Council of the European Union

Brussels, 21 December 2015
(OR. en)

Interinstitutional Files:
2012/0266 (COD)
2012/0267 (COD)

12800/15
ADD 3 REV 3

LIMITE

PHARM 42
SAN 326
MI 616
COMPET 447
CODEC 1310

NOTE

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and medical devices
No. prev. doc.:	12401/15 PHARM 40 SAN 301 MI 588 COMPET 426 CODEC 1251
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices**

In line with the information provided at the Working Party on Pharmaceuticals and Medical Devices on 14 December 2015, delegations will find attached the revised addendum 3 to the 'Block 1' document (Chapter I Scope and definitions) setting out the state of discussion with the European Parliament under the Luxembourg presidency.

Delegations are invited to **inform via e-mail the Presidency (at h.koppenaal@minvws.nl) and the Council Secretariat (at secretariat.pharmaceuticals@consilium.europa.eu) at the latest on 13 January 2016** if they have any objections to the Presidency Proposals/ Compromise text.

Changed text compared to document 12800/15 ADD 3 REV 2 is found in Article 2(3) IVD.

In this version, only definitions that belong to 'Block 1' have been included. IVD-specific definitions and other definitions belonging to other 'blocks' have been moved to the corresponding blocks.

Block 1 consists of the following elements:

- Recitals (1) to (30) and (32) to (33) of the proposed Regulation on medical devices	Set out in 12800/15 ADD 1
- Recitals (1) to (26) of the proposed Regulation on *in vitro* diagnostic medical devices	Set out in 12800/15 ADD 2
- Chapter I of both proposals and Annex XV of the proposed Regulation on medical devices.	Set out in 12800/15 ADD 3 REV 2
- Chapter II except Article 15 of both proposals	Set out in 12800/15 ADD 4 REV 1
- Chapter V, Section I of both proposals	Set out in 12800/15 ADD 5.
- Annex I of both proposals	Set out in 12800/15 ADD 6.
- Annex II both proposals	Set out in 12800/15 ADD 7.
- Annex III and IV of both proposals	Set out in 12800/15 ADD 8.
- Annex VII of the proposed Regulation on medical devices	Set out in 12800/15 ADD 9.
- Annex VII of the proposed Regulation on *in vitro* diagnostic medical devices	Set out in 12800/15 ADD 10.

Explanation of the document layout

X. This paragraph is neither changed by the European Parliament nor by the Council. It is written in plain text, which throughout the text means that it is identical to the Commission proposal and unless it is specifically pointed out it is the same for MD and IVD.

X. This slightly different paragraph is neither changed by the European Parliament nor by the Council. It is written in plain text, which throughout the text means that it is identical to the Commission proposal and since it is from the IVD proposal, it comes after the corresponding MD provision.

Where needed, provisions are preceded by indications **MD** or **IVD** to make clear to what proposal a certain text element belongs.

Where an Article or Section in the MD proposal directly corresponds to an Article or a Section in the IVD text but with another number, this is also indicated.

Please note that the numbering of paragraphs, sections and points is not always continuous since text elements that did not belong to the original Commission proposal have sometimes been deleted. As an example paragraph 1a might be followed by paragraph 1c. This is the result of deletions of text elements at a late stage. It was deemed that references might become incorrect if a renumbering was done at this stage.

Text that is amended by either the EP or the Council occurs in tables

Article Y Z. This paragraph is text from the MD proposal ***changed by the Council (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text). ***Elements to note are highlighted in grey.***	**Amendment W** Article Y Z. This paragraph is text from the MD proposal ***changed by the European Parliament (added text in bold italics*** and deleted text in ~~strikethrough~~ compare Council text). ***Elements to note are highlighted in grey***
IVD - Article U T. This paragraph is text from the IVD proposal ***changed by the Council (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text) and is different from the corresponding MD paragraph. ***Elements to note are highlighted in grey.***	IVD - Article U T. This paragraph is text from the IVD proposal ***changed by the EP (added text in bold italics*** and deleted text in ~~strikethrough~~ compare EP text) and is different from the corresponding MD paragraph. ***Elements to note are highlighted in grey***
Comment: This is the place for comments, e.g. to mention .what issue it concerns (for issues addressed in more than one place e.g. ingested products.	
Compromise text:	

