Council of the European Union
General Secretariat

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

Brussels, 09 June 2016

WK 455/2016 INIT

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WORKING PAPER

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WORKING DOCUMENT

From:	Council of European Union
To:	Working Party on Pharmaceuticals and Medical Devices - Medical Devices
N° prev. doc.:	9364/16 PHARM 30 SAN 211 MI 370 COMPET 316 CODEC 722 9365/16 PHARM 31 SAN 212 MI 371 COMPET 317 CODEC 723
N° 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

Delegations will find attached an explanatory document concerning technical issues in the two draft regulations. The document contains proposals for text changes. These concern transitional provisions related to Eudamed, Commission acts and harmonised standards. These changes will be added to the consolidated texts that will be put forward to Coreper for its meeting on 15 June.

TRANSITIONAL PROVISIONS REGARDING EUDAMED, HARMONISED STANDARDS AND REPEAL OF CERTAIN COMMISSION ACTS BASED ON THE THREE MEDICAL DEVICE DIRECTIVES

During the finalisation of the consolidated text of the two medical device regulations, the Commission services have drawn attention to a few issues of a technical nature that are not satisfactorily solved in the draft regulations. These are:

- transitional issues regarding Eudamed applying immediately after the repeal of the three medical device directives,
- the references to harmonised standards and
- the repeal or maintenance of some existing Commission acts adopted on the basis of the three medical device directives.

I. Transitional provisions for MD

Article 96

Article 96 in its present form reads:

"*Article 96*

Repeal

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from ~~[~~***the later of the two dates referred to in Article 97(2) and 97(3)(ba)***~~]~~ ~~[*date of application of this Regulation*]~~, with the exception of ***Article 10,*** Article 10a and point (a) of Article 10b(1) ***~~and Annex 7~~*** of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) ***and Article 15 ~~and Annex X~~*** of Directive 93/42/EEC which are repealed with effect from ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba)*** ~~[*18 months after date of application*]~~.

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI.".

This text needs to be corrected based on the following reasoning:

1) Only the application of the provisions in the new regulation that are directly dependent on the functionality of Eudamed should be delayed in case Eudamed is not fully functional three years after the new regulation has entered into force. The main part of the two directives 90/385/EEC and 93/42/EEC should therefore be repealed from three years after entry into force *i.e.* "the date of application".

2) If Eudamed is not fully functional on the date of application the following provisions should not be repealed until Eudamed is fully functional:
   in Directive 90/385/EEC:
   - Article 8 - centralised evaluation in MS of incidents;
   - Article 10 - authorisation of clinical investigations
   - Article 10b(1)(b) - data on vigilance in databank
   - Article 10b(1)(c) - data on clinical investigations in databank
   - Article 10b(2) - standardised format
   - Article 10b(3) - legal basis Eudamed

   in Directive 93/42/EEC:
   - Article 10 - centralised evaluation in MS of incidents
   - Article 14a(1)(c) - data on vigilance in databank
   - Article 14a(1)(d) - data on clinical investigations in databank
   - Article 14a(2) - standardised format
   - Article 14a(3) - legal basis Eudamed
   - Article 15 - clinical investigations

3) Article 94(5) foresees a transitional phase of 18 months for registration in Eudamed. The following provisions in Directives 90/385/EEC and 93/42/EEC should not be repealed until the transitional phase has ended (see below):
   Article 10a and 10b(1)(a) of Directive 90/385/EEC and Article 14(1), 14(2), 14a(1)(a) and 14a(1)(b) of Directive 93/42/EEC.

The Presidency therefore proposes that Article 96 be replaced[1] by:

"*Article 96*

Repeal

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from [~~***the later of the two dates referred to in Article 97(2) and 97(3)(ba)]***~~ [*date of application of this Regulation*], with the exception of

- ***Article 8,*** ***Article 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba),***
- Article 10a and point (a) of Article 10b(1) ~~***and Annex 7***~~ of Directive 90/385/EEC ***which are repealed with effect from 18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba),*** ~~and~~
- ***Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba), and***
- Article 14(1) and (2) and points (a) and (b) of Article 14a(1) ~~***and Article 15***~~ ~~***and Annex X***~~ of Directive 93/42/EEC which are repealed with effect from ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba)*** ~~[*18 months after date of application*]~~.

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI.".

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[1] Please see Section VII for the final wording of this article since also some issues regarding repeal of Commission acts need to be handled.

