Further support is needed for chronic, non-communicable diseases such as cardiovascular disease, cancer, diabetes and chronic respiratory disease. Globally, approximately 35 million deaths (i.e., 60 per cent of all deaths) are attributable to chronic diseases each year, 80 per cent of which occur in low- and middle-income countries.<sup>11</sup>

## Generic substitution policies

In the majority of cases, generically equivalent products are priced substantially lower than the originator brand.<sup>12</sup> Increasing the use of quality-assured generic medicines is therefore a key strategy for improving the affordability of medicine. A range of policy options is available to promote the use of generics, including allowing pharmacists to dispense a generically equivalent product in place of the originator brand listed on the prescription. Such generic substitution by pharmacists is allowed in many countries, sometimes with a requirement to inform the patient.<sup>13</sup> Legal provisions to allow and encourage generic substitution in the private sector exist in 86 and 100 per cent of the developed and transition economies, respectively. Such provisions are in place in fewer developing countries (72 per cent) (see figure 21). Less than half of the countries in South and Western Asia (40 per cent) and Oceania (38 per cent) have generic substitution policies.

Generic substitution is a key policy for ensuring access to affordable essential medicines which should be adopted by more countries

<sup>9</sup> World Health Organization Regional Office for the Eastern Mediterranean 2008, Survey of medicine prices, availability, affordability and price components: summary survey report for Syrian Arab Republic (available from <http://www.haiweb.org/medicineprices/surveys/200312SY/sdocs/EMPSyriasummarynewpricingWEB.pdf> (accessed on 5 June 2008)).

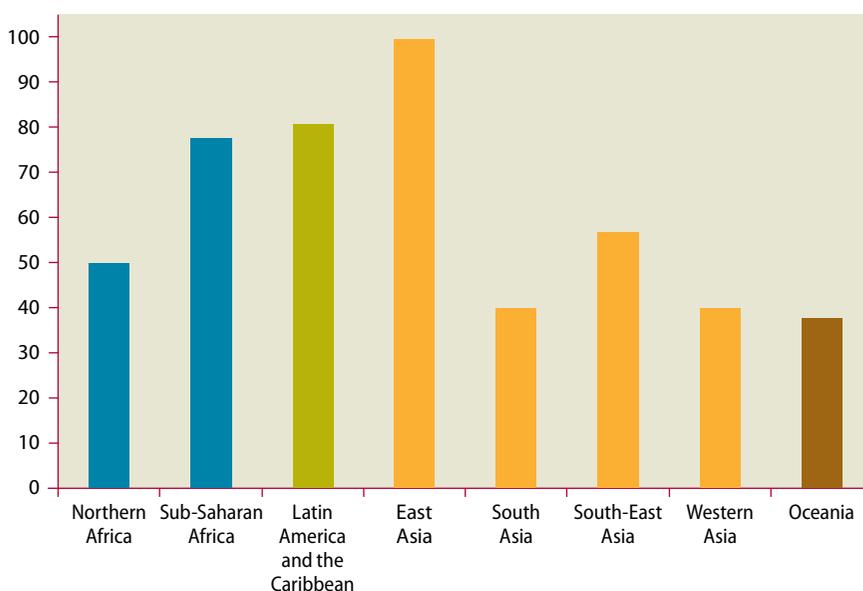
<sup>10</sup> M. Olcay and R. Laing, Pharmaceutical tariffs: what is their effect on prices, protection of local industry and revenue generation? (Geneva: Commission on Intellectual Property Rights, Innovation and Public Health, May 2005). Available from <http://www.who.int/intellectualproperty/studies/tariffs/en/index.html>.

<sup>11</sup> World Health Organization, *Preventing Chronic Diseases: A Vital Investment* (Geneva: World Health Organization, 2005).

<sup>12</sup> Surveys of medicine prices and availability using WHO/HAI standard methodology (loc. cit.).

<sup>13</sup> A. Nguyen, What is the range of policies that can be used to promote the use of generic medicines in developing and transitional countries? (unpublished, 2007).