Chapter I

Scope and definitions

Article 1

Scope

Article 1 1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to clinical investigations on medical devices conducted in the Union.***	**Amendment 59** 1. This Regulation establishes rules to be complied with by medical devices ~~and~~ accessories ***for human use,*** to medical devices ***and medical devices for aesthetic purposes*** that are placed on the market or put into service in the Union ~~for human use.~~
IVD - Article 1 1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to performance studies on medical devices conducted in the Union.***	
Comment: Difference in ***Council text*** *with IVD consists of having "performance studies" instead of "clinical investigations". IVD differences highlighted in grey.* *Issue* ***aesthetic devices****, related to:* *- Amendment 60 (article 1(1b)) and Amendment 69 (article 2(1)(2a) - definition of aesthetic devices);* *- Article 1(1a), Article 1(1b), Article 2(1)(1) last paragraph, Annex I, Part I, Section 6; Annex I, Part III, Section 19.3(r), Annex V, Part A, Section 2.16, Annex XV* ***EP has linked this to Article 1(1a) and 1(1aa) and stated it would agree to Council amendments if Article 1(1a) and 1(1aa) is changed as below. EP feedback expected.***	
Compromise text:	

Article 1 ***1a.*** ***This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of entry into force of common specifications or the date of application of this Regulation, whichever is the latest, adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management and of the general safety and performance requirements set out in Annex I and clinical evaluation.*** ***The necessary common specifications shall be adopted as soon as possible following entry into force of this Regulation and at the latest so that they enter into force on the date of application of this Regulation.***	
Comment: Issue ***aesthetic devices****, related to:* *- Amendment 60 (article 1(1b)) and Amendment 69 (article 2(1)(2a) - definition of aesthetic devices);* *- Article 1(1), Article 1(1b), Article 1(1c), Article 2(1)(1) last paragraph, Annex I, Part I, Section 6; Annex I, Part III, Section 19.3(r), Annex V, Part A, Section 2.16, Annex XV*	
Compromise text: ***This text is agreed in Coreper, sent to the EP and EP feedback is yet to be received.*** ***1a.*** ***This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of ~~entry into force~~ application of common specifications ~~or the date of application of this Regulation, whichever is the latest,~~ adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management ~~and of the general safety and performance requirements~~ as set out in Annex I for the group of products and, where necessary, clinical evaluation regarding safety.*** ***The necessary common specifications shall be adopted ~~as soon as possible following entry into force of this Regulation and~~ at the latest ~~so that they enter into force on~~ the date of application of this Regulation. They shall apply as from ~~one year~~ six months after their entry into force or from the date of application of this Regulation, whichever is the latest.*** ***Notwithstanding Article 96, Member States' measures regarding the qualification of the products covered by Annex XV as medical devices pursuant to Directive 93/42/EEC shall remain valid until the date of application pursuant to the first subparagraph of the required Common Specifications for that group of products.*** ***1aa. Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.***	

Article 1 ***1b.*** For the purposes of this Regulation, medical devices***,*** ~~and~~ accessories to medical devices ***and products listed in Annex XV to which this Regulation applies pursuant to paragraph 1a*** shall hereinafter be referred to as 'devices'.	**Amendment 60** Article 1(1) - second subparagraph For the purposes of this Regulation, medical devices ~~and,~~ accessories to medical devices ***and devices for aesthetic purposes*** shall hereinafter be referred to as 'devices'.
IVD - Article 1 ***1a.*** For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.	
Comment: Differences between MD and IVD text highlighted in grey. *Compare comments regarding* ***Aesthetic devices*** *under 1(1).*	
Compromise text: ***Council text***	

Article 1 ***1c***. ~~The~~ ***Where justified in view of the similarity between a device with a medical purpose placed on the market and a product without a medical purpose in respect of their characteristics and risks, the*** Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in ***Article 1(1a)*** ~~the last subparagraph of number (1) of paragraph 1~~, ***by adding new groups of products*** ~~in the light of technical progress~~***, in order to protect the health and safety of users or other persons or other aspects of public health*** ~~and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks~~.	
Comment: Former article 2(2). No correspondence in IVD. Issue ***aesthetic devices****. See comments under 1(1).*	
Compromise text: ***Council text***	

MD

2. This Regulation shall not apply to:

[IVD Article 1(2) set out after MD Article 1(2).]

(a) *in vitro* diagnostic medical devices covered by Regulation (EU) […/…];

Article 1(2) (b) medicinal products ***as defined in*** ~~covered by~~ Directive 2001/83/EC ~~and advanced therapy medicinal products covered by~~ ~~Regulation (EC) No 1394/2007~~. In deciding whether a product falls under Directive 2001/83/EC ~~or Regulation (EC) No 1394/2007~~ or under this Regulation, particular account shall be taken of the principal mode of action of the product.	
Comment: ***Issue -*** delineation towards medicinal products and advanced therapy medicinal products	
Compromise text: ***Council text***	

Article 1(2) ***(ba) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;***	
Comment: ***Issue -*** delineation towards medicinal products and advanced therapy medicinal products	
Compromise text: ***Council text***	

