February 2011 Occasional Information note – International Developments
Dear ECONMED participants:
In this occasion we are glad to share a brief information note on ongoing and upcoming developments regarding the discussions on counterfeit medical products at the WHO in Geneva.

- Following discussions at the 128th Session of WHO Executive Board meeting in connection with the first session of the working group on *substandard/spurious/falsely-labelled/falsified/counterfeit medical products*, originally scheduled for December 2010 as per Decision WHA63(10), the session of the working group has now been scheduled between February 28-March 2 2011, at the WHO in Geneva and is **open to all Member States**. The WHO Secretariat elaborated three working documents(A/SSFFC/WG/4, A/SSFFC/WG/3, A/SSFFC/WG/2) to support discussions within the meeting and which describe, amongst other issues, the Organization's role in ensuring quality medicines and progress in the fight against counterfeit and substandard medicines.
- "*WHO's role in measures to ensure the availability of good-quality, safe, efficacious and affordable medical products*" (A/SSFFC/WG/2) provides an overview of the WHO's technical program of work in promoting equitable access to quality medicines and their rational use. It also provides a snapshot of the public health consequences of counterfeit medicines and lays out the normative and technical work conducted by the WHO in important areas such as the development of the International Nonproprietary Names (INN) framework and the biennial International Conference of Drug Regulatory Authorities (ICDRA).
- "*WHO's Relationship with the International Medical Products Anti-Counterfeiting Taskforce*" (A/SSFFC/WG/4)describes the process leading up to the establishment in 2006 of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), the organization and objectives of the Taskforce, as well as the WHO's role within the Taskforce. The initiative, which sees – according to document A/SSFFC/WG/4 - the WHO as Secretariat, includes the participation of national medicines regulatory authorities, international organizations, international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers worldwide. Among its stated objectives are awareness, capacity-building, and coordination of activities across countries to guarantee quality and effective medicines. The Taskforce has drawn some criticism from WHO members-States, including members of UNASUR who proposed a joint draft resolution at the 63rd WHA (A63/A/Conf.Paper No.4 Rev.1), and from organized civil society representatives.
- After drawing out the obstacles and the challenges involved in combating counterfeit drugs, and describing the WHO program to combat counterfeit medicines, document A/SSFFC/WG/3 ("*WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labeled/falsified/counterfeit medical products*") lists the advocacy, normative and technical tasks that lay ahead, emphasizing the importance of global inter-institutional collaboration in tackling the problem.
- The documents that are to be presented note the challenge facing the Working group with regard to the definition of the word "counterfeit". There is no unanimous agreement on the definition of the word and the concern is that an ambiguous definition could impact on access to quality medicines in developing countries, and in particular to generic medicines. Document A/SSFFC/WG/3 proposes that the word "*counterfeit*" be modified to "*falsified*" and that the term "*counterfeit medicine*" be reserved for a falsified medicine with a counterfeit trademark, in accordance with existing WIPO definitions.

- Confusion around the definition of 'counterfeit' was highlighted during the circulation of the latest draft made available of the Anti-Counterfeiting Trade Agreement (ACTA), a proposed multilateral agreement to provide an international framework to increase and widen IP enforcement to "*combat the proliferation […] of counterfeit and pirated goods*," which provides a definition of *counterfeit drug* that could be interpreted as also including medicines that might not infringe any IP right in its territory of origin, such as legitimate, quality generic medicines. It has risen concerns by the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Mr. Anand Grover as expressed in his report to the Human Rights Council in March 2009 (A/HRC/11/12 p. 28 para. 93)
- A recent report by Oxfam, links the counterfeited medicines problem with inefficient medicine regulatory systems, especially in developing nations that are not able to effectively monitor nationally produced and imported medicines. The report references a number of ongoing regional initiatives, including in Latin America and the Caribbean, in line with improving and strengthening medical registration systems.

ECONMED counts on the contribution (through requests of information, sharing of best practices, dissemination materials of interest …) of its participants to keep building up collaborative spaces of work between public health professionals in the Americas. You can submit your communications on any topic related to the legal and economic regulation of pharmaceutical products for approval to econmed@listserv.paho.org