GUIDANCE DOCUMENT ON THE DEMARCATION BETWEEN THE COSMETIC PRODUCTS DIRECTIVE 76/768 AND THE MEDICINAL PRODUCTS DIRECTIVE 2001/83 AS AGREED BETWEEN THE COMMISSION SERVICES AND THE COMPETENT AUTHORITIES OF MEMBER STATES

PLEASE NOTE: THE VIEWS EXPRESSED IN THIS GUIDANCE DOCUMENT ARE NOT LEGALLY BINDING, SINCE ONLY THE EUROPEAN COURT OF JUSTICE ("COURT") CAN GIVE AN AUTHORITATIVE INTERPRETATION OF COMMUNITY LAW.

FURTHERMORE, THIS GUIDANCE SHALL ONLY SERVE AS "TOOL" FOR THE CASE-BY-CASE APPLICATION OF COMMUNITY-LEGISLATION BY THE MEMBER-STATES. IT IS FOR THE NATIONAL COMPETENT AUTHORITIES AND NATIONAL COURTS TO ASSESS ON A CASE-BY-CASE BASIS WHICH REGULATORY FRAMEWORK APPLIES.

1. INTRODUCTION

1. The clear determination of the demarcation between the scope of application of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[1] ("**Cosmetics Directive**") and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2,3] ("**Medicinal products Directive**") is crucial for the proper implementation of the two Directives and the correct interpretation and enforcement of transposing national laws.

2. The Commission organised, on 28 October 2004, a workshop in Brussels in order to understand stakeholders' and Member States' views on this issue. At this workshop the Commission concluded that a guidance document should be developed that would help both economic operators and the national competent authorities ("**NCA**") to determine which regulatory framework applies.

3. This document attempts to provide such guidance on the demarcation between the two Directives.[4] The content of this guidance document has been the result of

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[1] OJ L 262, 27.9.1976, p. 169 as amended; Non-official consolidated version at http://pharmacos.eudra.org/F3/cosmetic/Consolidated_dir.htm

[2] OJ L 311, 28.11.2001, p. 67; Non-official consolidated version at http://europa.eu.int/eur-lex/en/consleg/pdf/2001/en_2001L0083_do_001.pdf

[3] This guidance document considers the medicinal-products Directive as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, which introduced important legislative changes. These changes have entered into force on 30.04.2004 and are to be transposed into national law by the Member States by no later than 30.10.2005.

[4] For the sake of completion, the guidance documents on the borderline "**medicinal product/medical device**" (http://www.europa.eu.int/comm/enterprise/medical_devices/meddev/2_1_3___07-2001.pdf), **medicinal product/biocidal product** (http://europa.eu.int/comm/environment/biocides/pdf/bordermedvet.pdf), **biocidal product/cosmetic product** (http://europa.eu.int/comm/environment/biocides/pdf/cosmetic_products.pdf) and **General**

intensive discussion between the relevant services of the European Commission, representatives of Member States and representatives of industry.

4. However, it is important to note that this guidance shall only serve as a "tool" for the case-by-case application of community-legislation by the Member-States. It is for the national competent authorities and national courts to assess on a case-by-case basis which regulatory framework applies.[5]

2. THE LEGISLATIVE FRAMEWORK - SCOPE OF APPLICATION

2.1. The Cosmetics Directive

5. Art. 1(1) of the Cosmetic Directive defines "cosmetic product" as

> "any substance or preparation **intended to be placed in contact** with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity **with a view exclusively or mainly** to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."[6]

6. The definition is thus based on two cumulative aspects, i.e. the target site of application "placing on body/teeth/mucous membranes" and the "intended main (cosmetic) function" (i.e. cleaning, perfuming, changing appearance, correcting body odours, protecting, keeping in good condition).

7. Annex 1 to the Cosmetics Directive contains a non-exhaustive, illustrative list by category of cosmetic products.[7]

Product Safety Directive/cosmetics Directive http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf (p. 31-38) shall be mentioned here.

[5] Some Member States have already drafted guidelines on this issue: Cf. the guidelines of the Irish Medicines Board (http://www.imb.ie/uploads/publications/6342926_guidelines.pdf) and of the British Medicines and Healthcare products Regulatory Agency, MHRA Guidance Note No. 8 (April 2003) (http://medicines.mhra.gov.uk/inforesources/publications/gn8apr03.pdf).

[6] Emphasis added.