Article 1(2) (c) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market ***or put into service*** ~~or used in accordance with the manufacturer's instructions~~, such blood products, plasma or cells, except for devices referred to in paragraph 4;	
Comment: No correspondence in IVD.	
Compromise text: ***Council text***	

(d) cosmetic products covered by Regulation (EC) No 1223/2009;

Article 1(2) (e) transplants, tissues or cells of ~~human~~ ~~or~~ animal origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising tissues or cells of ~~human or~~ animal origin, or their derivatives, which are non-viable or are rendered non-viable.	
Comment: No correspondence in IVD. See also 1(2)(ea)	
Compromise text: ***Council text***	

Article 1(2) ~~However, human tissues and cells that are non-viable or are rendered non-viable and that have undergone only non-substantial manipulation, in particular those listed in Annex I of Regulation (EC) No 1394/2007, and products derived from such tissues and cells, shall not be considered devices manufactured utilising tissues or cells of human origin or their derivatives~~; ***(ea) transplants, tissues or cells of human origin or their derivatives, or products containing or consisting of them, unless a device is manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;***	
Comment: No correspondence in IVD. See 1(2)(e)	
Compromise text: ***Council text***	

Article 1(2) (f) products, ***other than those referred to in points (c), (e) and (ea)***, that contain or consist of ***viable*** biological substances or organisms***,*** ~~other than those referred to in points (c) and (e),~~ ~~that are viable~~, including living micro-organisms, bacteria, fungi or virus ***in order to achieve or support the intended purpose of the product***;	**Amendment 61** (f) ***all*** products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable~~,~~ ***and that achieve their intended purpose by pharmacological, immunological or metabolic means***, including ***certain*** living micro-organisms, bacteria, fungi or virus;
Comment: No correspondence in IVD.	
Compromise text: ***Council text***	

(g) food covered by Regulation (EC) No 178/2002.

IVD

2. This Regulation shall not apply to:

[All paragraphs completely different compared to MD]

IVD Article 1 (a) products for general laboratory use ***or research-use only products*****,** unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;	
Comment: No correspondence in MD	
Compromise text: ***Council text***	

(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;

IVD Article 1(2) (c) ~~higher metrological order~~ ***internationally certified*** reference materials~~.~~***;*** ***(d) materials used for external quality assessment schemes;.***	
Comment: No correspondence in MD.	
Compromise text: ***Council text***	

Article 1 3. Any device which, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~ incorporates as an integral part an *in vitro* diagnostic medical device as defined in Article 2 of Regulation (EU) […/..] [on *in vitro* diagnostic medical devices] shall be governed by this Regulation~~, unless it is covered by Article 1(3) of that Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I~~ of that Regulation shall apply ~~as far as the safety and performance of~~ ***to*** the *in vitro* diagnostic medical device part ~~are concerned~~	
IVD – Article 1 3. Any device which, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~ incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices ~~without being an *in vitro* diagnostic medical device,~~ shall be governed by ~~this~~ ***that*** Regulation~~, provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation~~. The ~~relevant general safety and performance~~ requirements ~~set out in Annex I to~~ ***of this*** ~~Regulation (EU) [Ref. of future Regulation on medical devices]~~ ***regulation*** shall apply ~~as far as the safety and performance of~~ ***to*** the ~~medical device part that is not an~~ *in vitro* diagnostic medical device ***part*** ~~are concerned~~.	
Comment: If mixed MD/IVD, primarily MD applies with IVD Regulation applying for IVD part.	
Compromise text: ***Council text***	

Article 1 4. Where a device, when placed on the market or ***put into service*** ~~used in accordance with the manufacturer's instructions~~, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. However, if the action of the medicinal substance is ***principal,*** not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC ***or Regulation (EC) No 726/2004, as applicable***. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.	**Amendment 62** 4. Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation ***following consultation with the national medicine agency or with the EMA***. However, if the action of the medicinal substance is not ancillary to that of the device, the product shall be governed by Directive 2001/83/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.
Comment: No correspondence in IVD	
Compromise text: ***Council amendments accepted. <u>However, EP insists on addition of last two lines at the end of the first subparagraph. To be discussed again in block 4.</u>***	

Article 1 5. Where a device is intended to administer a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, that device shall be governed by this Regulation, without prejudice to the provisions of Directive 2001/83/EC ***and Regulation (EC) No 726/2004*** with regard to the medicinal product. However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by Directive 2001/83/EC ***or Regulation (EC) No 726/2004, as applicable***. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.	
Comment: No correspondence in IVD. Technical issue - intention to cover also centrally authorised products	
Compromise text: ***Council text***	

