ENQUIRY TO
MEDICAL DEVICE COMPETENT AUTHORITIES

according to the draft procedure discussed at the 4th Medical Devices CA Meeting in Helsinki

Problem :	**Changes to regulatory control resulting from the new definition of a medicinal product**.	
Originator:	MHRA, United Kingdom	
Contact person :	Clare Headley	
E-mail : clare.headley@mhra.gsi.gov.uk		Fax : +44 207 972 8112
Circulated :	26/5/04	**Updated summary V4 14/9/05**

S U M M A R Y – update 4

Original Description of the problem

1. As you may be aware, the definition of a medicinal product is changing. The new definition will be effective as of October 2005.
2. In the light of this change, MEDDEV 2.1/3 will need to be revised and we will be requesting the Commission to look in to this as a matter of urgency.
3. In conjunction with our colleagues in the Medicines Section, MHRA Medical Devices has undertaken an exercise to identify products that might change regulatory control as a result of the change to the definition of a medicinal product.
4. We have identified a selection of products that are currently medicinal products, which, in the light of the new definition may come within the remit of the Medical Device Directives. We have not identified any products so far, which are currently devices that might become medicines.
5. For reference the new definition of a medicine is as follows:
   i) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
   ii) 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.

   Note that the following is also included in the revision of the medicines directive:

   "In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a product covered by other Community legislation the provisions of this Directive shall apply."
6. We are requesting your views on the products that we have identified as likely to change regulatory control. Please provide your opinion on the products listed below in the light of the definition of a medical device and the new definition of a medicinal product ONLY. Please do NOT refer to MEDDEV 2.1/3, since this requires revision in the light of the change in definition.
7. As this is a complex issue, the usual format for these enquiries has been amended slightly into a tabular format, providing details of the product groups, potential device classification, the UK view and rationale. We request that you mark the appropriate box 'agree' or 'disagree' and provide any further comments in the same box.
8. You may wish to consult with your colleagues in your Medicines Competent Authority with respect to this matter. Combined responses would be welcomed.

UK Position as consensus statement:

This enquiry was not intended to develop a definitive position on the regulation of these products. It was intended as a starting point for discussions for the revision of MEDDEV 2.1/3 in the light of the new definition of a medicine and to see if there was general consensus on the products identified so far as potentially moving regulatory control.

There appears to be general agreement on a number of the products mentioned in this enquiry, which is a positive result. Other products which require clarification when the MEDDEV is revised have also been mentioned, for example the definition of in vivo diagnostic agents, the regulation of certain products used in the IVF process and the classification of agents for transport , nutrition and storage of organs for transplantation. There may well be additional products that have not yet been identified.

It would be useful if Member States could advise MHRA of any additional products that they consider might change regulatory control.

Some Member States are still awaiting input from their Medicines Competent Authorities: Of these, some have provided provisional responses, whilst others have not yet replied as they wished to provide a combined response.

Since this is a complex issue, if you have not yet responded to this enquiry, please do so once you have considered the issues - we will issue updates to this summary as the responses are received.

We propose that this issue be moved forward as a matter of priority (since the new definition of a medicine becomes effective in October 2005). An initial discussion at the Classification meeting in June had been intended, however we propose that a working group be set up as a matter of priority to revise MEDDEV 2.1/3. The UK would be pleased to take an active role in this group.

<u>Additional products mentioned to date:</u>

In vivo diagnostic agents
Agents for transport , nutrition and storage of organs for transplantation
Regulation of certain products used in the IVF process
Aqueous eosin solution
Active coal solution
Lissamine strips (Opthalmic)

