



**International Pharmaceutical Federation  
Fédération internationale pharmaceutique**

**PO Box 84200, 2508 AE The Hague, The Netherlands**

## **FIP STATEMENT OF POLICY IMPROVING ACCESS TO MEDICINES IN DEVELOPING COUNTRIES**

### **Introduction**

Medicines are now the major weapon for successful prevention and treatment of many illnesses. Access to effective medicines should, therefore, be considered to be a basic human right.

However, one-third of the world's population lacks access to essential medicines. In the poorest parts of Africa and Asia, this figure rises to one-half of the population. There is a direct relationship between the incidence of tuberculosis (TB) and poverty. Non-affordability, lack of education on health, weak public distribution systems for medicines and shortage of trained healthcare personnel, all adversely affect ability to access medicines in developing countries. An estimated 200 to 450 million children infected with malaria parasites present with fever every year and malaria is responsible for 0.5 to 3.0 million deaths each year. Ninety-five percent of the 42 million people with HIV/AIDS live in developing countries. Research and development of medicines for diseases that affect the poor has stagnated because of the lack of economic incentives. The last major new medicine for TB was developed 30 years ago. Resistance to all infectious disease treatments is on the rise. There is serious concern over the threat of a new influenza pandemic or an epidemic of avian influenza.

The health and new medicines development statistics are themselves a matter of great concern but when considered together with the infrastructure and resource constraints in developing countries, there is even greater cause for concern. Although many developing countries have pharmacy regulatory systems staffed with well-trained individuals, other countries do not have either effective systems in place or staff resources available. And the human resources situation is growing worse with the continuing migration of health professionals from developing to developed countries, usually for career-enhancing reasons.

The situation is often aggravated by lack of other resources, corruption, or ineffective law enforcement. Some countries have been unable, to date, to stop the flow of counterfeit medicines despite possessing the appropriate technical knowledge and equipment to do so. Others do not have the resources to ensure that medicines that come on to their markets are of acceptable quality. In many instances, countries do not have the medicines management infrastructure and resources to procure, process, and distribute medicines effectively and efficiently, particularly in rural and remote areas. Where systems do exist to ensure satisfactory delivery of medicines, patients may not be able to afford treatment or to use the medicines in an appropriate manner.

Access to medicines is complex and has been described by the World Health Organization (WHO) as having four main components: rational selection, affordable prices, sustainable financing and reliable systems for purchase, storage, and distribution. The multidimensional aspect of access has been further defined by WHO and Management Sciences for Health (MSH) as being comprised of a medicine's availability, affordability, accessibility, and acceptability to the patient, with cross-cutting dimensions relating to the quality of both medicinal products and pharmaceutical services.

Within the past few years, progress in ensuring access to medicines has been significant. The WHO Model List of Essential Drugs, which in 2002 celebrated its 25th anniversary, is an important tool in the access equation. By adopting essential medicines lists, together with the development and use of standard treatment guidelines, national ministries of health have made significant advances in establishing the core tools that are necessary to treat public health problems in their countries.

In relation to HIV/AIDS, progress has also been significant. In 1997, the WHO and FIP issued a joint declaration on the Role of the Pharmacist in the Fight against HIV/AIDS<sup>1</sup>. The WHO has introduced an updated Model List of Essential Medicines that includes antiretroviral medicines and fixed-dose combinations. Furthermore, standard treatment guidelines for HIV/AIDS and related guidelines are being produced as part of the initiative to have 3 million people being treated by the end of 2005. In addition, WHO's pilot project on the pre-qualification of medicines has helped to identify sources of antiretrovirals and medicines for the treatment of tuberculosis and malaria, that meet recognised quality standards. Parallel with this, there have been changes in pricing policies over the past few years that have resulted in significantly lower prices for antiretrovirals in developing countries and a number of donor organisations have increased their commitments to helping resource-limited countries pay for the medicines needed. In addition, there have been initiatives to permit generic forms of antiretrovirals to be produced during a product's patent life.

However, much remains to be done. In spite of the recent developments in relation to rational use of medicines, improved supply, and decreases in prices, the conditions for access to medicines remain less than optimal in many countries, especially for the poor and underprivileged.

Pharmacy organisations, both national and international, have a vital role to play in accepting responsibility to promote to governments and other stakeholders, the need to take effective action to improve policy and practice in relation to access to medicines. The profession of pharmacy can also play a significant role in helping to improve access because of the wide range of technical expertise that exists among pharmacists world-wide.

Furthermore, FIP fully endorses the right to health as described in the 1948 UN Human Rights Declaration and actively engages in the defence and promotion of public health, particularly for neglected populations and those in need.