Article 94(5)

Article 94(5) in its present form reads:

"5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [*date of application*] until [*18 months after date of appl*ication], comply with Article 25(~~2~~***3***) and ***Article 25a(1)*** ~~(3)~~ and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.".

This text needs to be corrected based on the following reasoning:

1) This paragraph creates a transitional period by providing that certain obligations be still regulated under Directives 90/385/EEC and 93/42/EEC but that economic operators will be allowed to fulfil those obligations by applying the corresponding provisions in the new regulation.
2) In order for economic operators to do this, Eudamed must be fully functional, so the transitional period should start when Eudamed is fully functional and not from the date of application of the new regulation. The transitional period should run for 18 months from that point in time.
3) The provisions concerned are:
   in the new Regulation:
   - Article 25(3) - obligation of importers to verify that the manufacturer/authorised representative is registered - relevant - even though changed compared to Cion proposal. (25(2) was the obligation for manufacturers and authorised representative to register - see below.)
   - Article 25a(1) - obligation of manufacturers, authorised representatives and importers to register - corresponds to the previous 25(2).
   - Article 45(4) - notified bodies' obligation to register information on certificates

in Directive 90/385/EEC

- Art 10a - obligation for manufacturers and authorised representatives to inform MS about their address and their devices - importers and notified bodies not mentioned
- Article 10b(1)(a) - information on certificates to be stored in the data bank in Directive 93/42/EEC
- Article 14(1) - obligation for manufacturers to inform MS about their address and their devices - importers and notified bodies not mentioned
- Article 14(2) - - obligation for authorised representatives to inform MS about their address and their devices
- Article 14a(1)(a) - data on manufacturers and authorised representatives in data bank
- Article 14a(1)(b) - information on certificates to be stored in the data bank

The Presidency therefore proposes that Article 94(5) be replaced by:

"5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from ~~[*date of application*]~~ ***the later of the two dates referred to in Article 97(2) and 97(3)(ba)*** until ~~[*18 months after date of application*]~~ ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba)***, comply with Article 25(~~2~~***3***) and ***Article 25a(1)***~~(3)~~ and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.".

II. Transitional provisions for IVD

Article 89

Article 89 in its present form reads:

"*Article 89*

Repeal

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from ~~[*date of application of this Regulation*]~~ ***the later of the two dates referred to in Article 90(2) and 90(3)(d)*** with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from ~~[*18 months after date of application*]~~ ***18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d)***.

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV."

1) Only the application of the provisions in the new regulation that are directly dependent on the functionality of Eudamed should be delayed in case Eudamed is not fully functional five years after the new regulation has entered into force. The main part of directive 98/79/EC should therefore be repealed from five years after entry into force *i.e.* "the date of application".
2) If Eudamed is not fully functional on the date of application the following provisions in Directive 98/79/EC should not be repealed until Eudamed is fully functional:
   - Article 11 - centralised evaluation in MS of incidents;
   - Article 12(1)(c) - data on vigilance in databank
   - Article 10(1) third indent - obligation to notify Competent authorities about outcome of performance evaluation - Article 10 is however needed 18 months longer - see below!
   - Article 12(2) - standardised format
   - Article 12(3) - legal basis Eudamed

The Presidency therefore proposes that Article 89 be replaced by[2]:

"*Article 89*

Repeal

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [*date of application of this Regulation*] ~~***the later of the two dates referred to in Article 90(2) and 90(3)(d)***~~ with the exception of

- ***Article 11, point (c) of Article 12(1) and Article 12(2) and 12(3) which are repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d) and***
- Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from ~~[*18 months after date of application*]~~ ***18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d)***.

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV."

Article 87(5)

Article 87(5) in its present form reads:

"5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23~~(2)~~ and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU."

This text needs to be corrected based on the following reasoning:

1) This paragraph creates a transitional period by providing that certain obligations be still regulated under Directive 98/79/EC but that economic operators will be allowed to fulfil those obligations by applying the corresponding provisions in the new regulation.

[2] Please see Section VII for the final wording of this article since also some issues regarding repeal of Commission acts need to be handled.

2) In order for economic operators to do this, Eudamed must be fully functional, so the transitional period should start when Eudamed is fully functional and not from the date of application of the new regulation. The transitional period should run for 18 months from that point in time.