Questions	**<u>Artificial tears</u>**. **Currently regulated as medicinal products. Proposal to regulate as medical device** Typically indicated for dry eye syndrome. Simple lubricant action. Would simplify borderline as some products (e.g. those for use with contact lenses) are already devices. Some Competent Authorities may already allow dry eye products as devices	**<u>Alcohol Swabs</u>**: **Currently regulated as medicinal products. Proposal to regulate as medical device** Wound Cleansers and Preinjection Swabs: Mode of action is not pharmacological, immunological or metabolic. They are simple products that are already controlled as medical devices in some member states.	**<u>Antiseptic Swabs</u>** (e.g. containing iodine, chlorhexidine) **Currently regulated as medicinal products. Proposal to retain as such.** Wound Cleansers and Pre-injection Swabs: Active constituent acts not on the body but on the micro-organism, however it is currently accepted that antimicrobials are medicinal substances when used for treatment of human disease. Mode of action is not a simple chemical action. Because of the difficulty in drawing a line between these and other topical disinfectants, the products should remain as medicines.
MAJORITY VIEW	**Agree: 13 Disagree: 4 Depends:**	**Agree: 3 Disagree:** 9 **Depends: 5**	**Agree: 12 Disagree: 2 Depends: 3**
Belgium	we agree but think that the class must be clearly defined. If you consider that the use is transient it is a class I. This would be unconsistent with solutions for contact lenses that are class IIb according rule I5. For the same reason it makes no sense class artificial tears in class IIa. We would prefer also the words EYE DROPS because some manufacturers pretend their eye drops are not artificial tears and classify these at will. We need to be aware that by deciding against the borderline guideline we leave the door open for other similar interpretations: according the same logic one could decide to put plasma expanders on the market as medical devices. We need to solve this problem	Agree for cleaning swabs, but not for preinjection swabs with disinfection claim	Depends on the intended use. We suggest to take into consideration documents such as the "manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products" of 30/03/2005 The proposed decision would be contradictory with the status of existing products such as Inadine (antiadhesive dressing pads impregnated with 10% povidone-iodine and CE marked as medical devices)
Czech Republic	We agree on condition that if a product contains any medicinal substance, this substance will have only an ancillary action.	We do not see any difference between alcohol and other antiseptics because alcohol is also a bactericidal antiseptic and disinfectant	We agree. But antiseptic swabs, including alcohol swabs, should be classified as medical devices incorporating a medicinal substance as an integral part.
Denmark	Agree – where it is clearly stated the purpose is solely for lubrication ie a physical action.	Questionable – discuss at MEDDEV further to achieve a clear consensus. May be better to manage such products under the similar category of "Antiseptic swabs", see next entry, due to	Agree.

		similarity etc.	
Estonia	Yes If just lubricating function, then the mode of action is device-like. Agree, that it simplifies borderlines.	No. Killing bacteria on or in human body seems to act on metabolism of these. Also: very complicated demarcation line seems to appear, e.g. antibiotics, mixtures of alcohol with something etc.	Yes
Finland	Agree, in future artificial tears could be classified as medical devices, at present artificial tears are classified as medicinal products.	Agree with theory, but classification should be settled on case-specific consideration taking into account -intended purpose and -concentration.	Agree with theory, but classification should be settled on case-specific consideration taking into account -intended purpose and -concentration
France	Agree The class would be III if a component has an accessory pharmacological action	Disagree Medical device class III in reason of antiseptic action of alcohol or medicinal product if principal intended use is the action of alcohol However, we have to take into account the implementation of directive 98/8/CE	Disagree Medical device class III in reason of antiseptic action of antiseptic or medicinal product if principal intended use is the action of antiseptic However, we have to take into account the implementation of directive 98/8/CE
Germany	Disagree, retain as medicinal product. The mode of action is not pharmacological or metabolic but best served by medicine classification. If artificial tears were not considered to be medicinal products they would usually become only class I medical devices (in contrast to care solutions for contact lenses which are class IIb according to rule 15).	Disagree, retain as medicinal product. Alcohol Swabs are also topical disinfectants like the "Antiseptic Swabs" listed below.	Agree
Greece	Disagree (they could better served by medicine classification)	Disagree, skin disinfection is their principle intended purpose. Therefore should be categorized similarly to antiseptic swabs below	Agree
Holland	Device	Or a biocide because it purpose fit not within the definition of a medical device. On the body of the patient: medicinal product On the hands of the doctor: biocide For disinfection in general: biocide As an accessory to a medical device: a medical device. For demarcation between medical devices and biocides: see also the 'manual of decision of implementation of Directive 98/8/EC.	Agree

