

Third report of Committee B

Committee B held its fifth meeting on 25 May 2012 under the chairmanship of Dr Mohammad Hossein Nicknam (Islamic Republic of Iran).

It was decided to recommend to the Sixty-fifth World Health Assembly the adoption of the attached three resolutions relating to the following agenda items:

13. Technical and health matters

13.13 Substandard/spurious/falsely-labelled/falsified/counterfeit medical products:
report of the Working Group of Member States

One resolution entitled: Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

13.15 WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies

One resolution

13.11 Elimination of schistosomiasis

One resolution

Agenda item 13.13

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

The Sixty-fifth World Health Assembly,

Having considered the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products and its recommendations;

Welcoming the outcome of the sessions of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products;

Reaffirming the fundamental role of WHO in ensuring the availability of quality, safe and efficacious medical products;

Recognizing that many people in the world lack access to quality, safe, efficacious and affordable medicines and that such access is an important part of a health system;

Recognizing the importance of ensuring that combating “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” does not result in hindering the availability of legitimate generic medicines;

Recognizing the need, as expressed in the Rio Political Declaration on the Social Determinants of Health (2011),¹ to promote access to affordable, safe, efficacious and quality medicines, including through the full implementation of the WHO global strategy and plan of action on public health, innovation and intellectual property;

Acknowledging the need for improving access to affordable, quality, safe and efficacious medicines as an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy and in the decrease of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”;

Taking note of resolution 20/6 of the United Nations Commission on Crime Prevention and Criminal Justice entitled “Countering fraudulent medicines, in particular their trafficking”;

Expressing concern regarding the lack of sufficient financing for WHO’s work in the area of quality, safety and efficacy of medicines;

Recognizing the need to enhance support to national and regional regulatory authorities to promote the availability of quality, safe and efficacious medical products,

¹ See subparagraph 11.2 (xii).

1. REAFFIRMS the fundamental role of WHO in ensuring the quality, safety and efficacy of medical products; in promoting access to affordable, quality, safe and efficacious medicines; and in supporting national drug regulatory authorities in this area, in particular in developing countries and least-developed countries;
2. REITERATES that WHO should continue to focus on and intensify its measures to make medical products more affordable, strengthening national regulatory authorities and health systems that include national medicine policies, health risk management systems, sustainable financing, human resource development and reliable procurement and supply systems; and to enhance and support work on prequalification and promotion of generics, and efforts in rational selection and use of medical products. In each of these areas, WHO's function should be: information sharing and awareness creation; norms and standards and technical assistance to countries on country situation assessment; national policy development; and capacity building, supporting product development and domestic production;
3. FURTHER REITERATES that WHO should increase its efforts to support Member States in strengthening national and regional regulatory infrastructure and capacity;
4. DECIDES to establish a new Member State¹ mechanism for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in accordance with the goals, objectives and terms of reference annexed to the present resolution;²
5. FURTHER DECIDES to review the Member State mechanism referred to in paragraph 4 after three years of operation;
6. URGES Member States¹ to:
 - (1) on a voluntary basis, participate in and collaborate with the Member State mechanism referred to in paragraph 4;
 - (2) provide sufficient financial resources to strengthen the work of the Secretariat in this area;
7. REQUESTS the Director-General:
 - (1) to support the Member State mechanism referred to in paragraph 4;
 - (2) to support Member States in building capacity to prevent and control "substandard/spurious/falsely-labelled/falsified/counterfeit medical products".

¹ And, where applicable, regional economic integration organizations.

² Attached as Annex.

ANNEX

Member State mechanism on substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

Goal, objectives and terms of reference

General goal

In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and the Secretariat, the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products¹ and associated activities.

Objectives

- (1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” in order to strengthen national and regional capacities.
- (2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.
- (3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.
- (4) To identify actions, activities and behaviours that result in “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” and make recommendations, including for improving the quality, safety and efficacy of medical products.
- (5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.
- (6) To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”.
- (7) To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.

¹ The Member State mechanism shall use the term “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” until a definition has been endorsed by the governing bodies of WHO.

(8) To promote cooperation and collaboration on surveillance and monitoring of “substandard/spurious/false-labelled/falsified/counterfeit medical products”.

(9) To further develop definitions of “substandard/spurious/false-labelled/falsified/counterfeit medical products” that focus on the protection of public health.