3) The provisions concerned are:
in the new Regulation:
- Article 23(3) - obligation of importers to verify that the manufacturer/authorised representative is registered - relevant - even though changed compared to Cion proposal. (23(2) was the obligation for manufacturers and authorised representative to register - see below.)
- Article 23a(1) - obligation of manufacturers, authorised representatives and importers to register - corresponds to the previous 23(2).
- Article 43(4) - notified bodies' obligation to register information on certificates

in Directive 98/79/EC
- Article 10 - obligation to register manufacturers, authorised representatives and devices in data bank
- Article 12(1)(a) - data on manufacturers and devices in data bank
- Article 12(1)(b) - information on certificates to be stored in the data bank

The Presidency therefore proposes that Article 87(5) be replaced by:

"5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from ~~[date of application]~~ ***the later of the two dates referred to in Article 90(2) and 90(3)(d)*** until ~~[18 months after date of application]~~ ***18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d)***, comply with Article 23(~~2~~ ***3***) and ***Article 23a***(~~3~~ ***1***) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.".

III. Harmonised standards

Article 5 of Directive 90/385/EEC, Article 5 of Directive 93/42/EEC and Article 5 (!) of Directive 98/79/EC provide that devices that are in conformity with relevant harmonised standards shall be presumed to conform with the requirements of the respective Directive. Article 6 of the two new regulations provide the same.

The term "harmonised standard" is used many times in the two new regulations. Apart from in Article 6 there is however no mention of a reference in the OJ. In most cases this is not problematic, but in some cases *e.g.* Article 51a(3)(b):

"*(b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards;*"

it might be important to make it explicitly clear that "harmonised standards" cannot be read as meaning anything else than "harmonised standards the references of which have been published in the Official Journal of the EU".

In accordance with Regulation (EU) No 1025/2012 on European Standardisation, publication of a reference of a standard in the OJ means that the standard satisfies the requirements which it aims to cover (see Art. 10(6) of that regulation). Significantly, there is a procedure for objecting, the outcome of which will determine whether or not the publication goes ahead, is restricted or is withdrawn (Art. 11). Non-publication of the reference means that the harmonised standard does not cover the requirements it was supposed to cover.

As it can be assumed that what is meant in the two new regulations, wherever the term "harmonised standard" is used, is a harmonised standard the reference of which has been published following the procedure in Regulation (EU) No 1025/2012, the Presidency proposes to add a new subparagraph in Article 6(1), which will then read:

"1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance ~~plan~~ ***system***, clinical investigations, clinical evaluation or post-market clinical follow-up. [3]

References in the present regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the Official Journal of the European Union.".

The Presidency furthermore proposes to change the title of Article 6 to:

"*Article 6*

Use of *Harmonised standards*"

since that better reflects the contents of this article.

IV. Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012

Following extensive discussion at expert level, it was decided to maintain references to Commission Regulations 207/2012 and 722/2012 in the new Regulation on medical devices. They are nor referred to in the IVD Regulation. There are direct references to Commission Regulation (EU) No 722/2012 in Annexes I, V, VI, VIII and XI of the new MD regulation. Annex I contains the only reference to Commission Regulation (EU) No 207/2012. However, the legal bases for these Regulations will be repealed at the date of application of the new regulation on medical devices. A situation of legal uncertainty therefore arises.

[3] The wording of this subparagraph is slightly different in IVD - for (obvious) reasons. It is not changed and can be checked in the consolidated IVD text.

Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices has Article 9(10) of Directive 90/385/EEC and Article 11(14) of Directive 93/42/EEC as legal bases. These articles will be repealed at the date of application of the new regulation on medical devices. According to the correlation tables, there is no corresponding provision in the new Regulation. Article 11(14) of 93/42/EEC allows to supplement that Directive through the regulatory procedure with scrutiny with provisions on how the information provided by the manufacturer may be set out. Article 9(10) of 90/385/EEC is similar but directly related to the instructions for use. As the requirements on the instructions for use are laid down in Annex I, the uniform application of which is secured via an implementing act referred to in Article 4(5), it should be possible to use that article as basis for future changes to this Commission regulation.

Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin has Article 10c of Directive 90/385/EEC and Article 14b of Directive 93/42/EEC as its legal bases. These will be repealed at the date of application of the new regulation on medical devices. The corresponding article in the new regulation on medical devices is Article 74 which contains a provision based on which implementing acts can be adopted.

In order to avoid legal uncertainty, and following practice in other legislation[4], the Presidency proposes to explicitly provide that these two regulations shall remain in force by adding the following sentence in Article 96:

"***Notwithstanding the first subparagraph, Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.***".

