

Turkey Announces Working Principles for Secondary Packaging and Storage Facilities Related to Human Medicinal Products and Drug Substances

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Turkey's Medicines and Medical Devices Agency ("**Agency**") has announced the principles regarding the approval of secondary packaging and storage facilities, as set forth in Article 7(3) of the Regulation on Medical Products for Human Use published in Official Gazette numbered 30217 on 21 October 2017. The principles specify the requirements and certain circumstances required to allow authorized manufacturing facilities for human medicinal products and approved drug substances to also be used for veterinary medical products, food supplements, biocidal products applied to humans, human tissue and cell products, medical devices and cosmetic products.

Notable aspects of the decisions are as follows:

- Secondary packaging facilities and equipment of human medicinal products can now also be used for veterinary medical products, food supplements and medical devices if the following measures are taken and applied:
 - Under no circumstances can a facility work on different product groups at the same time. This rule should be written, recorded and detectable.
 - Production lines should be cleaned and a detailed procedure should be set to avoid the risk of commingling with previous products. Inspections should be recorded.
 - A procedure should be set (including cleaning instructions) for dealing with unexpected situations (such as breakage and dispersion etc.) where the product contacts the environment if its primary packaging loses its integrity.
- Using facilities and equipment for secondary packaging of human medicinal products is not appropriate for biocidal products applied to human, human tissue and cell products, nor cosmetic products. These products can only be manufactured in independent facilities. However, "medical devices" will be evaluated in accordance with the point above and can be manufactured in these facilities.
- If the proper circumstances and procedures are ensured, human medicinal products storage spaces can now be used for:
 - Veterinary medical products.
 - Food supplements.
 - Medical devices.
 - Biocidal products applied to human.
 - Human tissue and cell products.
 - Cosmetic products.

Please see this [link](#) for full text of the Agency's announcement (only available in Turkish)

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