

Disinfectant products
Distinguishing between biocidal products and
medicinal products (human and veterinary)

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Depending on the intended application, disinfectant products may fall under different legal frameworks. Professionals in the field frequently ask which legal framework applies to a particular product. These legal frameworks include biocidal products legislation, medicinal products legislation and the legislation on medical devices, as well as other types of legislation, such as the Commodities Act. The latter types of legislation will be excluded from further consideration in this policy document, which focuses on the distinction between biocidal products and medicinal products (human and veterinary) regarding the classification of disinfectant products.

Definitions

Biocidal product

Directive 98/8/EC defines a biocidal product as follows:

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.

For this policy document, the following two scopes of permitted use for biocidal products are relevant:

- biocidal products for human hygiene
- biocidal products for veterinary hygiene.

Medicinal product

The Dutch Medicines Act defines a medicinal product as:

A substance or combination of substances which is intended to be administered or used for curing or preventing a disease, a deficiency, wounds or pain in humans or is presented in any way as being suitable for these purposes (...)

A similar definition applies to veterinary medicinal products.

Interrelationships of legal frameworks

According to the Dutch Medicines Act, if a product can fall under multiple legal frameworks, the Dutch Medicines Act applies in any case. According to the Biocidal Products Directive, a product can fall under biocidal products legislation insofar it does not fall within the scope of medicinal products directives (human or veterinary). It is therefore important, based on the intended claim, to place the product in the correct legal framework. Especially when a manufacturer wishes to make multiple claims for a single product, a complex situation can result. The aim of this policy document is to clarify such situations.

Distinction

The legislation on medical devices (although this is stand-alone legislation) also addresses the distinction between medicinal and biocidal products. Regarding this distinction, it refers to two guidance documents from the European Commission: the Manual on borderline and classification in the community (version 1.14) and MEDDEV 2.1/3 rev.3.

Application to inert surfaces

Disinfectant products intended for use on inert surfaces fall under biocidal product legislation. This requires no further discussion.

Application to the skin of humans and animals

These uses lead to various situations, which are elaborated below.

Application to skin that is intact and remains intact, for the purpose of disinfection

This concerns general skin disinfection, including 'hygienic hand disinfection'. The skin is intact and remains intact. The claim concerns disinfection only. No claim is made with respect to curing or preventing disease or treating a wound. These products fall under biocidal product legislation.

Application to skin that is intact and remains intact, for the purpose of disinfection of the surgeon/surgical personnel, preceding a medical intervention (on a patient)

These products also fall under the previous category 'Application to skin that is intact and remains intact, for the purpose of disinfection'. This is because it does not concern skin that will be opened during a medical intervention, but the skin (hands and forearms) of the surgeon/surgical personnel. The claim concerns disinfection only. No claim is made with respect to curing or preventing disease or treating a wound. These products therefore fall under biocidal products legislation.

Application to non-intact skin (wound)

Given the definition of a medicinal product, products that are applied to a wound (non-intact skin) fall under the Medicines Act.

Application to skin which is intact, but which will subsequently be opened (thus creating a wound)

Because it is likely that the product will come into contact with a wound after the skin is opened, products for disinfecting the skin with the intention of opening the skin immediately afterwards are subject to the Medicines Act. It is irrelevant whether the skin is opened for a medical purpose, such as surgery or injection, or for another purpose such as tattooing, piercing or applying permanent makeup.

Multiple uses (claims) for a single product

Products for which multiple uses are claimed require particular attention. It is not always possible to combine all claims for a single product (within a single legal framework). In that case, the only option is to 'split' the product into separate products, each of which complies with the corresponding legal framework.

According to the Biocidal Products Directive, the basic principle is that a product, considering the claim, may fall under biocidal products legislation only if the claim does not fall within the scope of the Directives on human and veterinary medicinal products. Conversely, if the product falls under the Medicines Act due to one of its claims, the other claims (if any) can sometimes be included in its medicinal product trade authorisation. For example, a product that falls under medicinal products legislation due to the claim 'preoperative skin disinfection' will also be able to claim 'preoperative hand disinfection for surgical personnel' as part of its medicinal product trade authorisation. This has a practical advantage: two different packages containing the same product will not have to be available in the operating room. To be clear, if 'preoperative hand disinfection for surgical personnel' is the only claim, then the product would not fall under medicinal products legislation, but under biocidal products legislation. In addition, it should be noted that these possible combinations are limited. If the manufacturer wants to add 'disinfection of operating room floors' as a third claim, this is not possible for a single product. Application to inert surfaces is not compatible with the definition of a medicinal product.