Ireland	Disagree retain as Medicine	Disagree retain as a Medicine The principle intended purpose is to disinfect the skin, like antiseptic swabs below. Therefore should be categorised similarly.	Agree as Medicine
Italy	Agree:it has mechanical mode of action (alternatively: physically it's obtained reintegration of physiological function of eye lubrification)	Agree: if the function of the product is the cleaning of wounds without disinfecting, at least as primary function : Note: in Italy the product could be authorized as "medico-surgical defense" (= "presidio medico chirurgico, PMC) if used only as preinjection device	Agree, if antiseptic function is the main one (see above) For preinjections use could be PMC (see above)
Norway	Agree	Agree	Agree
Portugal	Agree. Only if it is possible to have an exception on classification rules for medical devices non chirurgical to be used on eyes; once comfort solutions for lens care are class IIb then the artificial tears only with an lubricant action also should be class IIb.	Disagree. The alcohol has disinfecting properties, it can only be considered a medical device if its intended use is for disinfecting a medical device. ?	Agree.
Spain	Disagree: Medicinal product. Dry Eye Syndrome is considered a disease (1)	Disagree: Medicinal product. Dry Eye Syndrome is considered a disease (1)	Agree: Medicinal product, as wound cleansers. Disagree: Biocide used for personal hygiene purposes, according to biocides directive, as preinjection swabs.
Slovenia	Agree	Disagree We do not see any reasons for different classification for alcohol and antiseptic swabs (alcohol has an antimicrobial mode of action as well). If disinfectants are used on intact skin they should be on the market as biocides. As wound cleansers they should be classified as medicinal products	See comments for alcohol swabs
Sweden	**Medical Device.** A more generic designation should be used e.g. dry eye syndrome products instead of artificial tears	Pre injection swabs containing alcohol shall be regulated as **medical device**.	**Medicinal product.** This group shall also include products containing chlor-hexidin.
Switzerland	Agree	Agree for cleaning swabs, but not for preinjection swabs with disinfection claim	Agree

Questions	**Fluoride Toothpastes, mouthwashes and brushing gels** **Currently regulated as medicinal products.** **Proposal to retain as such** Prevention of Caries Mode of action may be argued to be chemical but as fluoride is incorporated into dental enamel, a metabolic action is more appropriate. If fluoride was not considered to be a medicinal substance then products incorporating it would become class I medical devices. This means there would be no third party evaluation of fluoride dose, which has public health implications for children.	**Fluoride Varnishes:** **Currently regulated as medicinal products.** **Proposal to retain as such** Prevention of Caries As now, varnishes that provide a physical barrier would be classified as devices and any that are claimed to act mainly through the delivery of fluoride would be classified as medicines	**Tooth Desensitisers:** **Currently regulated as medicinal products.** **Proposal to retain as such** Desensitising teeth: No consensus on mode of action in the literature. Physical blocking of dentine tubules and metabolic effects on nerve transmission are both mentioned. Most products also contain fluoride so in practice many will have to remain as medicines. However those containing low levels of fluoride would be exempt from medicines control as now.
MAJORITY VIEW	**Agree: 15 Disagree: Depends: 2**	**Agree: 13 Disagree: Depends: 4**	**Agree: 10 Disagree:** 3 **Depends: 4**
Belgium	Agree but see borderline with cosmetics according the concentration	Agree	Agree
Czech Republic	We agree, but it is necessary to take into consideration that if fluorides concentration is max. 0.15 % in a product, then the product meets requirements of the Directive 76/768/EEC and can be classified as a cosmetic one. Over this border – medicinal product.	We agree – medicinal product or device depending on mode of action	We agree.
Denmark	Agree – the stated mode of action by the manufacturer is important. Caution is required here with respect to the product falling within the scope of the Cosmetics Directive.	Agree – the stated mode of action by the manufacturer is important.	Agree
Estonia	Yes	Yes	Yes
Finland	Agree, retain as medicine. National Agency for Medicines classifies "strong product" (depending the amount of fluorides) as medicinal products. Could be classified as cosmetic product, if fluorides concentration is max. 0,15 % in the product.	Agree.	Disagree, these products have the same mode of action as fluoride varnishes. Primarily medical devices.
France	Agree	Agree	Disagree This category of products could include dentine adhesives, which purely act by blocking dentine

