

Recommendations for Action: for WHO

Generics: Prequalification

- Continue and expand the Prequalification Project to include more medicines and expand to other disease categories.
- Continue to provide technical support to developing countries regarding Good Manufacturing Practice and other quality-related issues.
- Ensure that regularly updated outcomes of the Prequalification Project are widely available at country level.

Generics: Competition

- Avoid being caught in a brokering role for the solution of Paragraph 6 of the Doha Declaration. WHO should not be distracted from the important work it is currently doing in order to act as mediator for the WTO. The member states of the WTO need to address their own problem. Instead, WHO should participate more actively in trade discussions, especially concerning a solution to Paragraph 6 and continue to provide technical assistance to Member States regarding the public health implications of TRIPS.

Generics: Acceptance

- WHO needs to address the increasing problem of the artificial confusion that is being created between quality generics and counterfeits and poor quality medicines in general. This is a problem internationally, nationally and locally. Resources need to be generated to stop this confusion and to promote the use of generics and reduce the fear caused by false statements on this issue.

Pricing of Medicines

- Continue to support the WHO/HAI pricing project and encourage Member States to conduct pricing surveys in their countries.

Promotion

- WHO should continue its support for work that studies the impact of promotion on public health outcomes.

WHO relations with Civil Society and NGOs

- As called for in EB111/22, ensure that guidelines for accreditation and collaboration are articulated by the end of 2003, and that they are formulated with the direct and substantive inputs of NGOs.
- Address the current bias against Southern-based NGOs participation in the work of WHO at the international level.
- Make a clear distinction between NGOs that serve people's interests and are accountable to citizens and NGOs that serve corporate interests and that are accountable to corporate entities.
- Subject NGOs that serve corporate interests wishing to collaborate with WHO to revised, finalised and accountable guidelines for interactions with commercial enterprises. This is noted in EB111/22 in section 12(v), but the wording is too vague.
- Formulate, with the direct involvement of public interest/health NGOs, guidelines for WHO staff interactions with NGOs that will promote the increased substantive involvement of NGOs at all phases of policy and programme formulation and implementation.
- Ensure staff guidelines for interactions with NGOs provide adequate guidance on how to assess the potential for conflict of interest and have substantive provisions for avoiding it, monitoring for potential conflicts and acting on any conflicts if found.
- Ensure that a publicly available database is maintained that provides information about all NGOs accredited to WHO, including all information relevant to supporting their eligibility for accreditation.
- Actively promote the increased participation of NGO-based experts in its efforts to expand participation on expert advisory panels and in expert committees (A56/41).

Recommendations for Action: for Member States

Generics: Prequalification

- Ensure that national medicines approval mechanisms allow the use of the WHO prequalification information as a means to establish medicine quality.
- Insist that the Global Fund accept the results of prequalification as sufficient evidence of quality for procurement purposes.
- Continue and expand support of WHO's prequalification process.

Generics: Competition

- Introduce national legislation and provisions in regional trade agreements that support TRIPS safeguards, such as parallel import and compulsory licensing. If necessary, request technical support from WHO.
- Ministers of Health of Member States should contact their counterparts who represent their countries at the WTO to demand, in the name of public health, a resolution to the Paragraph 6 issue.

Generics: Acceptance

- Member States should resist validating misinformation they receive regarding generic medicines and counterfeit drugs. Confusion of these two terms could lead to the unnecessary purchase of more expensive products, resulting in the treatment of fewer people. Health professionals in-country should be encouraged to prescribe generics and to avoid strengthening the negative bias against their use.
- Emphasise careful selection through the development and implementation of an Essential Medicines List (EML), with emphasis on generics where possible.
- Review and reform national distribution, prescribing and dispensing habits and practices to ensure that processes and policies support the EML and principles of rational drug use.
- Promote generic competition, for example, through medicines legislation encouraging generic substitution and prescription.

Pricing of Medicines

- Conduct price surveys using the WHO/HAI methodology so policy options to make medicines affordable are based on reliable data.
- Introduce competitive tendering for generic medicines.
- Seek technical assistance where necessary to gain access to pricing evidence in order to improve negotiations with manufacturers when generic products do not exist. Investigate the possibility of pooled procurement on a national, regional or global level.
- Remove all taxes and tariffs on medicines in the EML.

Promotion

- Enact legislation to regulate promotion of medicines and prevent unethical and inappropriate practices. This regulation should include a mechanism for the pre-approval of promotional material and advertisements.
- Enact legislation to ban direct-to-consumer advertising of prescription medicines.
- Implement training of health professionals and consumers to educate them on issues associated with unethical promotion practices.

WHO relations with Civil Society and NGOs

- Member states should actively support the substantive improvement at country level of the direct involvement of NGOs in the formulation and implementation of health policy and programmes, including the development of WHO country cooperation strategies.
- Member states should strive to reduce barriers to NGO expression and participation in policy debates, locally and nationally.
- Member states should recognise that the NGO community is very diverse, and that policies for NGO interactions should recognise and embrace that diversity, otherwise NGO involvement is likely to be tokenistic and unrepresentative.