Substandard/Spurious/Falsely labelled/Falsified/Counterfeit Medical Products

The Impact on Public Health

Mr Kees De Joncheere
Director, Essential Medicines and Pharmaceutical Policy

World Health Organization
The WHO Perspective

- Those engaged in the manufacture and distribution of SSFFC medical products cause significant damage to public health.

- That damage can manifest itself in harm to the health of patients and consumers, or undermining public confidence in Medicine, Healthcare professionals and our supply chains.

- An incident involving multiple deaths can deter a population in taking any medicines leading to a greater health issue than the original SSFFC incident.

- The WHO approach this topic from a health perspective, separate to any trade or Intellectual property interests.
Scale and Scope

- SSFFC Products are usually difficult to detect.
- Some imitations so closely resemble the genuine article that they cannot be identified through visual examination alone.
- This creates difficulties in determining the accurate scope and scale of the problem, you will hear in the next session how the WHO are approaching this issue.
- SSFFC products do cause deaths and other very serious adverse reactions, but commonly they just fail to treat the illness for which the genuine product was designed. This makes identification of incidents very difficult.
- Sub potent medicines can also lead to the human body developing drug resistance to treatment. This can have devastating effects on the fight against some diseases.
Current WHO Activity

- At the 65th World Health Assembly held in May 2012 resolution 65.19 was passed establishing a new Member State Mechanism to tackle SSFFC medical products.
- This provided the WHO with a clear mandate from the Member States to tackle an issue in which much work had been done in the past.
- The resolution emerged after much negotiation arising from the controversy surrounding this issue between the protection of Public Health versus the protection of Intellectual Property Rights.
- The first meeting of the new mechanism met in Buenos Aires in November 2012.
- A draft work plan was discussed and work is now commencing.
Work Plan

- Strengthening and capacity building of Regulatory authorities and laboratories
- Collaboration and Co-operation amongst National and Regional regulatory authorities
- Communication, Education and Awareness raising
- Identify actions, activities and behaviours that result in SSFFC medical products
- Strengthen national and regional capacities in order to ensure the integrity of the supply chain
- Collaboration on surveillance and monitoring of SSFFC medical products
- Collaboration with and contribution to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products
Next Steps

- The meeting decided, as a **first activity** of the new Member State Mechanism, to establish an **open-ended working group** to identify the actions, activities and behaviours that result in SSFFC medical products, as outlined in the objective 4 of WHA65.19.

- A steering group of the Member State Mechanism represented by each of the 6 regions will meet during the Spring of 2013 to finalise the work plan.

- Progress will be reported to the 66\textsuperscript{TH} World Health Assembly in May 2013.

- A meeting of the full Member State Mechanism is scheduled for late 2013.

- The WHA resolution has laid down a solid foundation upon which the WHO and Member States can move forward.

- It is time to move forward on an issue that is undermining a basic human right of access to safe medicine, we will work hard to achieve tangible outcomes from the structures that have established.
Thank you

Kees De Joncheere
Director, Essential Medicines and Pharmaceutical Policy
World Health Organization
dejoncheerec@who.int