[7] This list includes the following categories: Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.); Face masks (with the exception of peeling products); Tinted bases (liquids, pastes, powders); Make-up powders, after-bath powders, hygienic powders, etc.; Toilet soaps, deodorant soaps, etc.; Perfumes, toilet waters and eau de Cologne; Bath and shower preparations (salts, foams, oils, gels, etc.); Depilatories; Deodorants and anti-perspirants; Hair care products; hair tints and bleaches; products for waving, straightening and fixing, setting products; cleansing products (lotions, powders, shampoos); conditioning products (lotions, creams, oils); hairdressing products (lotions, lacquers, brilliantines); Shaving products (creams, foams, lotions, etc.); Products for making up and removing make-up from the face and the eyes; Products intended for application to the lips; Products for care of the teeth and the mouth; Products for nail care and make-up; Products for external intimate hygiene; Sunbathing products; Products for tanning without sun; Skin-whitening products; Anti-wrinkle products.

8. Recital 5 of the Cosmetics Directive sets out that the Cosmetics Directive "is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease; whereas, moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics".

2.2. The Medicinal Products Directive

9. Art. 1(2) of the Medicinal Products Directive defines "medicinal product" as follows:

> "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
>
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

10. A product will thus be considered a medicinal product either by virtue of its "presentation" or its "function". A product constitutes a medicinal product if it falls within either of these two categories.[8]

11. Furthermore, Directive 2004/27/EC introduced Art. 2 (2)[9] of the Medicinal Products Directive which provides that

> "In cases of doubt, 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 of this Directive shall apply."

Art. 2 (2) intends to reflect the "**principle of non-cumulation**" as established by the Court in the *Upjohn*-ruling[10] (the principle of non-cumulation is described *infra*, 4.).

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[8] Cf., for the former Directive 65/65/EEC: ECJ, C- 290/90 of 20.5.1992 "Eye lotions", ECR 1992 I-3317, para. 9 – **online access to all rulings of the ECJ under http://europa.eu.int/eur-lex/lex/RECH_naturel.do**.

[9] This guidance document considers the medicinal-products Directive as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, which introduced important legislative changes. These changes have entered into force on 30.04.2004 and are to be transposed into national law by the Member States by no later than 30.10.2005.

[10] ECJ, C-1121/89 of 16.04.1991, "Upjohn", ECR 1991 I-1703: "Even though it may fall within the definition in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a 'medicinal product' and subjected to the relevant rules if it is presented for treating or preventing disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions" (paras 30, 32; Cf. also ECJ, C-369/88 of 21.3.1991 "Delattre", ECR 1991 I-1487, para. 22).

3. DETERMINATION OF THE PRODUCT CATEGORY

3.1. Preface

12. As a general rule a particular product cannot be regulated by both the Cosmetics Directive and the Medicinal Products Directive at the same time. The two regulatory frameworks are mutually exclusive. However, it is recognised that some products may fulfil at the same time the definition of a cosmetic product as well as the definition of a medicinal product. In these cases the question may arise as to which regulatory framework should apply (these cases are sometimes referred to as "so called borderline-products"[11]).

3.2. The definition of cosmetic product

(a) The mode of application

13. Cosmetic products are defined as being intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucuous organs of the oral cavity. It is clear (and set out in recital 5 of the Cosmetics Directive) that products "intended to be ingested, inhaled, injected or implanted into the human body do not come under the field of cosmetics".[12]

(b) Principal purpose

14. The principal purpose of a cosmetic product is defined by the Cosmetics Directive as "cleaning", "perfuming", "changing the appearance", "correcting body odours", "protecting", or "keeping in good condition".

15. This principal purpose refers to external parts of the body, oral mucuous membrane or teeth.

16. The part of the definition referring to "protecting or keeping in good condition" has created uncertainties as to the broadness of the scope of application. In this respect Council and Commission have made the following joint statement:

> "The Council and the Commission agree that the expression "protecting or keeping in good condition does not cover prevention of disease or protection against contamination […]."[13]

17. This reflects the recital of the Cosmetics Directive "whereas this Directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease."[14]

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[11] A product category of « borderline products » does not exist. Consequently, recital 7 of the Medicinal Products Directive mentions « so called borderline products».

[12] 5th recital of the Cosmetics Directive.

[13] Joint statement made by the Council and the Commission when adopting Council Directive 93/35/EEC, 6th amendment of Directive 76/768/EEC.

[14] 5th recital of the Cosmetics Directive.

18. A product may have a principal cosmetic purpose and *also* a secondary purpose to maintain the health. A secondary preventive purpose does not exclude the classification of a product as cosmetic product. However, if the product in question falls also within the definition of medicinal product (be it by virtue of its presentation or by virtue of its function, which is to be decided on a case-by-case basis), the principle of non-cumulation applies (see *infra*, 4).

