21 May 2015
EMA/CHMP/BWP/248233/2015
Committee for medicinal products for human use (CHMP)

Overview of comments received on 'Guideline on the adventitious agent safety of urine-derived medicinal products' (EMA/CHMP/BWP/126802/2012)'

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
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1. Specific comments on text

Line numbers of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
Line 65, 66	1	Comment: For purification of some urine-derived drug substances, e.g. hCG, the donor collection window is rather narrow (e.g. 10 weeks). Follow-up of donor selection criteria is more appropriate when the collection period is much longer. Question: Can EMA define more precisely what intervals should be used for donor criteria follow-up? Proposed change: Adjust the sentence to “Therefore manufacturers should follow up the donor criteria at defined intervals in case long collection periods of more than x months are used”?	Response: Partly accepted. It is difficult to specify an interval for the different products. Sentence has been reworded.
Line 66	1	Comment: It would be useful to add guidance on how the follow-up is performed. Should it be performed for example by re-applying the donor selection criteria, by asking the donor at pre-set intervals or at the end of the donation period?	See above
Line 111	1	Proposed change: We propose to include the use of a model for Hepatitis B virus in the guidance, e.g. a herpes virus or pseudorabies virus as a general model for Hepatitis B virus.	Response: The relevance of model viruses for HBV has been sufficiently discussed in the guideline. Pseudorabies (PRV) has been proposed as a model enveloped DNA Virus. However, PRV cannot be considered as a model for HBV at filtration steps because herpesviruses are much larger than HBV.

Line numbers of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
			SV40 has been proposed as a model for filtration steps. No modification of the guideline is considered necessary.
Line 115	1	Comment: For the enveloped viruses DNA and RNA viruses (lines 100 and 107) are discussed in separate sections. However, for non-enveloped viruses this distinction is not made. What is the reason for this difference? Proposed change: We propose to include a preferred model for both the non-enveloped DNA and RNA viruses.	Response: Animal parvoviruses are considered as an appropriate (worst case) model for both non-enveloped DNA viruses and non-enveloped RNA viruses. Only in cases, when a step is not efficient or not expected to be efficient against animal parvoviruses, then Hepatitis A virus (HAV) is recommended as an additional model virus. See modified text in the Guideline.
Line 117	1	Comment: It is stated that “SV40 is also relevant to represent HBV in size exclusion steps”. What is the reason for using a non-enveloped virus as a model for an enveloped virus? Is that because of the size of these viruses?	Response: Yes, SV40 is considered relevant at size exclusion steps because of its similar size. No modification of the text is necessary.
Line 117	1	Proposed change: We propose to have SV-40 in the virus panel as a model for JC and BK viruses (two viruses known to be present in human urine).	Response: This has been already mentioned in the Guideline. The Guideline has been further clarified.

Please add more rows if needed.