			tubules (physical).
Germany	Agree, as far as those products are not covered by the cosmetics products directive (primarily intended for cosmetic purposes and fluoride level less than 0,15 %).	Agree, however we would like to emphasize that fluoride varnishes usually are intended for the delivery of fluoride (like fluoride gels or mouth rinses) but do not provide a durable physical barrier.	Disagree. According to our knowledge, dentine adhesives are one group of desensitizers. Their primary mode of action normally is blocking of the dentine tubules. Hence, these products are currently marketed as medical devices in Germany; this should be retained.
Greece	Agree	Agree	Agree
Holland	Disagree: Could also be a cosmetic depending on the concentration and purpose.	Agree	No opinion
Ireland	Mouthwash : Agree as Medicine Note: mouthwashes that do not make a claim other than plaque removal/caries prevention, containing up to 1500ppm F may be regulated as cosmetics here. Brushing gels and toothpastes may be cosmetics, however if there is a medical claim like – for treatment of dry mouth these products may be medicines.	Agree, either a medical device or medicinal product depending on mode of action.	Agree as medicine, if metabolic action. However, these products could be MDs if the action is purely physical.
Italy	Depends. Some manufacturers claim that fluoride links to the dental enamel through a physical link (electrical charges should be involved);this mechanism has to be demonstrated.	Depends. Some manufacturers claim that fluoride links to the dental enamel through a physical link (electrical charges should be involved);this mechanism has to be demonstrated.	If doubts persist an mode of action, the product should remain as medicinal product (art. 2.2 of the directive 2001/83 as modified by dir 2004/27)
Norway	Agree, provided not falling within the cosmetics directive. We believe the mode of action should be decisive for the classification, and not the question of Notified Body involvement or not. If the latter should be decisive, it implies we find the classification rules under medical devices not to be adequate	Agree	Agree
Portugal	Agree.	Agree.	Agree. Tooth desensitisers having for instance K^+ block the nerve transmission acting by pharmacological means.

Spain	Depends on concentration of fluoride, its indication and its application. Some of them are medicinal products; others (at lower concentrations) are personal hygiene products, according to Spanish national legislation. (3) Others are cosmetics, as long as concentrations of fluoride and indications correspond to cosmetics legislation. Caries is not a disease.	Agree: Medical device, as physical barrier. Hiperfluoride gels, personal hygiene products, according to Spanish national legislation. (3)	Depends on concentration of active substances, its indication and its application. Some of them are medicinal products; others (at lower concentrations) are personal hygiene products, according to Spanish national legislation. (3)
Slovenia	Agree Currently they are on the market also as cosmetics (depending on the claims)	Agree	Agree, Currently they are on the market also as cosmetics.
Sweden	Toothpastes, mouthwashes and brushing gels, whose intended use is to clean**,** should be regulated as **cosmetic product**[1]**.** If the concentration of fluorine is above 0.15% the product shall be regulated as a medicinal product as it is today. [1] Directive 76/768/EEC on the approximation of the laws of the member states relating to cosmetic products	**Medical device or medicinal product** depending on intended use. as it is today.	**Medicinal product/Medical device/ Cosmetic product** depending on intended use, composition and mode of action. There are toothpastes on the market today with this intended use regulated as cosmetic products.
Switzerland	Agree	Agree	Agree