19. ***Example:*** An antiplaque product such as tooth paste may have as secondary purpose to keep the teeth healthy. This does not deprive this product from its definition of a cosmetic product. However, if this same product is a medicinal product by virtue of its presentation or by virtue of its function[15], the principle of non-cumulation determines that the Medicinal Products Directive applies (see *infra*, 4).

20. ***Example:*** A bath foam which bears a claim such as "relaxing" or which mainly refers to the "well being" will normally be considered by the consumer as a typical cosmetic product. On the other hand, such a bath foam may be considered to be a medicinal product if the product is mainly presented as a treatment for cold or flue.

3.3. The definition of medicinal product

(a) 'First definition' – 'definition by virtue of presentation'

21. The Medicinal Products Directive defines in its first definition medicinal product as "any substance or combination of substances presented as having properties for treating or preventing disease in human beings" ("definition by virtue of presentation"). According to this definition, a product may thus be considered as medicinal product if it is presented either for *treating* or *preventing* disease.

22. With regard to the presentation, the Court has ruled that "a product expressly indicated or recommended as having therapeutic or prophylactic properties has to be regarded as a medicinal product 'by virtue of its presentation' even if it has no known therapeutic effect"[16] and that the "averagely well-informed consumer" is to be considered as the addressee of the presentation.[17]

23. A Community-definition of "disease" does not exist yet.[18] The Court has ruled that a product presented as counteracting certain conditions or sensations, such as heaviness in the legs or tiredness or itching is not *per se* a medicinal product. Rather, all its characteristics need to be considered: Since these sensations may have no

[15] Cf. *infra*, 3.2.2. (b).

[16] ECJ, C-219/91, "Wilhelmus Ter Voort", ECR 1992 I-5485, para. 18, with regard to the former, slightly different-worded definition "any substance or combination of substances presented for treating or preventing disease in human beings or animals".

[17] ECJ, C-227/82, "Van Bennekom", ECR 1983 3883, para 18, with regard to the former, slightly different-worded definition "any substance or combination of substances presented for treating or preventing disease in human beings or animals".

[18] ECJ, "Delattre" (cf. note 10), para. 12.

pathological significance, "a reference to such states or sensations in the presentation of a product is not decisive."[19]

24. ***Example:*** Bath-salts are used to counteract certain sensations such as heaviness in the legs and tiredness. Therefore, they would normally not fall under the definition of medicinal products. However, bath salts may be medicinal products if the product is presented as treating/preventing theses symptoms as being of pathological origin and the product as a medicine to combat these symptoms. The same reasoning applies to foot-care products.

25. When assessing the presentation of a product "the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail."[20]

26. Also, consideration has to be given to the "external form given to the product in question", the "form of its packaging" and the "the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with the manufacture and marketing of the latter type of product."[21]

27. In the light of these rulings, a non-exhaustive and illustrative list of criteria to be taken into consideration may entail the following aspects[22]:

- all claims made for the product, both explicit and implicit, including any made regarding linked "helplines" or linked publications. "Implicit" claims may include product names.
- the context in which the claims are made, and the overall presentation;
- how a product appears to the public, or to those to whom it is promoted;
- the labelling, and packaging/package inserts including any graphics;
- the promotional literature, including testimonials and any literature issued by a third party on behalf of the supplier;

[19] ECJ, "Delattre" (cf. note 10), paras 33-35.

[20] ECJ, C-211/03, C-299/03 to C 318/03 of 9.6.2005, HLH Warenvertriebs GmbH, Orthica BC v Federal Republic of Germany, para. 51; Cf. also ECJ, C-290/90 of 20 May 1992, "Eye lotions", ECR 1992 I-3317, para. 17.

[21] ECJ, C-60/89 of 21.03.1991, „Monteil", ECR 1991 I-1547, para. 24.

[22] Examples partly taken from "A guide to what is a medicinal product", page 6, version April 2003, British Medicines and Healthcare products Regulatory Agency (http://www.mca.gov.uk/inforesources/publications/gn8apr03.pdf).

- advertisements, including those appearing in "advertorials", on television, other media and the Internet; marketing and sales channels

- any particular target of the marketing information/advertising material, for example, population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

28. In applying these criteria, the Court has ruled that "where eosin of a strength of 2% and modified alcohol of a strength of 70% are presented as antiseptic and antibacterial products for the treatment or prevention of infection and lesions of the skin, they come within the definition of medicinal products by virtue of their presentation".[23,24]

(b) 'Second definition' – 'Definition by virtue of function'

29. The Medicinal Products Directive defines in its second definition a medicinal product as "every product that restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action" ('definition by virtue of function').