Article 1 ***5a.*** ***Where a device, when placed on the market or put into service, incorporates, as an integral part, tissues or cells of human origin or their derivatives covered by Directive 2004/23/EC with action ancillary to that of the device, that device shall be assessed and authorised in accordance with this Regulation. In this case the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.*** ***However, if the action of the tissues or cells or their derivatives is principal, not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In this case, the relevant general safety and performance requirements set out in Annex I of this Regulation shall apply as far as the safety and performance of the device part are concerned.***	
Comment: No correspondence in IVD. Compare EP Amendment 63. These changes both go in the same direction by applying legislation relevant to tissues or cells of human origin even if part of a MD.	
Compromise text: ***Council text***	

Article 1	**Amendment 63** ***5a.*** ***This Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.*** ***Articles 10 (Personnel), 14 (Traceability), 15 (Notification of serious adverse events and reactions), 19 (Examination of donors) and 29 (Technical requirements and their adaptation to technical and scientific progress) of Directive 2002/98/EC ensure donor and patient safety and as such those existing standards shall be maintained.***
Comment: No correspondence in IVD. Compare the Council change above. ***EP insists to keep this amendment.***	
Compromise text: ***Presidency proposal: agree to EP amendment.***	

Article 1 6. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC ~~and within the meaning of Article 3 of Directive 2006/42/EC~~.	
Comment: Identical text and change in IVD Article 1(4).	
Compromise text: ***Council text*** ***Presidency proposal:*** *Introduce Section 6a of Annex I, Part 1 in the text of MD and delete it from Annex I, as this provision is not suitable for an annex.* *Introduce the same text as in Section 6a of Annex I, Part 1 of MD also in IVD, as paragraph 4a of Article 1, as the provision is also applicable for IVDs.* ***6a. Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in chapter II of this the Annex I of this Regulation."*** *SECTION 6a IN CHAPTER I OF ANNEX I (MD)* ***~~6a. Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in chapter II of this Annex~~***	

Article 1 7. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom nor of Council Directive 97/43~~***2013/59***/Euratom	
Identical text and change in IVD Article 1(5). Technical issue - update since new Directive adopted.	
Compromise text: ***Council text***	

Article 1	**Amendment 64 and IVD amendment 41** ***7a. The regulation of medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.***
Comment: In IVD Article 1(5a).	
EP amendment agreed by Coreper as worded above. EP proposes redrafting as follows: ***This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not regulated by this Regulation***	

Article 1 8. This Regulation shall not affect national law~~s which require~~ ***concerning the organisation, delivery or financing of health services and medical care, such as, the requirement*** that certain ***medical*** devices may only be supplied on a medical prescription***, the requirement that only certain health professionals or health care institutions may dispense or apply certain medical devices or that their application must be accompanied by specific professional counselling***.	
IVD Article 1	**IVD amendment 268** 6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.*** ***- The following devices may only be supplied on a medical prescription:*** ***1) Class D devices;*** ***2) Class C devices in the following categories:*** ***(a) devices for genetic testing;*** ***(b) companion diagnostics.*** ***- By derogation, justified by the attainment of a high level of public health protection, Members States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission.*** ***- The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders.***
Comment: MD Article 1(8) Corresponds to IVD Article 1(6). EP has not amended the corresponding MD text.	
*Compromise text****: For Medical Devices: Council text. For IVD, to be discussed at the IVD trilogue.***	

Article 1 ***8a. This Regulation shall be without prejudice to national law regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.***	
Comment: Identical with IVD Article 1(6a)	
Compromise text: ***Council text.***	

Article 1 ~~9.~~ ~~References to a Member State in this Regulation shall be understood as including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.~~	
Comment: Corresponds to IVD Article 1(7) - also deleted there.	
Compromise text: ***Council text.***	

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

[IVD - no paragraph numbering in Article 2.]

Definitions related to devices:

MD	**Amendment 65**
(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:	(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of:
	Amendment 66
– diagnosis, prevention, monitoring, treatment or alleviation of disease,	– diagnosis, prevention, monitoring, ***prediction,*** treatment or alleviation of disease,
– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,	– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
– investigation, replacement or modification of the anatomy or of a physiological ***or pathological*** process or state,	– investigation, replacement or modification of the anatomy or of a physiological process or state,
– ~~control or support of conception~~,	– control or support of conception,
– ~~disinfection or sterilisation of any of the above-mentioned products,~~	– disinfection or sterilisation of any of the above-mentioned products,
– ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,***	
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.	
~~The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.~~	

