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WORKING DOCUMENT

From: To:	General Secretariat of the Council Working Party on Pharmaceuticals and Medical Devices - Medical Devices
N° Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + 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

Delegations will find in this document comments regarding Annexes I-II and VIII-XI to the proposed Regulation on medical devices put forward by the Austrian delegation.

Proposals for Linguistic Improvements of Annexes I - II and VIII - XI of MDR

Linguistic Improvements of Annex I MDR:

in I.1a.(e) and (f) seem to be a doublette!

in I.1a.(f), 2nd line: **post-market~~ing~~** surveillance system

in I.4., 2nd line: .. **by** seems more logical than during

5a: not clear why 5a has been deleted; this has already been part of 93/42/EEC and people might see a reason behind such deletion!

II.7.1. should be reworded to better specify the task of this paragraph:
II.7.1. In order to address risks and performances related to the chemical, physical and biological properties of the device, particular attention shall be paid to: ...

II.8.4. and II.8.5. seem to carry more or less the same content!

in II.10.1.(b), 4th line and in II.10.2.(b), 4th line and in II.10.3., 5th line: add the highly important issue of sourcing:

.. shall be addressed **by appropriate methods of sourcing and** by implementation of ....

II.10.2.(b) add: **Sourcing,** processing, ...

in II.11.1. clarification proposed for last line: ... misconnection **under the principles of the risk management in section I.I.**

in II.17.2. 2nd line, something is missing! ... delivered amount **of energy or substances** which could pose a danger. ...

correction to II.19.2.(j), 1st and 2nd line: **data** to be replaced by **date**

in II.19.2.(r), 3rd line: "or mucous membrane" seems inconsistent with the provisions found for the chapter concerning "substances".

in III.19.3., 1st indent: add: cleaning, disinfection **or sterilisation**;

in 19.3.(i) add: ..., instructions **for appropriate reprocessing, if applicable,** in the event ...

Linguistic Improvements of Annex II MDR:

in 3.(aa) "their adjuvants," is unclear in this context!

4. plural for REQUIREMENT**S**

in 6.1.(c) severe miswording! Clarification needed:

(c) the clinical evaluation report and the documentation related to the clinical evaluation and its updates in accordance with Article 49(5) and part A of Annex XIII, including the clinical evaluation plan, the documentation on literature searching and the clinical investigation report(s);

Linguistic Improvements of Annex VIII MDR:
Title should be changed to:

CONFORMITY ASSESSMENT based on ASSESMENT OF THE QUALITY MANAGEMENT SYSTEM AND on ASSESSMENT OF THE TECHNICAL DOCUMENTATION

In 3.1. 8th and 9th indent the post-market surveillance plan should be changed to post-market surveillance **system**

[Comment: System is the overarching term and includes the plan]

in 3.2.(b), 2nd indent, 3rd line: and of **the** device ...

in 3.2.(c), 1st indent: add: **management of planned change(s),**
[Comment: Management of planned changes (to the device or its intended use or to the QMS) are important challenges to regulatory compliance of manufacturers]

in 3.2.(c), 3rd indent: better: the risk management according to section I.~~2~~ of Annex I,
[Comment: better to be more general here; risk management is basically addressed eg in paragraphs I. 1aa, 1a, 2 and 2b of Annex I]

in 3.2.(c), 4th indent: ..., including post-market clinical follow-up ~~**planning**~~,

[Comment: PMCF is the overarching term and includes the planning]

in 3.3.(d) last line: for clarification: and a reasoned **quality management system assessment** report
[Comment: important to clarify which kinds of reports are formally expected]

in 4.3., 3rd line, again: post-market surveillance plan should be changed to post-market surveillance **system**

in 5.3b., last line: instead of: **in** the risk analysis. better: **and** the risk analysis

in 5.3c., 4th line: maybe better: instead of benefit-risk assessment use the defined term: benefit-risk **determination**

in 5.3d., 2nd line: maybe better: instead of benefit-risk assessment use the defined term: benefit-risk **determination**

in 6.0.(d), last line: it's not clear whether this "conformity assessments report" covers the whole Annex VIII or only Annex VIII.6.0. or what is the relationship to the report mentioned in para 3.3.(d), see above

in 6.1.(d), 2nd indent: ... after receipt of **the** valid documentation.

in 6.2. (a), 10th line: instead of **and/or** more logical: **and**

in 6.2.(b), ... after receipt of **the** valid documentation.

in 6.2.(d): 6th line: The **authority consulted** shall take into account ...

in 6.2.(d): 10th line: add: benefit-risk **determination**

in 6.3.(d) add: within 150 days **after receipt of the valid documentation**.

Linguistic Improvements of Annex IX MDR:

in 3.1.(c), last line: change: in the risk analysis by: **and the benefit-risk determination**.

in 3.1d. for clarity on the report structure: **clearly document the outcome of its assessment in a preclinical and a clinical assessment report as part of the EU type examination report according to paragraph 3.5.**

in 5.1., 2nd line: or of its intended purpose **and use**.
{comment: to be consistent with wording in 5.2.]

in 5.2., 1st line: replace "limitations" by "**changes**"

Linguistic Improvements of Annex X, Part B MDR:

in 3. "post-market surveillance plan" should be changed to **post-market surveillance system**

Linguistic Improvements of Annex XI, Part B MDR:

in 1., last indent, we would also expect the documentation on the safety of these components:
add at the end: ... **and the documentation on the safety of those components.**