Structure

(1) The Member State mechanism will be open to all Member States.¹ The Member State mechanism should include expertise in national health and medical products regulatory matters.

(2) The Member State mechanism may establish subsidiary working groups from among its members to consider and make recommendations on specific issues.

(3) Regional groups will provide input into the Member State mechanism as appropriate.

(4) The Member State mechanism shall make use of existing WHO structures.

Meetings

(1) The Member State mechanism should meet not less than once a year and in additional sessions as needed.

(2) The default venue for the Member State mechanism, and its subsidiary working groups, will be Geneva. Meetings may, however, be held from time to time outside Geneva, taking into account regional distribution, overall cost and cost-sharing, and relevance to the agenda.

Relations with other stakeholders and experts

(1) As needed, the Member State mechanism should seek expert advice on specific topics, following standard WHO procedures for expert groups.

(2) As needed, the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics.

Reporting and review

(1) The functioning of the Member State mechanism shall be reviewed by the World Health Assembly after three years of its operation.

(2) The Member State mechanism shall submit a report to the Health Assembly through the Executive Board on progress and any recommendations annually as a substantive item for the first three years and every two years thereafter.

¹ And, where applicable, regional economic integration organizations.

Transparency and conflict of interest

- (1) The Member State mechanism, including all invited experts, should operate in a fully inclusive and transparent manner.
- (2) Possible conflicts of interest shall be disclosed and managed in accordance with the policies and practice of WHO.

Agenda item 13.15**WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies**

The Sixty-fifth World Health Assembly,

Having considered the report on WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies;

Recognizing that humanitarian emergencies result in avoidable loss of life and human suffering, weaken the ability of health systems to deliver essential life-saving health services, produce setbacks for health development and hinder the achievement of the Millennium Development Goals;

Reaffirming the principles of neutrality, humanity, impartiality and independence in the provision of humanitarian assistance, and reaffirming the need for all actors engaged in the provision of humanitarian assistance in situations of complex humanitarian emergencies and natural disasters to promote and fully respect these principles;

Recalling Article 2(d) of the Constitution of the World Health Organization on the mandate of WHO in emergencies, and resolutions WHA58.1 on health action in relation to crises and disasters and WHA59.22 on emergency preparedness and response;¹

Recalling United Nations General Assembly resolution 46/182 on the strengthening of the coordination of humanitarian emergency assistance of the United Nations, confirming the central and unique role for the United Nations in providing leadership and coordinating the efforts of the international community to support countries affected by humanitarian emergencies in full respect of the guiding principles therein, establishing, inter alia, the Inter-Agency Standing Committee, chaired by the Emergency Relief Coordinator, supported by the United Nations Office for the Coordination of Humanitarian Affairs;

Taking note of the humanitarian response review in 2005, led by the Emergency Relief Coordinator and by the Principals of the Inter-Agency Standing Committee aiming at improving urgency, timeliness, accountability, leadership and surge capacity, and recommending the strengthening of humanitarian leadership, the improvement of humanitarian financing mechanisms and the introduction of the clusters as a means of sectoral coordination;

Taking note of the Inter-Agency Standing Committee Principals' Reform Agenda 2011–2012 to improve the international humanitarian response by strengthening leadership, coordination, accountability, building global capacity for preparedness and increasing advocacy and communications;

¹ Resolutions WHA34.26, WHA46.6, WHA48.2, WHA58.1, WHA59.22 and WHA64.10 reiterate WHO's role in emergencies.

Recognizing United Nations General Assembly Resolution 60/124, and taking note of WHO's subsequent commitment to supporting the Inter-Agency Standing Committee transformative humanitarian agenda and contributing to the implementation of the Principals' priority actions designed to strengthen international humanitarian response to affected populations;

Reaffirming that it is the national authority that has the primary responsibility to take care of victims of natural disasters and other emergencies occurring on its territory, and that the affected State has the primary role in the initiation, organization, coordination, and implementation of humanitarian assistance within its territory;

Taking note of the 2011 Inter-Agency Standing Committee guidance note on working with national authorities, that clusters should support and/or complement existing national coordination mechanisms for response and preparedness and where appropriate, government, or other appropriate national counterparts should be actively encouraged to co-chair cluster meetings with the Cluster Lead Agency;