IVD	IVD Amendments 42 and 43
(1) ‘medical device’ means ***'medical device' as defined in Regulation (EU) No [Reference to the future Regulation on medical devices].*** ~~any instrument, apparatus, appliance, software, implant, reagent material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:~~ – ~~diagnosis, prevention, monitoring, treatment or alleviation of disease,~~ – ~~diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,~~ – ~~investigation, replacement or modification of the anatomy or of a physiological process or state,~~ – ~~control or support of conception~~, – ~~disinfection or sterilisation of any of the above-mentioned products,~~ ~~and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.~~	(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of: – diagnosis, prevention, monitoring, ***prediction, prognosis*** treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability, – investigation, replacement or modification of the anatomy or of a physiological process or state, – ***providing information concerning direct or indirect impacts on health,*** and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
Comment: EP amended the definition of medical devices differently for the MD and IVD regulation.	
Compromise text ***For MD: include MD amendment 66 and IVD amendment 42 and 44, only on 'prediction, prognosis'. The issue of "direct or indirect" is rejected by Council and will be further discussed.*** (1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of: – diagnosis, prevention, monitoring, ***prediction, prognosis*** treatment or alleviation of disease – investigation, replacement or modification of the anatomy or of a physiological ***or pathological*** process or state, – ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*** and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. ***Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.*** *For IVD:* ***Council text***	

[IVD definition (2)* 'in vitro *diagnostic medical device' belongs to Block 3.]

MD Article 2(1) (2) 'accessory to a medical device' means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)***;	**Amendment 68** (2) ***'***accessory to a medical device***'*** means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable ~~or assist~~ the device(s) to be used in accordance with its/their intended purpose(s); ***or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);***
IVD Article 2 (3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable ~~or assist~~ the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)***;	
Comment: Same change by both Institutions for MD. EP has made no amendment to the definition in the IVD Regulation.	
Compromise proposal: *Texts for MD identical - so kept.* ***Presidency proposal:*** *It is suggested to align the IVD definition to the MD definition as follows:* (3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable ~~or assist~~ the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically and directly assist the ~~medical~~ functionality of the in vitro diagnostic medical device(s) in view of its/their intended purpose(s)***;	

Article 2(1)	**Amendment 69** ***(2a) 'device for aesthetic purposes' means any instrument, apparatus, appliance, software, implant, material, substance or other article, intended by the manufacturer to be used, alone or in combination, for the purposes of modifying the physical appearance of human beings, without any therapeutic or reconstructive intent, by implanting it in the human body, attaching it to the surface of the eye or using it to induce a tissue or cell reaction on external or non-external parts of the human body.*** ***Tattooing products and piercings shall not be considered devices for aesthetic purposes.***
*Comment: Issue **aesthetic devices**, **See: 1(1)**. No corresponding amendment in IVD.*	
Compromise text: ***EP withdraws amendment.***	

Article 2(1) - continued (3) 'custom-made device' means any device specifically made in accordance with a written prescription of ~~a doctor of medicine, of a dental practitioner or of~~ any ~~other~~ person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient. However, mass-produced devices which need to be adapted to meet the specific requirements of ~~a doctor of medicine, a dental practitioner or~~ any ~~other~~ professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of ~~doctors of medicine, dental practitioners or~~ any ~~other~~ authorised person shall not be considered to be custom-made devices;	**Amendment 70** Article 2(1) - continued (3) 'custom-made device' means any device specifically made ~~in accordance with~~ ***by an appropriately qualified person exclusively to meet a specific patient's individual requirements and needs. In particular a 'custom-made device' may be produced on the basis of*** a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics~~, and is intended for the sole use of a particular patient.~~ However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;
Comment: No correspondence in IVD.	
Compromise proposal: (3) 'custom-made device' means any device specifically made in accordance with a written prescription of ~~a doctor of medicine, of a dental practitioner or of~~ any ~~other~~ person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient ***exclusively to meet their individual requirements and needs***. However, mass-produced devices which need to be adapted to meet the specific requirements of ~~a doctor of medicine, a dental practitioner or~~ any ~~other~~ professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of ~~doctors of medicine, dental practitioners or~~ any ~~other~~ authorised person shall not be considered to be custom-made devices;	

Article 2(1) (4) 'active device' means any device, the operation of which depends on ~~a source of electrical energy or any~~ ***a*** source of ~~power~~ ***energy*** other than that ~~directly~~ generated ***by the human body for that purpose or*** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices. ~~Stand alone software shall be considered an active device;~~	**Amendment 71** (4) 'active device***'*** means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated ***by the human body or*** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be considered to be active devices. **Amendment 72** ~~Stand alone software shall be considered an active device;~~
Comment: No correspondence in IVD	
Compromise text: ***Council text.*** ***Commission asks to reconsider deletion of "Stand alone software shall be considered an active device" which has the consequence that standalone software is classified as class I in all cases. Commission will send a note to EP and Council.***	

MD

(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended

– to be totally introduced into the human body or

– to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be considered an implantable device;

(6) 'invasive device' means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

[Definitions (5) and (6) have no correspondence in IVD.]

