Mechanisms to combat substandard/spurious/falsely-labelled/falsified/counterfeit medical products

The Member State Mechanism on Substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) Medical Products was established in May 2011 by the World Health Assembly at its sixty-fifth session. The goal of the SSFFC Mechanism is to promote international collaboration on strategies to address the falsification of medicines from the standpoint of public health, excluding trade and intellectual property considerations.

The first meeting of the Member State Mechanism on SSFFC Medical Products, was organized by the World Health Organization (WHO) and the Argentine Ministry of Health. On 21 November 2012, representatives from sixty-five WHO Member States met in Buenos Aires, Argentina, and agreed to promote strengthening of action to combat SSFFC medical products. The meeting ended with a call to all countries to jointly address this global public health problem that affects millions of people worldwide.

The 200 representatives at the meeting agreed on a workplan that highlights the importance of cooperation between different national authorities and the sharing of best practices and experiences. They agreed to establish a global committee comprising two delegates from each WHO Region to support implementation of a workplan which provides for the reinforcement of national regulatory bodies through capacity-building and networking.

The meeting also stressed the need to develop educational initiatives targeted at consumers, health professionals and industry to prevent SSFFC medical products. It called for the development of methodologies and instruments to obtain more accurate information on the nature and magnitude of the problem. Participants advocated the establishment of guidelines on how to respond to the detection of SSFFC medicines and on securing the distribution chain to avoid the infiltration of SSFFC medical products.

The manufacture, distribution and sale of SSFFC medical products is a problem that endangers the health of the population within all regions and Member States, and impacts on the credibility of health services. Globalization, free trade and Internet technology have all affected the way in which patients obtain their medicines and have made it more complex for national regulatory authorities to effectively control the distribution systems in their countries.

Through the Mechanism, WHO will also enable strengthening of national and regional capacity by developing strategies to prevent SSFFC medical products reaching patients.

Reference: SSFFC Mechanism and activities related to SSFFC medical products at http://www.who.int/medicines

Speeding up access to quality medicines in Africa

Ten African countries have joined a WHO initiative that aims to speed up access to medicines and develop local expertise in medicines regulation.
The Accelerated Registration Pilot Project is a new collaborative activity between medicines regulators in developing countries and international experts working with WHO’s Prequalification of Medicines Programme. WHO’s list of prequalified products is a vital tool for United Nations agencies and other organizations involved in bulk purchasing of medicines. The list includes medicines that have been evaluated for quality, safety and efficacy based on information from manufacturers and inspection of manufacturing and clinical sites.

The Accelerated Registration Pilot Project encourages national regulatory authorities to fast track the registration of medicines that have already been assessed and approved by WHO’s prequalification procedure. In many countries, the same medicines are also required to go through a national process of quality assurance before their use is authorized. This is a lengthy, expensive procedure that can discourage or delay pharmaceutical companies from applying to import their products.

The Global Fund to Fight AIDS, Tuberculosis and Malaria encourages use of the accelerated registration initiative and urges national authorities to use prequalification conclusions to avoid duplicating work and spending time and money on a procedure that has already been carried out. Some national medicines regulatory authorities may have limited resources and this project will help them to benefit from the international expertise and rigorous standards of WHO’s Prequalification of Medicines Programme.

Within the project, when a manufacturer applies to register a prequalified product in a participating country, it agrees to share the complete prequalification assessment and inspection file with a nominated person from the national regulatory authority via a secure internet site. The national authority may use the prequalification reports to make an independent decision on whether to register the medicine in that country. This provides an opportunity to take advantage of WHO prequalification without losing national autonomy.

The initiative establishes strong lines of communication on assessment and inspection outcomes with medicines regulatory authorities in developing countries and could serve as a model for collaboration among the authorities themselves, particularly in countries with similar health needs.

In countries which lack experts in medicines regulation, particularly in the assessment of quality and efficacy of medicines, the pilot project is an opportunity to build capacity and learn from best practices. It also provides a forum for information sharing and exchange with WHO’s prequalification experts who are drawn from well-resourced regulatory authorities around the world.

A major focus is on getting products registered and maintaining a two-way flow of information once the product is in use. WHO will inform the national authority of any withdrawals, suspensions or delisting of prequalified medicines and they, in turn, will keep WHO informed of any national deregistration or issues about the medicine’s safety or efficacy.

The accelerated registration project has the potential to improve medicines registration globally. Besides making treatment available to patients more rapidly, it also has a positive effect on training and capacity building in the partner countries, and gives them the ultimate responsibility for their own systems.