Questions	**<u>Corn Plasters with Salicylic Acid</u>:** **Usually regulated as medicinal products.** **Proposal to retain as such** Corn/Callous/Verruca Removal Chemical action on skin - a different mode of action from use of salicylates as analgesics. Some products containing salicylic acid, presented specifically for pressure relief, with no claims to 'removal' have been accepted as medical devices and are CE marked as Class III medical devices. With the change in the definition of a medicinal product, however, if salicylic acid if not considered to be a medicinal substance, such products would be Class I medical devices.	**<u>Water for Injection & Saline</u>** **Currently regulated as medicinal products.** **Proposal to retain as such** Small volume Solvent for parenteral powders and large volume for dehydration Mode of action not pharmacological or metabolic but best served by medicine classification**.**	**<u>Antacids</u>** **Currently regulated as medicinal products.** **Proposal to retain as such**. Dyspepsia etc Theoretically a simple chemical action but potential metabolic side effects. European Commission has indicated in meetings that they do not foresee a change to the regulation of this group
MAJORITY VIEW	**Agree: 12 Disagree:** 3 **Depends: 2**	**Agree: 17 Disagree: Depends:**	**Agree: 17 Disagree: Depends:**
Belgium	Agree	Agree but legally enforceable document needed. Meddev not sufficient	Agree
Czech Republic	We agree.	We agree.	We agree.
Denmark	Agree	Agree	Agree
Estonia	Yes	Yes Water for injection seems to have an intended purpose to be metabolised with the medicine. Water soluble medicines usually are not 'pure' or 'independent' medicines and carrier water, but form complexes of medicines with water, except suspensions.	Yes Purposeful changing of pH inside the body (including digestive tract) seems to be an action to change metabolism – if not a pharmacological action.
Finland	Corn plasters containing salicylic acid, presented for the primary intended purpose of corn removal should be regulated as medicinal products. Corn plasters containing salicylic acid, presented for the primary intended purpose of pressure relief may be regulated as medical devices (with medicinal substance ancillary action).	Agree	Agree

France	Agree	Agree	Agree
Germany	Agree	Agree	Agree
Greece	Agree as medicine, the principle intended purpose is to deliver the salicylic acid	Agree as medicine	Agree as medicine
Holland	NO it is a direct action of salycilic acid as a substance because other derivates don't have the same action. (Jos Kraus Pharmacist) Agree: Its primary action is the removal of the skin by salicylic acid. Plasters do have no keratolytic power. The plaster is just the vehiculum to keep the salicylate on the place of action.	Agree for historical reasons	Agree: For historical reasons.
Ireland	Agree as Medicine, principle mode of action is delivery of salicylic acid	Agree as Medicine as it is intravenous substance	Agree as Medicine
Italy	DEPENDS. MD if salicylic acid acts only in chemical means (as "peeling" agent). Only if not, or if doubts persist on mode of action, the products should be classified as medicinal product (see above:desensitising teeth)	Agree	Agree
Norway	Disagree. Our position is in line with the Norwegian Medicines Agency who does not classify these products as medicinal products today and propose likewise with the new definition. And again we believe the mode of action should be the decisive element, not into which class of medical devices the products would fall	Agree	Agree
Portugal	Agree. The classification as medicinal product should be retained, if the device intended purpose is obtained trough the salicylic acid., once salicylic acid is a medicinal substance with pharmacological action. ?	Agree.	Agree.
Slovenia	Agree We consider Salicylic Acid to be a medicinal substance, thus such products can`t be classified as class I medical devices. Considering the chemical/pharmacological action of salicylic acid on the skin corn/callous/verruca removal plasters should be	Agree	**Agree**

	classified as medicinal products.		
Spain	Disagree. Medical devices, according to their mode of action. They modify anatomy, don't treat a disease.	Agree. Medicinal product, because they are part of administered medicinal product or they are themselves medicinal products used to treat a disease. (1)	Agree. Medicinal product, because its purpose is to treat a disease. (1)
Sweden	**Medical device** when no pharmacological effect is claimed otherwise **medicinal product.**	Agree. Retain as **medicinal product**.	Agree. Retain as **medicinal product**.
Switzerland	Agree	Agree	Agree

