HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Webinar Q&A -19 May 2022
Variation Applications

Question 1
Can MAHs expect to receive an HPRA approval email for VNRAs or will we only receive the approval via the UPD?

Answer
For national VNRAs or when the HPRA is RMS, the MAH will receive and email notification from the on approval of the VNRA.

Question 2
In case of VNRA submission, which it has been received in all countries included the DCP, except for one country involved (in particular the RMS), what is your point of view about how to proceed after trying to submit the VNRA several times?

Answer
The EMA is aware of the issue of VNRAs that are not always visible to all MS and are actively working to address the issue in UPD.

Question 3
Has there been any discussion on reducing the timelines for Worksharing applications where the variation has been identified as a VRA(R)?

Answer
There has been no discussion of this to date, but as we gain more experience with the procedures, the CMDv will review the appropriate timetable for these procedures.

Question 4
For consequential VRA & VNRAs, how can the MAH predict the VNRA implementation date if they want it to match the VRA approval date?

Answer
If the timetable for the VRA is known before submission of the VNRA, the end-of-procedure date of the VRA can be included. Alternatively, a general 'future implementation date' can be indicated in the VNRA submission.

Question 5
For VNRA variation, is it acceptable to submit one change to more than one product or (product range), as UPD retrieve products with same product identification number only?

Answer
UPD does currently allow submission of several changes to one product but submission of identical changes to multiple products is not currently possible. This will be a future enhancement of the system.

Question 6
Can we submit a VNRA that impacts two DCPs where the RMS is identical but the CMSs are different as one VNRA in the UPD?

Answer
No this cannot be submitted as a single VNRA. One VNRA submission is required for each DCP.

Question 7
Is it a must to retrieve all products related to MRP/DC on UPD for MRP variation, as this cause the delay of submission if CMSs numbers were large? Some of NCA do not respond at all to the MAH request? A number of variations are on hold due to this issue.

Answer
All the CMS products related to the procedure must be in UPD before a submission can be made.

Question 8
For previous submissions of consequential VRA & VNRA if the supporting data has been included in the VNRA, will this VNRA be rejected?

Answer
These situations will be handled on a case-by-case basis, we will be pragmatic and if there are only minor to the documents, we would not necessarily refuse the VNRA.

Question 9
If we have a VRA that is related to Text and while it is under assessment a VNRA have been submitted and approved within 30 days before the end of VRA, will the text from VRA contain all the changes approved in VNRA text?

Answer
Yes, if there have been additional changes to text approved in another procedure, just before the end-of-procedure of the VRA, the MAH should submit updated texts that include all relevant changes.

Question 10
Can we submit in parallel non consequential VRA and VNRA like QRD template update and name change variation for the same procedures?

Answer
Yes, non-consequential VRAs and VNRAs can be submitted in parallel and in these cases it is up to the MAH to coordinate the submission of the variations in such a way that approval of the variations is at the same time.