(i) "Restores, corrects or modifies physiological functions"

30. The main element of the definition of a medicinal product by virtue of function is that the product "restores, corrects or modifies physiological functions". However, almost every product usually perceived as cosmetic product does, in some way or another, modify physiological functions.

31. ***Example:*** Every moisturising cream affects the skin-cells by adding water to the cell. Depilatories and anti-wrinkle-products (cf. annex 1 to the Cosmetics Directive), modify physiological functions by exercising an effect on somatic (skin-)cells.

32. This issue has been addressed by the Court in *Upjohn*[25]:

> "As regards the meaning of 'restoring, correcting or modifying physiological functions', it is clear from the aim of health protection pursued by the Community legislature that the phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body.
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> However, this criterion does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly

[23] ECJ, "Monteil" (cf. Note 21), para. 22 (emphasis added).

[24] Note, however, that disinfectants which do not have such claim of medicinal effect but which are used for a general hygiene purposes may fall under the Biocidal Products Directive 98/8/EC. Cf. the guidance document on the borderline between medicinal products and biocidal products, page 3 (http://europa.eu.int/comm/environment/biocides/pdf/bordermedvet.pdf), and the "Manual of decisions" concerning the Biocidal Products Directive 98/8/EC, chapter 2.1.2.4. (http://www.europa.eu.int/comm/environment/biocides/pdf/mod_040705.pdf).

[25] ECJ, "Upjohn" (cf. note 10).

affect the metabolism and thus do not strictly modify the way in which it functions."[26]

33. Considering that every product that effects the actual functioning of the body has also an affect on its metabolism, it is clear that an insignificant modification of physiological functions does not suffice for the Medicinal Products Directive to apply: Rather, the modification has to be more than insignificant.[27]

34. In application of these criteria, the Court has ruled that "the fact that [a product is] antiseptic and antibacterial […] is not in itself conclusive. Even if the inquiry is restricted to those products which may help to prevent or treat illness, the range of antiseptic and antibacterial products is still very extensive. It includes both ordinary soaps, which no-one classifies as medicinal products, and powerful antiseptics used in surgery which cannot be classified as anything other than medicinal products."[28]

(ii) "By exerting a pharmacological, immunological or metabolic action"

35. The specification of the type of action ("by exerting a pharmacological, immunological or metabolic action") as introduced by Directive 2004/27/EC does, on the one hand, confirm the jurisprudence set out above and covers, on the other hand, medicinal products such as gene therapy, radiopharmaceutical products and certain products for topical use[29].

    It also aims at drawing the demarcation between "medicinal products" and other product categories, including "medical devices" as defined in Art. 1 (2) (a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.[30]

36. The terms "pharmacological", "immunological" and "metabolic" can be defined as follows[31]:

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[26] ECJ, "Upjohn" (cf. note 10), paras 21-22.

[27] This approach is supported by a more recent ruling of the Court where it held with reference to the *Upjohn*-ruling: Cf. ECJ, C-150/00, "Vitamines", 29 April 2004, not yet published in the ECR, para 65. The English translation is not yet available. The French translation reads as follows: „Il est évident qu'un produit qui ne présente pas de risque réel pour la santé peut néanmoins avoir un effet sur le fonctionnement de l'organisme. Pour classer un produit en tant que médicament «par fonction», lesdites autorités devront s'assurer qu'il est destiné à restaurer, à corriger ou à modifier les fonctions de l'organisme et peut, dès lors, avoir des conséquences sur la santé en général."

[28] ECJ, „Monteil" (cf. note 21), para. 25. Note, however, that disinfectants may fall under the Biocidal Products Directive 98/8/EC. Cf. the guidance document on the borderline between medicinal products and biocidal products, page 3 (http://europa.eu.int/comm/environment/biocides/pdf/bordermedvet.pdf), and the "Manual of decisions" concerning the Biocidal Products Directive 98/8/EC, chapter 2.1.2.4. (http://www.europa.eu.int/comm/environment/biocides/pdf/mod_040705.pdf).

[29] Cf. recital 7 of Directive 2004/27. This has been reiterated in the conclusions of the Commission borderline workshop of 28 October 2004: *"the definition of a medicinal product has been made more precise by adding a detailed explanation of the term 'modifying physiological functions'; the classification of medicinal products on a case by case basis will have to be based on these criteria"*.