Questions	**Alginates** **Currently regulated as medicinal products.** **Proposal to retain as such** Dyspepsia etc Physical barrier to prevent/reduce gastric reflux. Products usually also contain antacids, as above European commission has indicated that they do not foresee a change in product regulation in this group.	**Peritoneal Dialysis Solutions** **Currently regulated as medicinal products.** **Proposal to retain as such** Large volume parenteral fluid which act osmotically. Arguably this might be regarded as inducing a metabolic effect but there could be differences of opinion on this. There is no difference in mode of action between peritoneal and haemodialysis solutions (which are regulated as devices) but the latter are not infused into the body.	**Non-Medicated dermatological creams** **Currently regulated as medicinal products.** **Proposal to regulate as medical device** Barrier Creams Physical barrier to moisture and body fluids Emollients for use in eczema/dermatitis Rehydrates skin In both cases there is no pharmacological, metabolic or immunological action.
MAJORITY VIEW	**Agree: 15 Disagree:** 1 **Depends: 1**	**Agree: 15 Disagree: Depends: 2**	**Agree: 12 Disagree:** 2 **Depends: 3**
Belgium	Agree	Agree	Agree
Czech Republic	We agree.	We agree.	We agree in essence, but we prefer case by case decision depending on composition and intended use and claims. Some of these products comply with Directive 76/768/EEC and are classified as cosmetic ones.
Denmark	Agree	Agree	Agree – where it is clearly stated the purpose is solely as a physical barrier ie a physical action. There should be no text on labelling/IFUs which directly or indirectly infers any pharmacological action.
Estonia	Can be a device	Can be a device	Is not a device, rather cosmetics. Or a general product, as hand- kerchief in the case of rhinitis
Finland	Agree	Agree, but could also be classified as medical devices.	Agree.
France	Agree	Agree because there is a significant difference: the haemodialysis solution acts with the haemodialysis filter	Agree Except if intended to be applied on a healthy skin. In this case, it would be cosmetic products.
Germany	Agree	Agree	Agree
Greece	Agree as medicine	Agree as medicine	We agree as medical device only if it acts as Physical barrier to moisture and body fluids or as Emollient for use in eczema/dermatitis. In both cases there is no pharmacological,

			metabolic or immunological action.
Holland	Agree: For historical reasons	Agree: For historical reasons	Device
Ireland	Agree as Medicine	Agree as Medicine	Agree as Medical Device if it is a physical barrier and has medical claims. Otherwise they may be a cosmetic. If products have pharmacological, metabolic or immunological action, they are medicines. Emollient creams/ointments being promoted for eczema/psoriasis would be considered as medicines - if only dry skin, or as adjuncts these products may be cosmetics.
Italy	Disagree. If the products don't contain antacids but only antireflux substances (as alginates) it should be classified as MD (no absorption or metabolic side effects)	Agree (see above, water for injection & saline)	Agree, if only barrier or rehidratation claims
Norway	Agree	Agree	Agree
Portugal	Agree.	Agree.	Agree. But non-medicated dermatological creams can only be considered medical devices if they have a medical purpose; the claim - rehydrates skin – is not enough to be considered a medical device, in this case it should be classified as cosmetic. Only creams with a medical purpose (ex: scars, eczema, dermatitis) should be classified as medical device.
Slovenia	Agree If the product contains antacids, it should be classified as a medicinal product, otherwise, according to the mechanism of action (a physical barrier), it could be classified as a medical device.	Agree	Disagree Currently they are on the market as cosmetics and as medicinal products (depending on claims) - we wouldn`t classify them as medical devices
Spain	Agree. Medicinal product, because its purpose is to treat a disease. (1)	Agree. Medicinal product, because its purpose is to treat a disease. (1)	Depends on its indications. It could be medical device if related to pathological conditions or benefits in health. Otherwise, cosmetics, as long as concentration and indications correspond to cosmetics legislation.

Sweden	Agree. Retain as **medicinal product**.	Agree. Retain as **medicinal product**.	- Barrier cream for which no medical claims are made shall be regulated as **cosmetic products**. - Barrier cream/Emollients for which medical claims are made shall be regulated as **medicinal products**, if the mode of action is of pharmacological nature otherwise as **medical devices.**
Switzerland	Agree	Agree For historical reasons	Agree

