European Commission

Eudamed

WG meeting

Brussels, 14th November 2012

Discrepancies between Eudamed NCAR pdf and Vigilance MEDDEV 2.12/1 – N79R11 form

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Objective

Eudamed NCAR pdf
shall match with
MEDDEV 2.12/1 rev. 7 annex 8 N79R11 form
as far as possible

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Some differences will remain

N79R11 form has been developed by GHTF Post-Market Surveillance/Vigilance-Study Group 2 in view of an **international NCAR exchange.**

Eudamed NCAR pdf must comply with the MD Directives and the Eudamed Decision and is intended to be exchanged at **European level only.**

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Eudamed release 4.4 improvements

- The title will be modified
- The wrong numbering will be corrected
- The wrong location of certain data will be corrected
- The wording will be adapted

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Remaining differences

- Field 2: Eudamed Reference
- Field 12: GMDN
- Field 13: Another nomenclature
- Field 26: Affected countries
- Field on comments (Eudamded tab)

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Future modifications

Need of new non mandatory fields

- Related NCA report nos. (if any)
- Local NCA reference no.
- Have the manufacturer's actions been made public?: [ ]Yes [ ] No
- The last NCAR distributed by this NCA was (>>>>>>>>>>)
- Field at the end listing the attachments

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Future modifications

impacting 4.4 xsd

Wording modification in the Device Module

Change the wording of Device Module Main tab field **Name-Make** into **Trade name**.

This is in line with N79R11 and the wording used in the MD regulations proposals

Please keep in mind that the modifications will probably have an impact on 4.4 release date

Thank you

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