Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

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A.I.S.E. Position Paper on labelling requirements of dual use Medical Devices & Biocidal Products
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Implementation of Recital 19 in conjunction with BPR Article 2(2)

A.I.S.E. would like to share with the Commission and the Member States its position regarding the labelling requirements for dual use products, namely Biocides and Medical Devices[1], in view of Recital 19 and Article 2(2) of the Biocidal Products Regulation.

Dual Use Products

Disinfecting products used in the hospitals for disinfection of medical inventory or medical instruments, e.g. endoscopes in a surgery room, are classified as Medical Devices in conformity with the Medical Devices Directive[2]. Products used in hospitals for disinfection of general surfaces, e.g. walls in a surgery room, are classified[3] as Biocidal Products and require an authorisation according the Biocidal Products Directive/Regulation.

In many cases, both mentioned products will have the exact same formulation and the exact same action. The difference between these two products is limited to the regulatory process for placing on the market, as they will be evaluated in parallel, using different legislative paths, by relevant Notified Bodies/Competent Authorities (medical/biocidal).

Current situation

Building on the above example, it is possible for cleaning staff at the hospital to have two spraying bottles with the exact same formulation in it, with the same classification and risk mitigation measures but with different label elements (e.g. registration numbers and CE-mark) and different applications areas. In order to avoid unnecessary confusion and possibility of wrong products being used for wrong applications, some of the Member States currently accept dual use products where MDD/BPD requirements are captured on the same label. This practice has been accepted by some Notified Bodies and European Competent Authorities. It allows for one product meeting authorisation criteria of both legislations[4] to have the dual use related claims and other obligatory labelling elements properly reflected on the label.

Biocidal Products Regulation

In the Biocidal Products Regulation, these disinfectants in the health care sector have been specifically addressed in **Recital 19** of the legal text

[1] Products complaiant with BPR (EU) No 528/2012 and MDD Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
[3] *"General disinfectants are not considered medical devices - they are within the scope of the BPD. Products that have the intended purpose to be a multipurpose disinfectant or a sterilisation agent, are also not covered by the MDD." (Citation from manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products, Chapter 2.1.5.1) and "Multipurpose disinfectants or sterilisation agents are not covered by MDD; they are covered by the directive on biocides." (Citation from: Guidance document - Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative, MEDDEV 2. 1*/3 rev 3, A.2.1.4)
[4] BPD and MDD have been adopted into national law and are in effect

> "*Biocidal products intended to be used not only for the purposes of this Regulation, but also in connection with medical devices, such as disinfectants used to disinfect surfaces in hospitals and medical devices, may pose risks other than those with which this Regulation is concerned. Therefore, such biocidal products should comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements set out in Annex I to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*."

This requirement has been implemented in **Article 2(2)** of the Regulation in a general manner:

> "*Notwithstanding the previous paragraph, when a biocidal product falls within the scope of one of the above mentioned instruments* [comment: among others including MDD] *and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as these purposes are not addressed by those instruments*."

Neither the BPD/BPR nor the MDD contain the principle of non-cumulation. Therefore, some regulatory authorities are of the opinion that one product can have a dual purpose claim when it falls under both regimes, the BPD and the MDD. Moreover, the legal text of the BPR does not provide any indication that the different labelling provisions need to be kept (optically) separate.

A.I.S.E. proposal

Where a given product is used for both medical and disinfection applications, A.I.S.E. would like to propose that combining the "horizontal" legal requirements of the BPD/ MDD on the label is accepted, wherever possible. Where needed, the specific requirements could be clearly separated or optically grouped on the label. In our opinion, harmonisation of the label elements/requirements across the EU will help to minimise the number of products being misused and will facilitate the Mutual Recognition process. Moreover, acceptance of dual use products will help the future BPR implementation as this concept has been included in the legal text of BPR.

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