Figure 21  
**Percentage of countries with legal provisions to allow/encourage generic substitution in the private sector, 2007**



Source: WHO, Questionnaire on structures and processes of country pharmaceutical situations, 2007.

## Recognition of essential medicines and technologies in national constitutions

Most national constitutions do not specifically recognize access to essential medicines or technologies as part of the fulfilment of the right to health

National constitutions define the fundamental political principles of a country and usually guarantee certain rights to their people. Health is a fundamental human right recognized in at least 135 national constitutions. Access to health care, including access to essential medicines, is a prerequisite for realizing that right. However, only five countries specifically recognize access to essential medicines and technologies as part of the fulfilment of the right to health.

## Recently updated national medicines policies

A large proportion of developing countries have national medicines policies, but many have not been updated in the past five years

A national medicines policy (NMP) plays an important role in defining the national goals and objectives for the pharmaceutical sector, and in identifying the strategies needed to meet them. An NMP is an essential part of health policy which should be adopted and regularly updated. Worldwide, 71 per cent of countries have a published NMP.<sup>14</sup> However, only 48 per cent of developing countries have updated their policies in the past five years, compared to 86 per cent of developed countries. In Africa, for example, 73 per cent of countries have an NMP, but only 33 per cent of those policies have been updated in the last five years.

<sup>14</sup> World Health Organization, Questionnaire on structures and processes of country pharmaceutical situations, 2007.

## Towards a strengthened global partnership to improve access to affordable essential medicines

Assured access to essential medicines occurs when there is government commitment, careful selection, adequate public sector financing, efficient distribution systems, and control on taxes, duties and other markups. Ensuring rational use of these medicines is critical to preventing resistance and overconsumption. This complex web of activities requires cooperation between the public and private sectors, between prescribers and dispensers, and between different government institutions. Consumers also need to be informed through a transparent system that addresses widespread patterns of information asymmetry.

Formerly, WHO stated that one third of the world's population lacked access to essential medicines. With the more accurate estimates provided by the WHO/HAI survey methodology, we now know that in about 40 developing countries, public sector medicine availability is only one third, while private sector availability is about two thirds. The prices people pay for lowest-priced generic medicines vary from 2.5 to 6.5 times IRPs in the public and private sectors, respectively. Clearly, all developing countries should be measuring access using this survey methodology at least every two years. The fact that some developing countries have better availability and lower prices than others shows that access to essential medicines can be improved.

No doubt the MDG target to **provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries** has served to mobilize resources and improve coordination aimed at increasing access to essential medicines and treatments to fight HIV/AIDS, malaria and tuberculosis in many countries. Access to essential medicines in developing countries, however, is not yet adequate.

Part of the difficulty in assessing progress towards this commitment has been the lack of a quantitative target. Recent efforts to develop reliable indicators to measure access (namely, those related to availability and price) will improve accountability in respect of global actions to expand sustainable access to essential medicines. Information available in a number of countries suggests the existence of large gaps in the availability of medicines in both the public and private sectors as well as a wide variation in prices—much higher than IRPs—which render essential medicines unaffordable to poor people. A wide range of policy and programmatic options exist for countries, companies and consumers for improving access to essential medicines in the different sectors of developing countries.

Accelerated progress requires explicit national and global targets in a number of areas.

### At the **national level**:

- Eliminate taxes and duties on essential medicines;
- Update national policy on medicines;
- Update the national list of essential medicines;
- Adopt generic substitution policies for essential medicines;
- Seek ways to reduce trade and distribution markups on prices of essential medicines;

- Ensure adequate availability of essential medicines in public health care facilities;
- Regularly monitor medicine prices and availability.

At the **global level**:

- Encourage pharmaceutical companies to apply differential pricing practices to reduce prices of essential medicines in developing countries where generic equivalents are not available;
- Enhance the promotion of the production of generic medicines and remove barriers to uptake;
- Increase funding for research and development in areas of medicines relevant to developing countries, including children's dosage forms and most neglected diseases.