[4] The provision in Article 96 and in Recital (70) are based on Article 26 and Recital (25) of Regulation (EU) No 517/2014 on fluorinated greenhouse gases.

The Presidency also proposes to clarify in Recital (70) which Commission acts shall be repealed and which Commission acts shall be maintained (Compare Sections V and VI):

"(70) Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation. ***However, in order to ensure a smooth transition from the old regime to the new regime, it is appropriate to provide that Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012 should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation. Also Commission Decision 2010/227/EU adopted in implementation of those Direcitves and Directive 98/79/EC should remain in force and continue to apply until the date when the European databank on medical devices set up pursuant to this Regulation and Regulation (EU) No [future Regulation on*** **In Vitro D*iagnostic Medical Devices] and is fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC and 2005/50/EC and Commission Implementing Regulation (EU) No 920/2013***".

V. Repeal of Commission Directives 2003/12/EC and 2005/50/EC and Commission Implementing Regulation (EU) No 920/2013

COMMISSION DIRECTIVE 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices has Article 13(1)(b) of Directive 93/42/EEC as it legal basis.

COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices also has Article 13(1)(b) of Directive 93/42/EEC as its legal basis.

COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices has Article 11(2) of Directive 90/385/EEC and Article 16(2) of Directive 93/42/EEC as its legal basis.

The legal bases of these three Commission acts will, pursuant to Article 96 of the new Regulation on medical devices be repealed three years after entry into force of that regulation. They will thus be repealed without this being explicitly provided for in the enacting terms. The Presidency for reasons of clarity proposes to refer to the repeal in Recital (70). (See Section IV of this document.)

VI. Commission Decision 2010/227/EU

COMMISSION DECISION of 19 April 2010 on the European Databank on Medical Devices (Eudamed) *(2010/227/EU)* has Article 10b(3) of Directive 90/385/EEC, Article 14a(3) of Directive 93/42/EEC and Article 12(3) of Directive 98/79/EC as its legal bases. This Commission Decision establishes Eudamed and contains obligations for Member States that are replaced by obligations under the new regulations. Article 89 of the IVD Regulation (and Article 96 of the MD Regulation) provides that the last of these legal bases is repealed at the point in time when Eudamed is functional or at the time of application of the new regulation on *in vitro* diagnostic medical devices, whichever happens last. The Presidency therefore proposes to add the following sentence in Article 87 of the IVD regulation:

"***Commission Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d).***".

The Presidency also proposes to add a sentence in Recital (66):

"(66) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation. ***Also Commission Decision 2010/227/EU adopted in implementation of that Direcitve and Directives 90/385/EEC and 93/42/EEC should be repealed as from the date when the European databank on medical devices set up pursuant to Regulation (EU) No [future Regulation on Medical Devices] and this Regulation is fully functional.***".

Finally, the Presidency proposes to address this issue in Recital (70) of the MD Regulation (see Section IV).

VII. Resulting text of Article 96 MD and Article 89 IVD

Adding the texts from Sections IV, V and VI to Article 96 MD and Article 89 IVD as appropriate, they will read:

"*Article 96*

Repeal

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from [***~~the later of the two dates referred to in Article 97(2) and 97(3)(ba)~~***] [*date of application of this Regulation*], with the exception of

- ***Article 8,*** ***Article 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba),***
- Article 10a and point (a) of Article 10b(1) ***~~and Annex 7~~*** of Directive 90/385/EEC ***which are repealed with effect from 18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba),*** ~~and~~
- ***Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC which are repealed with effect from the later of the two dates referred to in Article 97(2) and 97(3)(ba), and***
- Article 14(1) and (2) and points (a) and (b) of Article 14a(1) ***~~and Article 15~~*** ***~~and Annex X~~*** of Directive 93/42/EEC which are repealed with effect from ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(ba)*** ~~[*18 months after date of application*]~~.

Notwithstanding the first subparagraph, Commission Regulation (EU) No 207/2012 and Commission Regulation (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI."

and

"*Article 89*

Repeal

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [*date of application of this Regulation*] ~~***the later of the two dates referred to in Article 90(2) and 90(3)(d)***~~ with the exception of

- ***Article 11, point (c) of Article 12(1) and Article 12(2) and 12(3) which are repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d) and***
- Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from ~~[*18 months after date of application*]~~ ***18 months after the later of the two dates referred to in Article 90(2) and 90(3)(d)***.

Commission Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the two dates referred to in Article 90(2) and 90(3)(d).

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV."