



Health Action International

HAI Briefing Paper

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Medicines Strategy

Prequalification of Generics

HAI congratulates the WHO on its work with the prequalification of medicines that are essential for treating HIV/AIDS, malaria and tuberculosis. This important improvement in procurement information and guidance must continue, and the list should be updated and expanded on a regular basis. WHO/EDM should not be limited to prequalification of diseases targeted by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); they should be encouraged to include information on a broader range of essential medicines, concentrating in particular on diseases of poverty.

Prequalification of quality essential medicines, including generics, should be recognised as an integral and ongoing part of WHO/EDM's work. WHO should ensure that the prequalification system and information about medicines on it are widely available at country level. Priority should be given to promoting its value to national medicines regulatory bodies and ministry staff, notably in countries that have Global Fund grants that include medicines procurement.

Developing countries that have very limited means for conducting independent quality assurance benefit especially from the prequalification information. Prequalification can ensure that they have the necessary quality assurance information to be able to register and procure needed medicines in the short term. This prevents gaps in medicines provision while a government seeks to strengthen their national quality assurance systems. Member States should insist that WHO prequalification status of any medicine be sufficient evidence of quality for procurement using Global Fund grants. Acceptance of additional requirements limits the choices Member States can make in their procurement efforts.

Acceptance of Generics

The inclusion of generic products on the WHO prequalification list for antiretrovirals (ARVs) has rapidly proved instrumental in improving acceptance of affordable high quality generic products around the world. HAI welcomes the indication by US President George Bush in his 2003 State of the Union speech that low cost quality medicines can help fight HIV/AIDS in developing countries. The quoted figure of US\$ 300

per person per year is an important recognition of the role of generics to increase access to medicines.

Prequalification is a significant step towards improving generic availability and acceptance. However, much work remains to be done in this area, particularly in light of confusing messages to the public. For example, in the past year, a sector of the pharmaceutical industry has started a campaign to make a link between generics and counterfeits. Industry has done this to discredit generics and make people mistrust them, while not providing real evidence of this link. Moreover, the fact remains that most counterfeits are of expensive, branded medicines. And many examples exist of cases where authorities have found substandard medicines—and they were manufactured by large, multinational firms. This adds to existing negative bias towards generic medicines based on social, economic and cultural factors, as well as the influence of other actors such as doctors and pharmacists. The truth is that well-manufactured generics are of as high quality as well-manufactured branded medicines. As it has effectively done in other areas of its work, WHO must invest at national, regional and global level in confidence building measures in this regard. HAI believes that the commitment of WHO to work with generic manufacturers sends a clear, positive message.

Generic competition

Reports have shown that generic competition, as part of a system of equity pricing, is the most effective way to ensure the greatest price reductions.ⁱ The US Congressional Budget Office estimates that the generic competition saves the US between US\$8 billion and US\$10 billion a year. The market share of generics has accordingly risen from 19% to 43% in the last decade.ⁱⁱ In the past five years, global prices of ARVs have decreased from approximately US\$10,000 per year to less than US\$300 per year for some combinations. This is primarily due to the price competition resulting from the introduction of generics in that time period.ⁱⁱⁱ Generic competition is possible in some countries because of the lack of product patents and by the use of (or threat of the use of) TRIPS safeguards in other countries. The Doha Declaration clearly acknowledged the explicit link between patent protection and access to medicines, stating:

We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices. (para 3)

The Declaration further states:

We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002. (para 6)

Five months after the deadline to resolve Paragraph 6, Member States without manufacturing capacity still do not have a mechanism to introduce generic competition into their markets to respond to their public health crises. This problem will be exacerbated after 2005, when those middle-income countries that currently have the freedom to produce generics will be bound to more strict rules that adhere to the TRIPS agreement. Efforts to solve the Paragraph 6 problem have stalled, primarily due to the actions of one country that itself freely makes use of TRIPS safeguards. In the solution to Doha, there should be equal ability for all countries to address public health situations effectively. Why should the rich countries be able to invoke a (threat of) compulsory licence, when poor countries with little or no manufacturing capacity cannot? The Doha Declaration calls for a solution to this unfair situation. HAI urges the WHO to engage in discussions with the WTO to solve this problem but urges WHO not to get involved in brokering any compromise to the Doha declaration. HAI rejects any interpretation of Doha and Paragraph 6 that limits disease scope. Rich countries are not limited in the public health crises where TRIPS safeguards may be used, and developing countries' options must not be limited either. WHO can play a more active role in discussions on trade and health at the international level. WHO can contribute significantly to health and trade issues at country level by reaffirming its commitments to provide technical support.

Affordable drug prices

In developing countries, medicine prices matter because most people have to buy medicines out of their own pocket and they have minimal incomes. Medicines save lives and improve well-being, but only if people can afford to purchase them.

Little is known about the prices people pay for medicines in developing countries. To address this issue, WHO and HAI have developed a robust and reliable method to collect and analyse:

- the prices that people have to pay for a selection of important medicines across local sectors (public, private-for-profit, private not-for-profit)
- the affordability and availability of medicines.

- price composition (duties, taxes, mark-ups, fees etc.)

Public Procurement Price

For generics, the most effective way to control purchase price is through an open-tender process. Pooled or bulk purchase nationally, regionally or globally is also effective but only in specific circumstances where multiple parties share similar goals and resources. Stress should be given to the development of a country-level Essential Medicines List and procurement should be rationalised to the EML process.

Concerned about Medicines Pricing? Attend the launch of the **WHO/HAI Drug Pricing Manual** on **Tuesday, 20 May 2003** in **Salle VIII** at the **Palais des Nations** from **17.30 to 18.30**. We warmly welcome all people attending the WHA to attend this briefing.

When generics of a specific medicine do not yet exist, a procurer needs to engage the manufacturer in a professional negotiation process, including using price evidence from other countries. Parallel importation, where possible, could reduce the procurement price because large international price differences for the same medicine are common. Other tools include voluntary and compulsory licensing.

Domestic Add-on Costs

The domestic distribution system also determines the price people pay for medicines. Tariffs, fees, mark-ups, taxes etc. all contribute to higher prices. Policies should be implemented to control these add-ons. Options include exempting essential medicines from tariffs and taxes (as occurs in many countries), fee waivers for market approval of EML products, examining the competitiveness and efficiency of the distribution system (monopolies, pricing collusion, theft etc.), introducing capped generic-friendly policy on wholesale mark-ups, providing incentives to prescribers to support cost-effective practice and introducing fixed dispensing fees (rather than retail mark-ups).

Efforts to curb unethical & inappropriate drug promotion

Unethical and inappropriate promotion by the pharmaceutical industry continues to contribute to irrational, wasteful and sometimes even dangerous medicines prescribing and consumption. The industry is gaining influence through the funding of patient groups, the setting of research agendas and the sponsoring of continuing medical information. Now, there is a move towards direct-to-consumer advertising, where allowed (e.g., the United States &

New Zealand), or so-called disease-awareness campaigns that concentrate on lifestyle and emotive messages and prey on consumer insecurities and lack of knowledge, e.g., trying to create a market for “female sexual dysfunction.” Furthermore, there is no evidence to show that direct-to-consumer advertising of prescription medicines leads to better health outcomes in spite of clear evidence that it increases health care costs.

The Ethical Criteria for Medicinal Drug Promotion was published in 1988 and provides guidance to Member States regarding ethical and appropriate promotion. HAI supports the Criteria but the fight against inappropriate promotion rages on. Given increased attempts to reach consumers directly and the mixed messages communicated to health care providers, governments should require pre-approval of promotional material and advertisements by regulatory authorities. Furthermore, direct-to-consumer advertising of prescription medicines should be banned entirely.

As a first step to raising awareness, WHO and HAI have coordinated the development of a database (www.drugpromo.info) of available information on medicines promotion. The website also contains information about what further research is needed. WHO and HAI are developing a tool, primarily for health science students and health professionals, aimed for improving their ability to evaluate medicines promotion and to recognise and reject unethical promotional practices. Further work is needed by WHO and concerned NGOs to develop and disseminate information to improve consumers' ability to evaluate and monitor promotion and to pressure their governments to clamp down on unethical practices.

WHO relations with Civil Society and NGOs

In recent years, WHO has made substantive efforts to improve its working relations and collaboration with NGOs, for example setting up the WHO/EDM-public interest NGO Roundtable and launching the Civil Society Initiative. The 56th WHA will consider EB111/22, “Policy for relations with nongovernmental organisations.” It states that, “The objectives of relations between WHO and nongovernmental organisations are to strengthen mutually beneficial relations at global, regional and national levels in ways that improve health outcomes, strengthen health actions and place health issues on the development agenda.” This policy goes a long way toward simplifying and clarifying WHO's relations with NGOs. It is a step forward in many ways.

But the lack of clarity about important aspects of implementation needs to be highlighted.