Recalling resolution WHA64.10 on strengthening national health emergency and disaster management capacities and resilience of health systems, which urges Member States, inter alia, to strengthen all-hazards health emergency and disaster risk-management programmes;

Reaffirming also that countries are responsible for ensuring the protection of the health, safety and welfare of their people and for ensuring the resilience and self-reliance of the health system, which is critical for minimizing health hazards and vulnerabilities and delivering effective response and recovery in emergencies and disasters;

Recognizing the comparative advantage of WHO through its presence in, and its relationship with Member States, and through its capacity to provide independent expertise from a wide range of health-related disciplines, its history of providing the evidence-based advice necessary for prioritizing effective health interventions, and that the Organization is in a unique position to support health ministries and partners as the global health cluster lead agency in the coordination of preparing for, responding to and recovering from humanitarian emergencies;

Recalling WHO's reform agenda and taking note of the report in 2011 by the Director-General on Reforms for a healthy future,¹ which led to the creation of a new WHO cluster, Polio, Emergencies and Country Collaboration, aimed at supporting regional and country offices to improve outcomes and increase WHO's effectiveness at the country level, by redefining its commitment to emergency work and placing the cluster on a more sustainable budgetary footing;

Welcoming the reform in 2011 transforming the WHO cluster Health Action in Crisis into the Emergency Risk Management and Humanitarian Response department as a means of implementing these reforms, ensuring that the Organization becomes faster, more effective and more predictable in delivering higher quality response in health, and that the Organization holds itself accountable for its performance;

Recalling resolutions WHA46.39 on health and medical services in times of armed conflict; WHA55.13 on protection of medical missions during armed conflict; and the United Nations General Assembly resolution 65/132 on safety and security of humanitarian personnel and protection of United

¹ Document A64/4.

Nations personnel, considers that there is a need of systematic data collection on attacks or lack of respect for patients and/or health workers, facilities and transports in complex humanitarian emergencies,

1. CALLS ON Member States¹ and donors:

(1) to allocate resources for the health sector activities during humanitarian emergencies through United Nations Consolidated Appeal Process and Flash Appeals, and for strengthening WHO's institutional capacity to exercise its role as the Global Health Cluster Lead Agency and to assume health cluster lead in the field;

(2) to ensure that humanitarian activities are carried out in consultation with the country concerned for an efficient response to the humanitarian needs, and to encourage all humanitarian partners, including nongovernmental organizations, to participate actively in the health cluster coordination;

(3) to strengthen the national level risk management, health emergency preparedness and contingency planning processes and disaster management units in the health ministry, as outlined in resolution WHA64.10, and, in this context, as part of the national preparedness planning, with the Office for the Coordination of Humanitarian Affairs where appropriate, identify in advance the best way to ensure that the coordination between the international humanitarian partners and existing national coordination mechanisms will take place in a complementary manner in order to guarantee an effective and well-coordinated humanitarian response;

(4) to build the capacity of national authorities at all levels in managing the recovery process in synergy with the longer-term health system strengthening and reform strategies, as appropriate, in collaboration with WHO and the health cluster;

(5) to establish health response teams on a voluntary basis and develop a mechanism for deployment in case of humanitarian emergencies, depending on the choice of each Member State;

¹ And, where applicable, regional economic integration organizations.

