



World Health Organization Department of Essential Health Technologies

LOCAL PRODUCTION OF INJECTION DEVICES WITH REUSE PREVENTION FEATURES INCLUDING AUTO-DISABLE SYRINGES:

TERMS OF REFERENCE FOR ASSISTANCE BY WHO IN TECHNOLOGY TRANSFER ACTIVITIES

Background

- Single use syringes are manufactured in many countries around the world. Conversion of local production capacity to a capacity to produce injection devices with reuse prevention features for general purposes (including reuse prevention syringes and auto-disable syringes for immunization purposes) may help in ensuring sustainable and widespread access to these products;
- Local production of reuse prevention injection devices that meet international standards of (1) product design and (2) quality systems may be a viable alternative to imported products for national health care programmes;
- The assistance of the World Health Organization (WHO) in technology transfer must fit in with its broader public health mandate. It must be compatible with WHO rules, regulations, policies and practices and is provided in accordance with the terms of the Basic Agreement in force between WHO and the government of the country concerned.
- These terms of reference propose a framework for WHO to act as a resource for countries interested in the various options available to introduce injection devices with reuse prevention features into their health care services.

Objectives of WHO assistance in technology transfer

- Provide advice to the Ministry of Health in making decisions regarding transfer of technology to produce reuse prevention injection devices locally;
- Assist governments in ensuring that national regulations on single use injection devices are consistent with international norms and standards;
- Facilitate contacts between local manufacturers and various parties from industry willing to transfer technology in the field of reuse prevention injection devices.

It is understood that:

- WHO does not become involved in the negotiation of any agreements between such local manufacturers and the companies willing to transfer their technology;
- It is and will at all times remain the responsibility of the local manufacturer to ensure that the local production, sale and use of reuse prevention injection devices does not infringe any provisions of national or international laws, including but not limited to those relating to intellectual property rights such as patents.

Proposed activities for WHO

Assessment

1. WHO can assist the Ministry of Health and the National Regulatory Authority in an assessment of local production capabilities, by:
 - Discussing overall policies and priorities of the Ministry of Health and the various health programmes as the potential users of reuse prevention injection devices;
 - Reviewing country data, strategies, planned activities and proposed expansions for all health programmes to forecast quantities and types of reuse prevention injection devices needed over time;
 - Reviewing the capabilities (including financing) of the National Regulatory Authority in the area of injection devices, with respect to its capacity for inspection, testing, licensing and post-marketing surveillance;
 - Reviewing (a) quality system standards and (b) product standards used for regular single use injection devices produced locally with a view to assisting the Ministry of Health in determining the need for alignment with international standards.

Information exchange

2. Presenting information to the Ministry of Health and other national stakeholders regarding:
 - The burden of disease associated with unsafe injections;
 - The effectiveness and cost-effectiveness of the provision of standard single use syringes to prevent injection-associated infections;
 - The effectiveness of introduction of reuse prevention injection devices;
 - The global market situation of reuse prevention injection devices in terms of supply and demand;
 - The expected benefits of regulating medical devices - including single use injection devices - on the basis of international norms and standards;
 - The WHO procedure for assessing the acceptability, in principle, of single use injection devices for procurement by United Nations agencies;
 - The integration of potential technology transfer plans within national injection safety strategies.

Contact facilitation

3. Facilitating contacts between (1) local manufacturers and (2) the International Association for Safe Injection Technology (IASIT) who may provide updated and public information regarding the various technology options available from all IASIT members.

Quality assurance

4. WHO can offer assistance to countries in addressing quality issues relating to the production of single use injection devices by:
 - Providing information to the Ministry of Health and local manufacturers regarding the WHO recommended (1) product standards and (2) quality system standards that local production of single use injection devices need to meet;
 - Providing information to the National Regulatory Authority regarding the measures that should be adopted to regulate medical device safety, using WHO recommendations as a reference (Medical devices regulations: global overview and guiding principles, WHO 2003).