Guidance document agreed between the Commission services and the competent authorities of the Member States for the Biocidal Products Directive 98/8/EC and for the Medicinal Products for Human Use Directive 2001/83/EC and the Veterinary Medicinal Products Directive 2001/82/EC

BORDERLINE BETWEEN DIRECTIVE 98/8/EC CONCERNING THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS, DIRECTIVE 2001/83/EC CONCERNING MEDICINAL PRODUCTS FOR HUMAN USE AND DIRECTIVE 2001/82/EC CONCERNING VETERINARY MEDICINAL PRODUCTS

Introduction

The determination of a clear borderline between the Biocidal Products Directive 98/8/EC[1] (BPD), the Human Medicinal Products Directive 2001/83/EC[2], as amended by Directive 2004/27/EC[3] and the Veterinary Medicinal Products Directive 2001/82/EC[4], as amended by Directive 2004/28/EC[5] is identified as a crucial issue for a proper implementation of the Biocidal Products Directive as well as of the Medicinal Products Directives (MPDs). Many borderline cases have been identified so far and there is a need to give practical guidance and examples.

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The present document has been elaborated on the basis of discussions held in an expert group including experts from Member States' competent authorities for Biocidal Products, the services of the European Commission, as well as industry trade associations. A questionnaire on borderline cases has been circulated to contact points for the Biocidal Products Directive and the contributions received have been taken into account. The results have been discussed during the CA meeting of Directive 98/8/EC held on 18 May 1999. Further contributions have been received from the biocides contact points and discussions took place with the service of the Commission responsible for the Medicinal Products Directives. A revised version was discussed in again in the expert group referred to above on 25 September 2001.

This document attempts to provide guidance to Member States on borderline cases. It has been conceived as an opinion of the Commission Services involved, but it does not oblige Member States to adopt the same attitude and it is not legally binding since only the Court of Justice can give an authoritative interpretation of existing Community law.
A proposal for amendments to the BPD (notably to the description of Product types in Annex V) will be presented subsequent to the report on the implementation of the Directive in accordance with Article 18(5) of the BPD to introduce among others in the

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1 OJ L 123, 24.4.98. p. 1.

2 OJ L 311, 28.11.2001, p. 67.

3 OJ L 136, 30.4.2004, p. 34

4 OJ L 311, 28.11.2001, p. 1.

5 OJ L 136, 30.4.2004, p. 58

legal text the agreed adjustments on scope. The Commission is also collecting information received from the Member States on individual decisions regarding borderline cases, which are consolidated and then published in a reference document (Manual of Decisions) available on the internet[6]. The Manual is regularly updated.

This document has been endorsed by the competent authorities of all Directives involved.

General principles

The Medicinal Product Directives (MPDs) are listed in Article 1(2) of Directive 98/8/EC. Article 1(2) excludes from the scope of Directive 98/8 products that are defined in or within the scope of the listed instruments for the purposes of the Directives mentioned in Article 1(2).

In accordance with Article 2 (2) of Directive 2001/83/EC and Directive 2001/82/EC, in cases where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions (and requirements) of Directive 2001/83/EC and Directive 2001/82/EC, respectively, shall apply.

A product at the borderline of biocidal products or medicinal products is regulated either by the BPD or by the MPDs. A medicinal product with intended medicinal use and/or demonstrated medicinal claims (including prevention and treatment of disease), containing an active substance with biocidal activity, may be authorised through the procedures laid down in the Directives on medicinal products (human or veterinary). The authorisation procedure to be followed prior to the placing on the market of a given product will therefore be governed either by the BPD or by the relevant MPDs.

A product applied on human skin could be either a medicinal or a cosmetic or a biocidal product. However the exclusion provision contained in Article 1(2) of the BPD gives a kind of priority to the Directives mentioned there: if the product under investigation is within the scope of one of those Directives, it is excluded from the BPD. In cases where uncertainty remains regarding a specific product, the competent authorities of the Directives mentioned in Article 1(2) and those of the Biocides Directive should be consulted to find an agreed solution on whether or not the product is covered by one of those Directives and hence excluded from the scope of the Biocides Directive. It would be useful, if the Member States informed the Commission of the outcome of such decisions.

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6 Available at: http://europa.eu.int/comm/environment/biocides/main_subjects.htm#Manualofdecisions

Definitions

Some definitions from the BPD and the Medicinal Products for Human Use Directive are reproduced here for reference.

Biocidal Product (98/8/EC)

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V.

Harmful organism (98/8/EC)

Any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

Human and Veterinary Medicinal Product (2001/83/EC and 2001/82/EC)

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be used in or administered to human beings or animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis in human beings or in animals is likewise considered a Medicinal product.

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Criteria for borderline setting

In order to decide which regime applies, the following criteria should be examined:

Step 1. The compliance of a product with the relevant definition.
Step 2. The intended purpose of the product.

