Agence nationale de sécurité du médicament et des produits de santé

Questions/Answers

Status of disinfectants used in the medical sector (Borderline with biocidal products PT2 and medical devices)

For several years the French hea (ANSM) has been asked questions concerning the qualification of disinfectants used in the health sector.
With the entry in force of European Regulation 528/2012 regarding biocidal products on September 1st 2013, the ANSM would like to clarify some points for manufacturers and users of these products.
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1. What is the qualification of disinfectants ?

Depending on the manufacturer's claims, the disinfectants used in the medical sector may fall under the scope of European Medical Devices Directive (MDD) 93/42/EEC regarding medical devices or under the scope of European Biocides Regulation 528/2012. So, qualification of disinfectants is based on the intended use(s) of the product.

A disinfectant cannot be considered as an accessory of a medical device and therefore have medical device status, unless it is specifically intended for the disinfection of medical devices that must be disinfected before use in accordance with their instructions for use. This is the case of disinfectants for endoscopes or for contact lenses.
Hence, the claim "disinfection of medical devices" does not in itself constitute an intended use falling within the definition of a medical device.

Also, a product that claims to be for general or multi-purpose use is considered to be a biocidal product. This is the case of disinfectants used to disinfect medical devices in the context of preventing risks of transmission of environmental infectious agents.
Disinfectants of medical devices for the control of microbiological risks related to the environment (e.g., beds, operating tables, monitors, etc.) are biocidal products.

2. May a biocidal product also be a medical device ?

EU biocidal products Regulation 528/2012 which came into force on September 1st 2013, allows a manufacturer to put on the market a product with intended uses that fall under the scope of biocidal product status and under the scope of medical device status. In this case, the product is in compliance with both regulations.
The labelling and instructions for use of the product should easily distinguish instructions for the treatment of medical devices from instructions for biocides usages.
However, the ANSM recommends that claims corresponding to a biocidal status are clearly distinguished from those for a medical device status.

3. What is the regulation of biocidal products ?

Disinfectants which meet the definition of a biocidal product are regulated by EU Regulation No. 528/2012 concerning the making available on the market and use of biocidal products.
The aim of this Regulation is to harmonise European regulation and ensure the placing on the market and use of effective biocidal products and the control of risks associated with their use.

The implementation of the regulation is divided into two stages: assessment of active biocidal substances leading to their approval or not followed by the submission of products containing them for marketing authorisations issued in France, by the Ministry responsible for ecology.

During the assessment phase of substances at European level, biocidal products already present on the market are subject to a so-called "transitional" system during which they are not subject to the market authorisation process established by EU biocide Regulation 528/2012.

However, certain regulatory provisions are already effective for these products including in particular:

- the obligation to only contain active substances under evaluation in the European work program for proper use,
- the notification obligation to the French Ministry of Ecology (www.simmbad.fr),
- the reporting requirement of the composition to the National Institute for Research and Safety (INRS) for the prevention or treatment of toxicovigilance poisoning (www.declaration-synapse.fr)
- the obligation for products to be labelled in accordance with Article 10 of the Decree of 19 May 2004 on the control of marketing of active biocidal substances and authorisation of placing on the market of biocidal products.

References and useful websites

- Guide d'interprétation de la directive 93/42/CEE relative aux dispositifs médicaux MEDDEV 2.1/3 rev 3
- Manuel of decision for implementation of directive 98/8/CE relatif aux biocides
- EU Regulation No 528/2012 concerning the making available on the market and use of biocidal products Directive 93/42/CEE concerning medical devices
- www.developpement-durable.gouv.fr
- www.anses.fr
- www.helpdesk-biocides.fr
- www.simmbad.fr
- www.declaration-synapse.fr
- ansm.sante.fr
- ec.europa.eu