Questions	**Medical Gases** **Currently regulated as medicinal products.** **Proposal to retain as such** Various uses by inhalation such as anaesthesia and potentially lung function It is understood that sections of the medical gas industry believed these could be devices. Clearly a metabolic/pharmacological mechanism of action and no possibility of a move to device control. Tissue separation during surgery In theory these would be medical devices but MHRA is not aware of any gases used only for this purpose	**Zinc Oxide** **Currently regulated as medicinal products.** **Proposal to regulate as medical device** Often used on bandages and in various non medicated barrier creams Some CA's already accept zinc oxide bandages as medical devices. No pharmacological action.	**Aluminium sulphate / salts.** **Currently regulated as medicinal products.** **Proposal to regulate as medical device** Used in dental applications as an astringent Probable action is by precipitation of proteins.
MAJORITY VIEW	**Agree: 16 Disagree: Depends: 1**	**Agree: 9 Disagree:** 1 **Depends: 6** **No comment: 1**	**Agree: 11 Disagree: 5 Depends: 1**
Belgium	Agree for medical gases with pharmacological action such as oxygen or anaesthetic gases but not for other medical gases for example CO2 used to inflate the abdomen for laparoscopy or gas used for tissue separation. These would be medical devices	(no comment made)	Disagree Astringent action is a precipitation of cell proteins.
Cech Republic	We agree – medicine	Zinc oxide has also an antiseptic effect. Therefore, we prefer case by case decision depending on composition and intended use and claims because, in general, products with zinc oxide can be medical devices or medicinal or cosmetic ones.	We agree – medical device
Denmark	Agree Agree with the theory.	Agree – where it is evident that no pharmacological claims are stated or implied.	Agree – where it is evident that no pharmacological claims are stated or implied.
Estonia	Yes	Depends of intended purpose. If not intended to release zinc oxide, e.g. into the wound cavity to kill the bacteria, but just to inhibit the growth in or on bandage, then it is a device. Zinc oxide cream seems to have pharmacological purpose.	No Chemical interaction with body proteins seems to form a basis of majority of pharmacological actions. Can be a general product or cosmetics, if used on the surface of body.

Finland	Agree.	Agree-if no pharmalogical claims are stated or implied.	Agree.
France	Agree For use by inhalation, because gases are inhaled for metabolic action (breathing) Agree with theory	Agree if zinc oxide has not pharmacological action but it seems it's not the case	Agree
Germany	Agree	(Agree) with 2 reservations: 1. Zinc ointments and creams with a medical purpose (wound treatment) should be retained as medicinal products because pharmacological or metabolic effects (enzymic processes, support of wound granulation) are also published. According to article 2, paragraph (2) of the amended Directive 2001/83/EC in cases of doubt … this Directive shall apply. 2. Zinc ointments and creams can also be covered by the cosmetics products directive.	Disagree, retain as medicinal product. The astringent action can also be interpreted as pharma-cological in the broader sense (interaction with a cellular constituent). According to article 2, paragraph (2) of the amended Directive 2001/83/EC in cases of doubt … this Directive shall apply.
Greece	We agree as medicines	Depends. It is preferable to have a case by case evaluation. It could be medical device or medicinal product or cosmetic depending on the intended use and mode of action	We agree only if it is evident from the scientific documentation that the mode of action is not pharmacological
Holland	CO2 is used to inflate the under part of the body during MIC. And therefore a medical device. It is in the margin and therefore we consider it as a medicinal product. Compressed air for equipment in the OR could be considered as an accessory to a medical device	Medical device is in line with the definition	Agree
Ireland	Agree as Medicine	Disagree, retain as medicine, but open to debate.	Disagree. Retain as Medicine Aluminium sulphate used in styptics-stops bleeding by stimulating clotting-metabolic action therefore this would be a medicinal product.
Italy	Agree	Agree	Agree
Norway	Agree	Agree	Agree
Portugal	Agree.	We consider that the zinc oxide used in bandages can be considered medical device, if the zinc oxide had only an ancillary action of the	It only could be considered medical device if there is scientific data which proves that the mechanism of action is not pharmacological.

