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Cosmetics: Mouthwash case

Full title:	Chemische Fabrik Kreussler & Co GmbH v Sunstar Deutschland GmbH [2012] ECR 1-000 – C-308/11[1]
Summary	The case concerned the classification of a mouthwash solution called 'PAROEX 0,12%' which was being marketed as a cosmetic product. The mouthwash contained 0,12% Chlorhexidine[2], an antiseptic/ anti-bacterial which was said to exert a pharmacological action and thus be classified as a medicinal product (as per "functional limb" of the definition[3]). This was based on a 1994 monograph on chlorhexidine, in which mouthwash solutions containing 0.2% of chlorhexidine were shown to reduce salivary bacteria and in this way, have a therapeutic or clinical effect in cases of preventing or treating gingivitis.
Findings	1. Commission guidance documents can be used to resolve a problem of interpretation – so Cosmetics Guidance documents should be used to resolve cosmetic borderline disputes. Whilst they are not legally binding or enforceable - since only the Court of Justice has the jurisdiction to give a binding interpretation of European Union law - they provide useful information for the interpretation of the relevant provisions of EU law and also contribute to such provisions being applied uniformly. 2. Both the Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83[4] AND guidance document on medical devices (MEDDEV 2.1/3 rev.3[5]) provide that "pharmacological action" in the context of the definition of medicinal products should be understood as "an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response or blocks the response of another agent" The CJEU ruled that the concept of "pharmacological action" should be interpreted broadly to include interaction between the molecules of a substance with cellular constituents present within the user's organism, even if these cellular constituents are not human but bacteria, viruses or parasites harbouring in the human subjects. Such interaction may nevertheless have the effect of restoring, correcting or modifying physiological functions in human beings (meaning interaction with cellular constituents within a user and not "of" a user)

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62011CJ0308

[2] Annex V CPR 1223/2009 provides a list of preservatives a cosmetic product may contain; includes a concentration of up to 0.3% chlorhexidine – however in this case it is not being used as a preservative. 'Preservatives' means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product (Art. 2(l) CPR)

[3] Article 1(2)(b) of Directive 2001/83: medicinal products are substances or preparations consisting of substances: '... which may be used in or administered to human beings or animals either with a view to
(a) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or
(b) making a medical diagnosis.'
And that capability must have been scientifically established (Hecht-Pharma [2009] ECR I-41, paragraph 26)
In this context, it was a product whose pharmacological properties had been scientifically proven to have physiological effects.

[4] http://ec.europa.eu/DocsRoom/documents/13032/attachments/1/translations/en/renditions/native

[5] http://ec.europa.eu/DocsRoom/documents/10328/attachments/1/translations/en/renditions/native

URL of source: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62011CJ0308

Practical Implications	This decision, together with previous CJEU decisions, provides further guidance on classification of borderline products. • Each product should be assessed on a case-by-case basis, taking account of the product characteristics and underlying properties (Hecht-Pharma[6] and BIOS Naturprodukte[7]). • To fall within the definition of a medicinal product 'by function', product characteristics should be assessed with reference to its composition, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (BIOS Naturprodukte paragraphs 18 and 20). • For the effect to count as pharmacological: Have regard to its **composition**, including its content in active substances (constituents), there is a need to consider, if **used as intended**, whether the product concerned is capable of **appreciably** restoring, correcting or modifying physiological functions in human beings[8] (*Hecht-Pharma*, paragraph 42, and *BIOS Naturprodukte*, paragraph 23) • As a result of this case – we now know that the effect does not necessarily have to be direct; in deciding whether a product exerts a pharmacological action, it is not necessary for there to be a direct interaction between the constituent molecule of the product and the cellular constituent of the human body. An indirect interaction may be sufficient to infer a pharmacological action (Chemische Fabrik Kreussler – para. 36).

[6] http://curia.europa.eu/juris/document/document.jsf?text=&docid=76342&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=842480

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62008CJ0027:EN:HTML

[8] i.e. So for the effect to be pharmacological or for there to be a pharmacological property one must look at:

1. an effect, which must be appreciable
2. composition – including its content in active substances
3. use as intended (the purpose for which a product is used and/or marketed is often a critical factor in distinguishing between medicinal and non-medicinal products.

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