MD and IVD

(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

[Definition (7) is identical in IVD and MD.]

[MD and IVD definition (8) 'single use device' and EP definition (8a) 'reusable device' belong to Block 2.]

Article 2(1) – continued ***(8a) 'falsified device' means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.***	
Comment: identical to IVD Article 2 definition (8a). Compare EP Amendment 98 Chapter II (EP Chapter VI), Article 5(2b) which has similar ideas.	
Compromise text: ***Council text***	

MD

[MD definition (9) 'single use device for critical use' belongs to Block 2.]

Article 2(1) ***(9a) 'procedure pack' means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;***	
Comment: No correspondence in IVD.	
Compromise text: ***Council text***	

Article 2(1) ***(9b) 'system' means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;***	
Comment: No correspondence in IVD.	
Compromise text: ***Council text***	

Article 2(1) (10) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;	**Amendment 354** (10) 'intended purpose' means the use for which the device is intended according to the ~~data supplied by the manufacturer on the~~ ***clinical evaluation, to be reflected in the conformity certificate, the product*** label, in the instructions for use ~~or~~ ***and if applicable*** in promotional or sales materials or statements;
IVD Article 2 (9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;	
Comments: No EP amendments of this definition in the IVD Regulation. ***Parliament insists on reference to clinical investigation in which the claims are demonstrated.***	
Compromise text:	

MD and IVD

(11) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

(12) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;

[Identical to IVD Article 2 definitions (10) and (11) that are also not changed.]

[Definition MD (13), which is identical to IVD (12), belongs to Block 2.]

MD

(14) 'non-viable' means having no potential for metabolism or multiplication;

[No correspondence in IVD]

Article 2(1) ***(14a) 'derivative' means a "non-cellular substance" extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case shall not contain any cells or tissues;***	
Comment: No correspondence in IVD.	
Compromise text: ***Council text***	

(15) 'nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials;

[No correspondence in IVD]

Article 2(1) ***(15aa) 'particle',*** for the purposes of the definition of nanomaterial ***in paragraph 1(15)***, ~~'particle', 'agglomerate' and 'aggregate' are defined as follows: 'particle'~~ means a minute piece of matter with defined physical boundaries;	
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: ***Council text***	

Article 2(1) ***(15ab)*** 'agglomerate'***, for the purposes of the definition of nanomaterial in paragraph 1(15),*** means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;	
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: ***Council text***	

Article 2(1) ***(15ac)*** ‘aggregate’***, for the purposes of the definition of nanomaterial in paragraph 1(15),*** means a particle comprising of strongly bound or fused particles;	
Comment: No correspondence in IVD. The Council change is just a split in order not to have definitions within definitions.	
Compromise text: ***Council text***	

MD and IVD

Article 2(1) ***(15a) ‘performance’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer;***	**Amendment 79** ***(31a) ‘performance’ means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use;***
IVD Article 2 (30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device;	**IVD amendment 55** (30) ***'***performance of a device***'*** means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of ~~the~~ ***attainment of technical capabilities,*** analytical ***performance*** and, where applicable, the clinical performance supporting the intended purpose of the device;
Comment: EP definition of performance completely different in MD, not taken over from IVD. *Very many issues with performance / clinical performance. See also Council MD definition (37c) and IVD definition (32).* ***EP can withdraw amendments 79 MD and 55 IVD.***	
Compromise text: ***Council text.***	

Article 2(1) ***(15b) ‘safety’ means the absence of unacceptable risks, when using the device according to the intended purpose given by the manufacturer;***	
IVD Article 2 ***(15a) ‘safety’ means the absence of unacceptable risks, when using the device according to the intended purpose;***	
Comment: ***EP does not agree to the Council text as it does not see a need for such a definition.***	
Compromise text: ***Presidency proposal: Council should withdraw its amendment.***	

Article 2(1) ***(15d) ‘risk’ means the combination of the probability of occurrence of harm and the severity of that harm;***	
Comment: Identical to IVD Article 2 definition (15aa)	
Compromise text: ***Council text***	

Article 2(1) ***(15e) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;***	
(15b) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose;	
Comment:	
Compromise text: ***Council text***	

Article 2(1) ***(15f)*** '***compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:*** ***- perform without losing or compromising the ability to perform as intended, and/or*** ***- integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or*** ***- be used together without conflict/interference or adverse reaction.***	
Comment: Identical to IVD Article 2 definition 15c	
Compromise text: ***Council text***	