[30] OJ L 169, 12.7.1993, p.1 as amended. Non-official consolidated version at http://europa.eu.int/eur-lex/en/consleg/pdf/1993/en_1993L0042_do_001.pdf.

"Pharmacological action": 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 which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.

"Immunological action": action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction.

"Metabolic action": action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function. The fact that a product is metabolised *by* the human body does not necessarily mean that the substance contained in the product has a metabolic action *upon* the body.

(iii) NCA have to assess on a case-by-case basis whether a product is a medicinal product 'by virtue of function'

37. Just as for medicinal products 'by virtue of presentation'[32], the ultimate decision whether a product is a medicinal product 'by virtue of function' is to be taken on a case-by-case basis: The Court has repeatedly held that "the national authorities, acting under the supervision of the courts, must proceed on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail".[33]

38. This includes also consideration of the degree of exposure to the substance in question, eg. applied quantity, frequency and size of application, etc.: The ECJ has ruled that "[t]he risk to health […] is an autonomous factor that must also be taken into consideration by the competent national authorities in the context of the classification of the product as a medicinal product by function".[34]

4. THE PRINCIPLE OF NON-CUMULATION

39. In some cases, a product may fall within the definition of both a cosmetic product and a medicinal product.

40. ***Example:*** A product treating natural baldness may fall under the definition of both cosmetic product and medicinal product: Cosmetic product, as it is placed on external parts of the human body with a view to changing the appearance of this part

[31] Cf. MEDEV guidance document 2. 1/3 rev 2 July 2001, page 3: http://europa.eu.int/comm/enterprise/medical_devices/meddev/2_1_3____07-2001.pdf

[32] Cf. *supra* 3.2 (b), 3.3 (a).

[33] ECJ, HLH Warenvertriebs GmbH (cf. note 20), para. 51; cf. also ECJ, C-290/90 of 20 May 1992, "Eye lotions" (cf. note 20), para. 17.

[34] ECJ, HLH Warenvertriebs GmbH (cf. note 20), para. 53.

of the body. Medicinal product, as this product may modify physiological functions of the body in a more than insignificant way.

41. In these cases, the question arises whether both regimes apply or if one regulatory framework prevails. This issue is addressed by the principle of non-cumulation (cf. *supra* 2.2):

42. Art. 2 (2) of the Medicinal Products Directive sets out that

> "In cases of doubt, 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 of this Directive shall apply."

43. Art. 2 (2) of the Medicinal Products Directive intends to reflect the non-cumulation principle as set out by the Court in the *Upjohn*-ruling:

> "Even though it may fall within the definition in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a 'medicinal product' and subjected to the relevant rules if it is presented for treating or preventing disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions."[35]

44. The non-cumulation principle excludes the possibility that both regulatory regimes apply cumulatively to the same product: If a products falls within the definition of both, medicinal product *and* cosmetic product, the non-cumulation principle provides that the Medicinal Products Directive is applicable.[36]

45. However, the wording of Art. 2 (2) of the Medicinal Products Directive shows that the principle of non-cumulation only applies if, after a case-by-case assessment, taking in consideration all the characteristics of a product (cf. *supra* 3.), it is clear that the product in question falls within the definition of both, cosmetic product and medicinal product.[37] Art. 2(2) of the Medicinal Products Directive does not deprive the NCA of the obligation to make a detailed assessment whether the product falls *only* under the definition of medicinal products or *only* under the definition of cosmetic products.

[35] ECJ, "Upjohn"(cf. note 10), paras 30, 32; Cf. also ECJ, "Delattre" (cf. note 10), para. 22).

[36] As concerns medicinal products by virtue of presentation, this is also set out in recital 5 of the Cosmetics Directive which sets out that the Cosmetics Directive "is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease".

[37] This reading has been confirmed recently by the Court in a ruling concerning the demarcation between the legislation for food and medicinal products: "Only the provisions of Community law specific to medicinal products apply to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product." (ECJ, "HLH Warenvertriebs GmbH, (cf. note 20), operative conclusions 2, cf. also paras 43, 44).

46. The wording “in cases of doubt” do not add further prerequisites for the principle of non-cumulation to apply. Rather, the wording reflects the case-law set out above and in particular the *Upjohn*-ruling[38].

5. ADMINISTRATIVE COOPERATION

47. Decisions are to be taken by individual Member States on a case-by-case basis. It is therefore crucial for NCA’s to inform each other about decisions taken to avoid conflicting approaches in the single market. The Commission does encourage administrative cooperation with a view to exchange information on decisions taken by NCA’s.

[38] Cf. ECJ, “Upjohn” (cf. note 10), para 30.