Examples

To clarify these situations, here are a few examples.

Example 1

A manufacturer wishes to place a product on the market which is designed to disinfect skin prior to the application of permanent makeup, a tattoo or a piercing.

Distinction: because the intention is to open the skin after the application of the product, it is likely that the product will come into contact with a 'wound'. It is therefore a **medicinal product**.

Example 2

A manufacturer wishes to market a product as a medicinal product for which the only claim is 'disinfection of haired skin'.

Distinction: Because this concerns disinfection of skin that is intact and remains intact, the product is a **biocidal product**. If registration as a medicinal product is still desired, it may be possible to modify the claim to 'disinfection of haired skin to prevent infections'. This means that the claim would fall under the definition of a medicinal product (prevention of disease).

It should be noted that this claim (prevention of infection) must be supported scientifically before a marketing authorisation as a medicinal product with this use can be granted.

Example 3

A manufacturer wishes to market a product with the claims 'preoperative hand disinfection for surgical personnel' and 'hygienic hand disinfection, general'.

Distinction: for both applications, it is the intention that the skin is intact and remains intact. It is therefore possible to combine both claims in a single product as a **biocidal product**.

Example 4

A manufacturer wishes to market a product with the claims 'preoperative skin disinfection' and 'hand disinfection for surgical personnel'.

Distinction: with the first claim, it is the intention to open the skin after applying the product. It is therefore likely that the product will come into contact with a 'wound'; consequently, it is a **medicinal product**. However, it is possible to include the second claim, 'hand disinfection for surgical personnel', in the trade authorisation for this medicinal product.

Example 5

A manufacturer wishes to market a product as a biocidal product with the claims 'disinfection of the skin prior to insertion of stud earrings' and 'disinfection of the hands of the operator who inserts stud earrings'. This cannot be marketed as biocidal product. Due to the first claim – the skin is opened during the insertion, creating a wound – it is considered to be a **medicinal product**. However, the second claim could possibly be included in the medicinal product trade authorisation. If classification as a biocidal product is still desired, then the first claim must be dropped.

Example 6

A manufacturer wishes to market a product with the claims 'preoperative skin disinfection', 'hand disinfection for surgical personnel' and 'disinfection of the operating table'. Due to the first claim, it is considered to be a **medicinal product**. However, the claim 'disinfection of the operating table' cannot be included in the medicinal product trade authorisation because this is not compatible with the legal definition of a medicinal product. Two options are to drop the third claim (the product remains a medicinal product) or to drop the first claim, after which the product could fall under the **legislation on biocidal products**. A third option is to split the product so it complies with multiple types of legislation.

Example 7

Although formally not part of the distinction between biocidal products and medicinal products (human and veterinary), for the purposes of clarity the following example is provided. A manufacturer wishes to market a disinfectant product with the claim 'disinfection of dialysis equipment'. A dialysis machine is a medical device. A product

intended for the disinfection of this medical device is considered to be an accessory for a medical device, and therefore falls under the **legislation on medical devices**.

Closing remarks

The following applies to veterinary medicinal products: as commissioned by the Ministry of Economic Affairs, the MEB Veterinary Medicinal Products Unit (CBG-Bureau Diergeneesmiddelen) can provide advice on whether a particular veterinary medicinal product is subject to authorisation. The Veterinary Medicines Board (Commissie Registratie Diergeneesmiddelen) advises the Minister on these products. It also approves changes to authorisations, suspends authorisations, removes such suspensions or cancels authorisations, but has no role in determining the status of a product.

The aim of this policy document is to provide guidance concerning questions asked by professionals in the field. However, no rights can be derived from this document. The final assessment remains the responsibility of the relevant licensing authorities (authorisation bodies) or the relevant regulators. If deemed necessary, this policy document can, over time, be amended or withdrawn.

Where appropriate, the term 'medicinal product' can be replaced with 'veterinary medicinal product'.