Article 2(1) ***(15g) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to*** ***- exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or*** ***- communicate with each other, and/or*** ***- work together as intended.***	
Comment: Identical to IVD Article 2 definition 15d	
Compromise text: ***Council text***	

Definitions related to the making available of devices:

Article 2(1) (16) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	**Amendment 76** (16) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market ~~in the course of a commercial activity~~, whether in return for payment or free of charge;
IVD – Article 2 (13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	
Comment: The Council has made no amendment to the Commission texts in MD and IVD. *EP amended the MD text, but not the corresponding IVD text.*	
Compromise text: ***MD: Council text. EP can withdraw this amendment.*** ***IVD Presidency proposal:*** (13) 'making available on the market' means any supply of a device, other than a ***performance study*** device ~~for performance evaluation~~, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge; *Note: this is further discussed in the definitions related to Chapter VI*	

Article 2(1) (17) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;	
IVD Article 2 (14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;	
Comment:	
Compromise text: MD: No changes by any Institution. ***IVD Presidency proposal:*** (14) 'placing on the market' means the first making available of a device, other than a ***performance study*** device ~~for performance evaluation~~, on the Union market; *Note: this is further discussed in the definitions related to Chapter VI*	

Article 2(1) (18) 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;	
IVD Article 2 (15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;	
Comment:	
Compromise text: MD: No changes by any Institution. ***IVD Presidency proposal:*** (15) 'putting into service' means the stage at which a device, other than a ***performance study*** device ~~for performance evaluation~~, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose; *Note: this is further discussed in the definitions related to Chapter VI*	

No Council change	**IVD Amendment 50:** Article 2 - continued ***(15a) 'Information Society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;***
Comment:This EP amendment has no correspondence in MD.	
Compromise text: ***EP may withdraw this amendment (due to mentioning in Article 5).***	

Definitions related to economic operators, users and specific processes:

Article 2(1) (19) 'manufacturer' means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.	
IVD Article 2 (16) 'manufacturer' means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.	**IVD Amendment 51** (16) 'manufacturer' means the natural or legal person ~~who manufactures or~~ ***with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufacturers also apply to natural or legal persons who assemble, package, process,*** fully ~~refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device~~ ***refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market*** under ~~his~~ ***that person's own*** name or trademark.
Comment: EP amendment of IVD but not MD.	
Compromise text: ***Council text***	

Article 2(1) ***(19a) 'fully refurbishing',*** for the purposes of the definition of manufacturer, ~~fully refurbishing is defined as~~ ***means*** the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;	
Comment: Identical to IVD Article 2 definition (16a)	
Compromise text: ***Council text***	

Article 2(1) (20) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, ***located outside the European Union,*** to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	
Comment: Identical to IVD Article 2 definition (17). Council made identical changes.	
Compromise text: ***Council text***	

(21) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;

(22) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;

[Wording of MD (21) and (22) identical to IVD definitions (18) and (19).]

Article 2(1) (23) 'economic operators' means the manufacturer, the authorised representative, the importer***,*** ~~and~~ the distributor ***and the person referred to in Article 20 (1) and 20 (3);***	
IVD Article 2 (20) 'economic operators' means the manufacturer, the authorised representative, the importer***,*** and the distributor;	
Comment:	
Compromise text: ***Council text***	

Article 2(1) (24) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	**Amendment 77** (24) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ~~or the promotion of public health~~;
IVD Article 2 (21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	**IVD Amendment 52** (21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ~~or the promotion of public health~~ ***and which has the legal capacity to carry out such activities***; ***commercial laboratories which provide diagnostic services shall not be considered to be health institutions***;
Comment:	
Presidency proposal: *Coreper agreed to add recital to address EP concerns, EP feedback expected.* ***(X) It is appropriate to provide that certain rules of this Regulation as regards devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the health care system and/or address patient needs, but may not treat or care for patients directly, should not apply since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the notion of health institution does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to those establishments.***	

(25) ‘user’ means any healthcare professional or lay person who uses a device;

(26) ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

[Wording of MD (25) and (26) identical to IVD definitions (22) and (23)]

[MD definition (27) 'reprocessing' belongs to Block 2.]

Definitions related to conformity assessment:

[All such definitions belong to Block 4.]

Definitions related to clinical evaluation and clinical investigations:

[All such definitions belong to Block 2.]

IVD - Definitions related to clinical evidence:

[All such definitions belong to Block 2.]