Proposal for general and specific borderline

Three main categories of products were brought to the attention of the scope group and discussed in depth:

- **Disinfectant products applied on human and animal skin**
- **Products having only a repellent activity, without any lethal effect**
- **Products having a lethal effect on external parasites including lice, fleas or ticks on humans and animals**

1. Disinfectant products applied on human and animal skin:

Although it was discussed whether it could be possible to draw a borderline for disinfectants applied on skin on the basis of the nature of the skin (products used on wounded skin would be medicinal products, products used on intact skin would be biocidal products), it is concluded that this borderline is not applicable in practice.

If a disinfectant has an intended and/or demonstrated claim of medicinal effects it should be classified as a medicinal product.

On the other hand, disinfectants are often used on skin for a general hygiene purpose, for example by workers working in contact with food in restaurants or in the food industry in general, to destroy a wide range of micro-organisms. Besides those that could affect human and animal health, these products could control other micro-organisms that could have a detrimental effect for human activities, for example spoiling or contaminating food. Products of this kind seem outside of the scope of MPDs.

They are therefore considered as biocidal products in view of their claim of general disinfecting and preventive activity. More specifically they would be considered as human hygiene biocidal product disinfectants for skin, scalps and mucous membranes of the oral cavity if the purpose of the use and the claim of the products is general disinfection for hygiene purposes without therapeutic claim. As such products could also be considered as cosmetics, a further verification of whether they are within the scope of the Cosmetic Products Directive 76/768/EEC will be necessary (see separate guidance document on the borderline with this Directive[7]).

Veterinary hygiene biocidal products are disinfectants used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported. They include products used on animals for the purpose of general disinfection and exclude products intended to have a medicinal effect. The following could be examples of biocidal products:

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Human hygiene biocidal products (PT 1)	**Veterinary Hygiene biocidal products (PT3)**
Hand disinfectants	General disinfectants used on animals
Fresh-up towels with a general disinfecting claim	General disinfectants used in footbaths for animals for prevention of cross contamination

It has also now been clarified through an amendment to Regulation (EC) No 853/2004, which lays down specific hygiene rules for food of animal origin[8], that disinfectants used on animal skin during milking, such as teat dips or udder cleaning products, shall be used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC. However, where a medicinal claim is made, those disinfectants shall then be regarded as veterinary medicinal products and shall only be used if authorised in accordance with the provisions of Directive 2001/82/EC.

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7 Available at: http://europa.eu.int/comm/environment/biocides/pdf/cosmetic_products.pdf

8 Available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_320/l_32020061118en00010010.pdf#page=6

2. Products having only a repellent activity, without any killing effects and without medicinal claim:

Traditionally these products do not seem to be covered by the definition of Medicinal Products, whereas they are fully in line with the definition of Biocidal Products and therefore they should be regarded as Biocidal Products (PT 19).

Examples of such products are collars, neckties, ear marks containing repellents, repellents directly applied to human and animal skin; when they have no killing effects on the harmful organisms and when they are presented without medicinal claim.

3. Products having a lethal effect on external parasites including lice, fleas or ticks on humans and animals:

Products used in areas in which animals are housed, kept or transported in order to kill external parasites by treating the structures but not the animal, including situations where the products are intended to be active while animals are in the structures, are classified as biocidal products.

The classification of products containing active substances with lethal effects on external parasites to be used on human beings or animals will depend on the intended use and/or demonstrated claim.

Generally, such products used on human beings/animals are at present considered and authorised as human/veterinary medicinal products with precise medicinal indications (including prevention or treatment of disease).

On the basis of this criterion, the following examples would normally be considered medicinal products, in particular when there is a medicinal claim, but in the absence of such a claim and in specific cases could be considered as biocidal products:

- Products (insecticides) used for sheep dipping for the control of external parasites
- Products for the control of external parasites of fish, used by adding the products to the water where fish swim
- Products/articles which contain an insecticide or another active substance with a lethal activity or with an effect on growth or reproduction of the harmful arthropods, for example collars, neckties, ears marks etc.

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4. Further sources of guidance

A guidance document on the interface between medicinal products and medical devices, MEDDEV. 2.1/3 Rev. 2 – July 2001 'Guidelines relating to the demarcation between Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 65/65/EEC relating to medicinal products and related Directives'[9], contains a number of detailed practical examples of products that are considered medicinal products. These cases have already been discussed for the clarification of the borderline between Medical Devices and Medicinal products. The document also contains general principles.

Conclusion

In case of uncertainty for a specific product, the competent authorities of one of the MPDs and of the BPD should be consulted, considering the exclusion provision contained in Article 1(2) of Directive 98/8/EC. In cases, where uncertainty remains, industry might consult the authorities if all the proposed uses are considered as medicinal uses. In accordance with Article 2 (2) of Directive 2001/83/EC and Directive 2001/82/EC, in cases where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions (and requirements) of Directive 2001/83/EC and Directive 2001/82/EC, respectively, shall apply.

It is obvious that a close co-ordination among the authorities competent for biocidal products and those competent for medicinal products is vital to ensure coherent decisions.

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9 Available at: http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/baseguidelines.htm