Conflict of Interest: HAI calls on the WHO to act on its commitments to increase transparency when interacting with commercial enterprises. The EB considered WHO's interactions with the private sector at the EB 105 and 107 and during the latter session, considered draft guidelines on WHO interactions with commercial enterprises. Although HAI was told that the guidelines have been implemented, we refer back to our earlier call for transparency on this issue in our letter addressed to EB members (24.10.01). The EB was told in 2001 that an electronic working group would be established to facilitate ongoing discussion of this issue. That particular initiative was abandoned and it is currently unclear to HAI how the WHO will continue to manage dialogue on potential conflict of interest and interactions with commercial entities.

The WHO review of NGO relations^{iv} pointed up a concern about the lack of guidance and clarity for WHO staff at all levels, but especially at regional to country levels, about how to interact with civil society. At headquarters, guidelines still need to be developed, especially concerning collaboration with NGOs. The Country Focus Initiative (EB111/33) stresses the central role of country cooperation strategies in improving WHO effectiveness. Notably, these strategies are supposed to include ways to involve civil society. Yet regional offices and country-level staff remain unclear about their mandates and their means for improving interactions with NGOs and wider civil society.

A pressing need is to provide adequate guidance concerning relations with NGOs that represent commercial interests and to avoid at all times any conflict of interest. HAI notes with deep concern that draft guidelines for interactions with commercial enterprises (EB107/20), have never been finalised and publicly released. That document states that it is applicable “to a variety of other institutions, including ...associations representing commercial enterprises....” It is imperative, therefore, for WHO to address outstanding problems with the draft guidelines and finalise them without further delay. Revisions should address accountability and transparency issues and the need for independent monitoring that includes public health NGO representation.

HAI believes very strongly that health policies and interventions require the substantive involvement of civil society in the design and formulation, as well as implementation. In Africa, HAI is working closely with WHO to identify new ways and strengthen existing processes to promote the substantive involvement of civil society in policy dialogues and programme design and implementation. Initial activities show that this should be a promising area of collaboration and positive change.

Undue duress: evidence of commercial pressure on the WHO: The UK's Guardian (21.04.03) reported how the World Sugar Organisation is lobbying the US Congress to stop American funding from going to the WHO unless its report on diet and nutrition is withdrawn. The report, which recommends that sugar should account for no more than 10% of a healthy diet, has angered the industry and, as a result, the WHO's funding is at risk. Since the first attempt to introduce a report on diet and nutrition in 1990, WHO has accredited the International Life Sciences Institute, which was founded by Coca-Cola, Pepsi-Cola, General Foods, Kraft and Procter and Gamble. This is but one example of how industry and industry-supported groups masked as NGOs exert pressure on the WHO to act in the interest of commercial interests instead of acting in the interest of public health.

HAI is concerned that changes to WHO relations with NGOs (EB111/22) do not adequately address the current bias against relationships and collaboration in Geneva with Southern-based NGOs. These NGOs, which because of historical distortions in power, resources and purpose have not become international, have vital expertise and experience to contribute at headquarters level. The current list of NGOs due to be automatically accredited to WHO, is comprised almost totally of Northern-based, professional/technical NGOs. Effective WHO policy making and normative work needs to include a broader range of expertise and experience, e.g., Southern-based NGOs that are working effectively on diseases of poverty, such as HIV/AIDS, TB and malaria. WHO should not perpetrate a system whereby Southern NGO perspectives have to be filtered through Northern-based international NGOs to be heard in Geneva.

References:

ⁱ Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries, 4th Edition. Médecins Sans Frontières, 24 April 2003.

ⁱⁱ US S. 812, The Greater Access to Affordable Medicines Act, 2001.

ⁱⁱⁱ Samb, B. UNAIDS as quoted in WHO Health Technology and Pharmaceuticals, Revised Drug Strategy, April 2000.

^{iv} Review Report: WHO's Interactions with Civil Society and Nongovernmental Organisations, WHO Civil Society Initiative. Geneva. Unpublished paper. Undated

WHO & HAI

HAI has worked in many different ways with WHO over the years and the types of projects, collaborations and initiatives continue to expand. Here are some examples:

- WHO/EDM HAI Africa Regional Collaboration for Action on Essential Medicines
- HAI/WHO Drug Pricing Project
- HAI/WHO Drug Promotion Project
- NGO Roundtable
- HAI Members on Expert Groups
- Informal and Formal Consultations
- Engagement during the WHA and EB
- Meeting of Interested Parties
- Technical Briefings
- Civil Society Initiative
- Representation at Mini-Assemblies at regional level

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