Definitions related to standards and other technical specifications:

(49) ‘harmonised standard’ means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];

[Wording of MD (49) identical to IVD definition (57)]

Article 2(1) (50) 'common ~~technical~~ specifications' ***(CS)*** means a document other than a standard that prescribes technical ***and/or clinical*** requirements that provide a means to comply with the legal obligations applicable to a device, process or system.	
Comment: Identical to IVD Article 2 definition (58)	
Compromise text: ***Council text***	

Article 2 – continued ~~2.~~ ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list in Annex XV referred to in the last subparagraph of number (1) of paragraph 1, in the light of technical progress and taking into account the similarity between a medical device and a product without a medical purpose in respect of their characteristics and risks.~~	
Comment: Has become Article 1(1c); No correspondence in IVD.	
Compromise text: ***Council text***	

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to adapt the definition of nanomaterial set out in number (15) of paragraph 1 in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

[No correspondence in IVD]

Article 3
Regulatory status of products

Article 3 1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83 at a duly substantiated request of a Member State*** ***the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	**Amendment 93 and amendment 66 of IVD** Article 3 1. The Commission may ***on its own initiative or shall***, at the request of a Member State ~~or on its own initiative~~, by means of implementing acts~~,~~ ***on the basis of the opinions of the MDCG and the MDAC referred to in Articles 78 76 and 78a 76a respectively***, determine whether or not a specific product, or category or group of products, ***including borderline products,*** falls within the definitions of 'in vitro medical device' or 'accessory to a an in vitro diagnostic medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88 84 (3).
1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83***, ***at a duly substantiated request of a Member State, the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an *in vitro* diagnostic medical devices or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
Comment: Corresponds to Article 3(1) in IVD, just reference to MD/IVD different and reference to article concerned at the end of the para. IVD differences highlighted in grey. *The same amendment for EP as well, only reference to devices and articles different.* *See Article 3(1a)*	
Compromise text: *For MD:* ***EP accepts Council text, if (MD and IVD) recital 8 is amended as in EPs MD amendment 9 and IVD amendment 6.*** *For IVD, the reference to the medicinal products directive is not pertinent. Therefore, the IVD text should read:* IVD ~~The~~ ***~~Without prejudice to Article 2(2) of Directive 2001/83~~***, ***at a duly substantiated request of a Member State, the*** Commission ~~may~~ ***shall,*** ~~at the request of a Member State or on its own initiative~~ ***after consulting the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an *in vitro* diagnostic medical devices or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). ***To be noted that the article is subject to agreement on role of MDCG and MDAC.***	

Article 3 - continued ***1a.*** ***The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.***	
Comment: Corresponds to Article 3(1a) in IVD. See Article 3(1)	
Compromise text: ***Council text***	

Article 3 - continued 2. The Commission shall ensure the sharing of expertise between Member States**,** in the fields of medical devices, *in vitro* diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.	**Amendment 93 and IVD amendment 66** Article 3 - continued ~~2.~~ ~~The Commission shall ensure the sharing of expertise between Member States in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.~~
IVD Article 3 - continued 2. The Commission shall ensure the sharing of expertise between Member States**,** in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.	
Comment: Corresponds to Article 3(2) in IVD, just order of medical devices, in-vitro medical devices changed. The EP has deleted Article 3(2) in both MD and IVD. ***Further discussion needed.***	
Compromise text	

ANNEX XV

LIST OF *GROUPS OF* PRODUCTS *WITHOUT AN INTENDED MEDICAL PURPOSE* ~~COVERED BY THE LAST SUBPARAGRPAH OF THE DEFINITION OF 'MEDICAL DEVICE'~~ REFERRED TO IN ~~NUMBER (1) OF~~ ARTICLE *1* ~~2~~(1*a*)	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

1. Contact lenses ***or other articles intended to be introduced into or onto the eye***;	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

2. ~~Implants~~ ***Products intended to be totally or partially introduced into the human body through surgically invasive means*** for ***the purpose of*** ~~modification~~ ***modifying the anatomy*** or fixation of body parts ***with the exception of tattooing products and piercings***;	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

3. ***Substances, combinations of substances, or articles intended to be used for facial*** ~~Facial~~ or other dermal or mucous membrane ~~fillers~~ ***filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing***;	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

4. Equipment ***intended to be used to reduce, remove or destroy adipose tissue, such as equipment*** for liposuction***, lipolysis or lipoplasty***;	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

~~5. Invasive laser equipment intended to be used on the human body;~~	
Comment: ***EP accepts Council amendments if Article 1(1a) is changed as the Presidency proposes.***	
Compromise text:	

6. ***High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense*** ~~Intense~~ pulsed light equipment**,** ***for skin resurfacing, tattoo or hair removal or other skin treatment;***	
Comment: ***EP accepts Council amendments if Article 1, paragraph 1a is changed as the Presidency proposes.***	
Compromise text:	

6a. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.	
Comment: ***EP accepts Council amendments if Article 1, paragraph 1a is changed as the Presidency proposes.***	
Compromise text:	