<Date of submission>

Submission of comments on 'Guideline on the quality requirements for drug-device combinations' (EMA/CHMP/QWP/BWP/259165/2019)

Comments from:

Name of organisation or individual
Apotekarsocieteten (Swedish Pharmaceutical Society), Section for medicinal device Box 1136, S-111 81 Stockholm, Sweden

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

Apotekarsocieteten (Swedish Pharmaceutical Society) is a non-profit organization for professionals engaged in the field of Pharmaceuticals. The aim of the organization is to support research and innovation in medicines and healthcare, and to promote high professional standards through supporting education and professional development.
The organization has 5 300 individual members, the society is divided into 14 scientific sections, 11 regional divisions and 3 interdisciplinary interest groups.
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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Typo on line 140, should be quality target product profile (QTPP).	
	EMA draft guidance Annex 1 proposes a new template for the Notified Body (NB) opinion. Annex 2 provides template cover sheet for the NB opinion. Suggest EMA to provide further guidance concerning the document package for notified body review against MDR Annex I.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
112- 113, 116-117 and 413-417		Comment: Chapter 2 Scope list both in scope (row 112-113) and out of scope items such as ATMPs (row 116-117) and additionally ATMPs are addressed in row 413-417. Chapter 2 Scope (row 112-113) states this guideline applies only to devices that are considered PART of the container closure system but rows 413-417 states medical devices that are USED AS container closure system for ATMPs. This could pose interpretation difficulties. As stated in REGULATION (EC) No 1394/2007 (4) .. For these products, whatever the role of the medical device, the pharmacological, immunological or metabolic action of these cells or tissues should be considered to be the principal mode of action of the combination product. Such combination products should ALWAYS be regulated under this Regulation. Proposed change (if any): Harmonise wording and provide examples for clarification and how it related to regulation No 1394/2007, see text above.	I
118-119 and 271-272, 371		Comment: Chapter 2 Scope list out of scope items such as Electromechanical components (row 118-119), yet electrical functional components are addressed in 271-272, and	

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		communication with software in 371. Proposed change (if any): Keep and develop more guidance text concerning electromechanical drug-device combination products, including connectivity.	
170-171		Comment: Guidance document state 'take precedence over ISO standards'. Within the field of Medical Devices there are ISO, IEC and ETSI standards that can be applicable to Medical Devices. If these standards are harmonised this indicate a strong recommendation to use these standards as a tool to show compliance and the text in 171 may not be accurate. Proposed change (if any): Propose EMA to have discussions with Medical Device Regulators for harmonised view and wording.	
192-193, 699-701, 812-815		Comment: …data for those aspects of the device which pertain to the **'platform'** should be presented. Definition for **platform technology** does not provide enough information in 699-701. Proposed change (if any): Since Integral DCC as described in row 68 "intended exclusively for use in the given combination" includes testing in the given final combination (e.g. as per ISO 11608-series) more guidance is needed on what can be considered be platform data that could be used	

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		in the context described and intended, including Annex 2 point 2.	
242		Comment: DIN EN ISO 14971, DIN indicate German version of the standard. It is enough with EN ISO 14971. Proposed change (if any): Remove DIN	
363-365		Guideline Section P.7 Container Closure system require the applicant to provide detailed information in the MAA. Since detailed information of the device design can be proprietary information not to be exposed to other companies more tools and guidance are needed. Proposed change (if any): To protect confidential information between collaborating companies an additional submission procedure to transfer this information directly to NB and/or CA (similar to Active Substance Master File procedure, for device, e.g. FDA Device Master File) should be developed and described.	
616-619		Comment: EU Variations Guideline (2013/C 223/01) Table B.IV does not provide enough guidance for the different types of devices and classification of changes or if a change in the drug part would generate a mandatory update in the device part to e.g. updated standards or regulations covering the device part or vice versa.	

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		Proposed change (if any): More guidance is needed concerning changes and the impact of changes both for device and drug parts in combination products. Propose EMA to have discussions with Medical Device Regulators for harmonised view and wording. Propose to include a flowchart of variation/change notification process of drug-device combinations. Suggest to provide a high level decision flow for the evaluation of the significance of a device change, from safety and effectiveness perspective.	

Please add more rows if needed.