		bandage. Zinc oxide used on non-medicated barrier creams could only be considered medical device to be used on intact skin as a mechanical barrier to prevent for example dipper redness. If the zinc oxide is to be used on skin lesions it only could be considered medical device if it was scientific and clinical data that its action is not pharmacological.	
Slovenia	Agree Such classification is in accordance with CPMP/QWP/1719/00 Note for guidance on medicinal gases	Agree The classification depends on what is the primary purpose of the product. If Zinc Oxide is added to a medical device to achieve an action which is ancillary to the principal mode of action of the medical device, the product should be classified as a medical device.	Disagree We consider the precipitation of proteins as a chemical mechanism of action, thus Aluminium Sulphate, when used alone, cannot be classified as a medical device.
Spain	Agree. Medicinal products, because they are administered with the purpose of "in vivo diagnosis" (2)	Agree, Medical Devices	Agree, Medical Devices
Sweden	Agree. Retain as **medicinal products**.	**Medicinal product /Medical Device /Cosmetic product** depending on intended use and mode of action	**Medical Device**
Switzerland	Agree	Agree, if no pharmacological claims are stated or implied	Agree, the definition (art. 1,b,2,b of 2004/27/EC) must be considered, but effect is not metabolic or pharmaceutical. Therefore the product should be a medical device. Other such products containing adrenalin as active ingredient, these will stay as medicinal products.

Additional rationale and remarks

Italy:
We don't consider that the discussion on the new medicinal directive 2004/27 implications should be solved with the usual "enquiry" system. We make a proposal to conduct an in-depth analysis on the text of that directive (preamble and definitions above all) during next July MDEG meeting to define its real purpose and scope, with the aim to reach a consensus. So, this form has be filled only as a contribution to, or a starting point for, the discussion: actual opinions might be reconsidered depending on the interpretation of the new definitions, that should be clearly explained by Commission. In fact, we consider that some areas of overlapping between medicinal products and MD definitions persist.

Sweden:
Due to the new definition of medicinal products Läkemedelsverket finds it important to update/revise the borderline document MEDDEV 2.1/3 as soon as possible. This Enquiry has taken up a number of important issues. There are more classification issues to discuss such as is x-ray contrast media a true in vivo diagnostic device (the x-ray instrument certainly is) or an accessory. A clearer standpoint in the classification of agents for transport, nutrition and storage of organs intended for transplantation is needed. How to classify solutions, media and products/devices used in in vitro fertilization?
The Swedish comments have been prepared by experts within Läkemedelsverket on the legislation for medical devices, medicinal products and cosmetic products.

Norway:
We have forwarded your inquires to the Norwegian Medicines Agency who will come back to us at a later stage. This means we have not discussed thoroughly and our opinions given should be regarded as preliminary.
We think it is important to discuss what is the purpose of the new definition, e.g. what should be decisive for what is/is not a medicinal product, and we would like to propose a discussion at the Borderline/Classification meeting late June.

Hungary:
Many thanks for providing us with information regarding the new directive concerning medicines. The change of definition can really influence the borderline issues of medical devices.
The Authority for Medical Devices is not intended to vote in the questions you sent in a table form. We are willing to accommodate the decision of the Meddev Sector.

Holland:
The answer is still under internal consultation. I can send you my answer but not the official Dutch position.

Spain:
The first dash in the definition of medicinal products does not make a difference regarding mode of action, therefore it seems that any substance or combination of substances whose purpose is the treatment, alleviating or preventing of a disease is considered medicinal product, without taking into account its mode of action in achieving this purpose. The critical factor, in our opinion, is to reach an agreement about which is considered disease and which is not.
The second dash in the definition of medicinal products only makes a difference regarding mode of action of substances that act on physiological functions, but not substances whose purpose is a medical diagnosis. So, it seems that any "in vivo" diagnostic means is considered a medicinal product, without taking into account its mode of action.
In Spain, personal hygiene products are defined by law as "substances or preparations that, without having a legal consideration of medicinal products, medical devices, cosmetics or biocides, are to be applied on the human skin or mucosae with hygiene or estetic purposes, or to neutralize or eliminate ectoparasites". These products are not regulated by harmonizing directives. Some of them are dental whiteners, peelings, tattoo inks, permanent makes up, fat-loss patches, vaginal moisturizings, hyper fluoride toothpastes, anti louse products, etc.

France:
We would like to add some others products in these considerations: eosin, active coal solution, lissamine strips subject of recent enquiries