**Against this background, FIP undertakes to:**

- promote the safe and effective use of quality medicines and so help to protect public health;
- promote improved access to essential medicines, particularly in disadvantaged and underserved populations;
- help to facilitate the transfer of knowledge, expertise and information from developed to developing countries, for example, through seminars organised by the Boards of Pharmaceutical Sciences and Pharmaceutical Practice and the support of Pharmabridge;
- explore and support links between developing countries, especially through the WHO/FIP Forums and their national pharmaceutical associations;
- develop policies and programmes designed to benefit developing countries and promote these to international organisations at interdisciplinary meetings; and

**FIP recommends that:**

- governments and international organisations with a focus on health should recognise the unique contribution pharmacists can make, through their technical expertise, to improving access to medicines for people in developing countries.
- in line with the WHO/FIP Guidelines on Good Pharmacy Practice (GPP)<sup>2</sup> and taking into account the FIP's recommendations on step-wise implementation of GPP in developing countries<sup>3</sup>, governments should apply laws and practices to encourage regulatory systems within which pharmacists and other health care providers can employ their skills to ensure the appropriate management of quality medicines to their populations.
- governments and pharmaceutical associations in developed countries should take the lead, in co-operation with their counterparts in developing countries, to minimise the migration of health professionals from developing to developed countries and develop sound policies to support this goal.
- governments and the profession of pharmacy should promote the use of, and apply, WHO's treatment guidelines, model essential medicines lists and other tools to ensure appropriate, timely, and rapid build-up of capacity for the treatment of HIV/AIDS, tuberculosis and malaria and all other devastating diseases.
- governments in developing countries should endeavour to provide incentives to encourage pharmacists to provide services in rural areas to ensure that essential medicines of high quality are also available in these areas.
- pharmacy organisations should share information on the barriers to access to medicines within their countries and work with their governments and health professional colleagues to devise strategies at the local, national, and international levels on ways to overcome those barriers.
- regional pharmacy groups, including WHO/FIP Forums, should work together to share technical expertise and experiences with the aim of improving relevant competencies to ensure the quality of medicines and their regulation, distribution and use. This can include the mutual

recognition or harmonisation of standards for registration of the professionals involved, joint procurement and supply, licensing of pharmacies, information reporting and sharing, and educational programmes for all those involved in provision of health care. For pharmacists, educational programmes should be in line with the recommendations in the FIP Statement of Policy on Good Pharmacy Education Practice<sup>4</sup> and the FIP Statement on Continuing Professional Development<sup>5</sup>.

- pharmacy organisations should strengthen their work towards combating counterfeit medicines in their countries, in accordance with the FIP Statement of Policy on Counterfeit Medicines<sup>6</sup>.
- pharmacy organisations should press at national and international levels for rational practices for donation of medicines, taking into account the FIP Statement of Policy on Good Practice in Donation of Medicines<sup>7</sup> and the current WHO Guidelines, while recognising that donations cannot contribute to sustainable increases in access to essential medicines in the long run and may, in practice, contribute to irrational use of medicines.
- governments, the pharmaceutical industry and the profession of pharmacy should take steps to ensure that essential medicines supplied to developing countries for humanitarian reasons either as donations or at significantly lower than market prices, or manufactured in a developing country under special licensing arrangements, are not exported to other countries.
- pharmacists, in accordance with the FIP Code of Ethics for Pharmacists<sup>8</sup>, should avoid corrupt or unethical behaviour that may contribute to impeding access to medicines. The interests of individual patients and of public health generally should be placed above commercial interests. Practices that allow, promote, and/or support irrational use of medicines and the manufacture or distribution of substandard medicines as well as predatory pricing practices must be avoided.

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1. WHO/FIP Joint Declaration on the Role of the Pharmacist in the Fight Against the HIV-AIDS Pandemic (1997, Vancouver)
  2. FIP/WHO Guidelines for Good Pharmacy Practice (1997)
  3. Good Pharmacy Practice in Developing Countries – Recommendations for step-wise implementation by the FIP Community Pharmacy Section (1998)
  4. FIP Statement of Policy on Good Pharmacy Education Practice (2000, Vienna)
  5. FIP Statement of Professional Standards on Continuing Professional Development (2002, Nice)
  6. FIP Statement of Policy on Counterfeit Medicines (2003, Sydney)
  7. FIP Statement of Policy on Good Practice in Donations of Medicines (1997, Vancouver)
  8. FIP Statement of Professional Standards on Codes of Ethics for Pharmacists (2004, New Orleans)