2. CALLS ON the Director-General:

- (1) to have in place the necessary WHO policies, guidelines, adequate management structures and processes required for effective and successful humanitarian action at the country level, as well as the organizational capacity and resources to enable itself to discharge its function as the Global Health Cluster Lead Agency, in accordance with agreements made by the Inter-Agency Standing Committee Principals; and assume a role as Health Cluster Lead Agency in the field;
- (2) to strengthen WHO's surge capacity with global health cluster partners and Member States including developing standby rapid response arrangements and mechanisms in order to deploy and sustain response teams with appropriate resources in response to humanitarian emergencies;
- (3) to ensure that in humanitarian crises WHO provides Member States and humanitarian partners with predictable support by coordinating rapid assessment and analysis of humanitarian needs, including as a part of the coordinated Inter-Agency Standing Committee response, building an evidence-based strategy and action plan, monitoring the health situation and health sector response, identifying gaps, mobilizing resources and performing the necessary advocacy for humanitarian health action;
- (4) to define the core commitments, core functions and performance standards of the Organization in humanitarian emergencies, including its role as the Global Health Cluster Lead Agency and as Health Cluster Lead Agency in the field, and to ensure full engagement of country, regional and global levels of the Organization to their implementation according to established benchmarks, keeping in mind the ongoing work on the Inter-Agency Standing Committee transformative humanitarian agenda;
- (5) to provide a faster, more effective and more predictable humanitarian response by operationalizing the Emergency Response Framework, with the performance benchmarks in line with the humanitarian reform, and to ensure the accountability of its performance against those standards;
- (6) to establish necessary mechanisms to mobilize WHO's technical expertise across all disciplines and levels, for the provision of necessary guidance and support to Member States, as well as partners of the health cluster in humanitarian crises;
- (7) to support Member States and partners in the transition to recovery, aligning the recovery planning, including emergency risk management as well as disaster risk-reduction and preparedness, with the national development policies and ongoing health sector reforms, and/or using the opportunities of post-disaster and/or post-conflict recovery planning;
- (8) to provide leadership at the global level in developing methods for systematic collection and dissemination of data on attacks on health facilities, health workers, health transports, and patients in complex humanitarian emergencies, in coordination with other relevant United Nations bodies, other relevant actors, and intergovernmental and nongovernmental organizations, avoiding duplication of efforts;
- (9) to provide a report to the Sixty-seventh World Health Assembly, through the Executive Board, and thereafter every two years, on progress made in the implementation of this resolution.

Agenda item 13.11**Elimination of schistosomiasis**

The Sixty-fifth World Health Assembly,

Having considered the report on the elimination of schistosomiasis;

Recalling resolutions WHA3.26, WHA28.53, WHA29.58 and WHA54.19 on schistosomiasis;

Noting the resolution EM/RC54/R.3 on neglected tropical diseases: an emerging public health problem in the Eastern Mediterranean Region, adopted by the Regional Committee for the Eastern Mediterranean, which called on Member States, inter alia, to sustain successful control activities in areas of low transmission in order to eliminate schistosomiasis;

Expressing concern that schistosomiasis remains a major public health problem in countries endemic for the disease, and that the goal set in resolution WHA54.19 of attaining a minimum target of regular administration of chemotherapy to at least 75% of school-age children at risk of morbidity was not achieved by 2010;

Noting the extension in coverage of treatment of schistosomiasis from 12 million people in 2006 to 32.6 million people in 2010, the greater access to praziquantel as a result of donations, and increased support from partners to disease-endemic countries for neglected tropical diseases control;

Congratulating Member States, the Secretariat and partners for increasing access to praziquantel and resources to scale up schistosomiasis control;

Encouraged that some countries endemic for schistosomiasis have interrupted its transmission;

Congratulating those countries endemic for schistosomiasis that, with strengthened control programmes and surveillance, have reported no new autochthonous cases of schistosomiasis,

1. CALLS ON all countries endemic for schistosomiasis:
 - (1) to attach importance to prevention and control of schistosomiasis, analyse and develop applicable plans with progressive targets, intensify control interventions and strengthen surveillance;
 - (2) to take full advantage of non-health programmes to improve the environment, in order to cut the transmission of schistosomiasis and accelerate the elimination of the intermediate host;
 - (3) to ensure the provision of essential medicines;
2. URGES Member States, the Secretariat and partners to provide support to countries endemic for schistosomiasis to expand control programmes;

3. REQUESTS the Director-General:

- (1) to encourage Member States and the international community to make available the necessary and sufficient means and resources, particularly medicines, and water, sanitation, and hygiene interventions, to intensify control programmes in most disease-endemic countries and initiate elimination campaigns, where appropriate;
- (2) to prepare guidance for Member States in order to determine when to initiate elimination campaigns, along with methods for implementing programmes and documenting success;
- (3) to assess, on request, the interruption of transmission in the appropriate Member States, to analyse the global status of schistosomiasis prevention and control, the epidemic model, and key challenges, so as to provide targeted recommendations and guidance;
- (4) to elaborate a procedure to evaluate the interruption of transmission in the countries concerned with a view to certifying that transmission has been eliminated in these countries;
- (5) during the post-elimination phase, to support countries that have been certified free of schistosomiasis to pursue preventive actions designed to avoid the reintroduction of transmission of the disease;
- (6) to report every three years through the Executive Board, to the World Health Assembly, on progress in implementing this resolution.

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