HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Variation Applications

Mary O'Grady, Pharmaceutical Assessment Manager VS, HPRA

HPRA webinar – Update on the implementation of Regulation 2019/6 in Ireland

19 May 2022

This presentation covers

- VNRA Submissions: General Comments
- VRA Submissions: General Comments
- Consequential VRAs and VNRAs

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

VNRA submissions: General comments

- VNRA's are recorded in UPD, no procedure number is required: A submission ID is allocated to VNRA's in UPD.
- MAH should include a contact email - in cover letter or submission comment.
- The precise scope of the variation(s) **should always be** stated in the submission comment field.
- Where the VNRA involves changes to data the present and proposed data **should be clearly indicated** in the submission comment field.
- Supporting documents should be product specific.
- For MRP/DCP products a VNRA submission usually has to cover all marketing authorisations in the RMS and all CMSs. The CMDv has agreed that for some VNRAs it is acceptable that the submission is only made to the RMS and the CMS(s) affected by the change.

Updated BPG expected in June

VNRA submissions: General comments

- Initially flexible where error/issue is not critical
  - Inserted comment in Decision comment

    The MAH should note that……
- Reasons for rejection:
  - Incomplete/incorrect QP declarations
  - Updated SPC not provided or updates incorrect
  - LOC ID for new sites not included

Overall quality of submissions is good ➡ low level of rejections

Clear, well laid out submission = reduce likelihood of rejection

VRA submissions: General comments

General submission comments

- Classifications are essentially similar to previous classifications
- CMDv Q&A on variations

I variations: former line extensions

- For RMS procedures – Need to book slot with HPRA in advance
- Identify in cover letter if the variation is to result in new authorisation or variation to existing product
- Submit on new product application form

VRA submissions: General comments

G.I.18 Variation to update the product information to QRD version 9.0.

- Proposal for a regulation - COM(2022)76

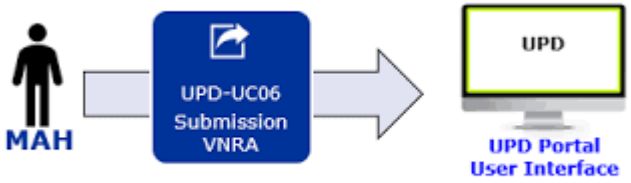
  Draft Regulation laying down transitional rules for the packaging and labelling of veterinary medicinal products to address the serious concerns raised by national competent authorities ('NCAs') and stakeholders related to the interpretation of Article 152(2) Regulation (EU) 2019/6...

Publication expected end of May 2022.

- Required to be completed prior to Subsequent Recognition Procedure (SRP)
- SPC/Labelling can be updated in open new MAs **if requested prior to Day 120**

Consequential VRAs and VNRAs

- Submit the VNRA as a VRA under the appropriate z-variation classification together/grouped with the other VRA
- Submit the VRA and VNRA in parallel i.e. coordinated to allow approval at the same time
- Consequential VNRAs recorded at the same time as VRAs are not restricted with respect to timelines and they may/will be in UPD for > 30 days based on VRA timetables.



Consequential VRAs and VNRAs

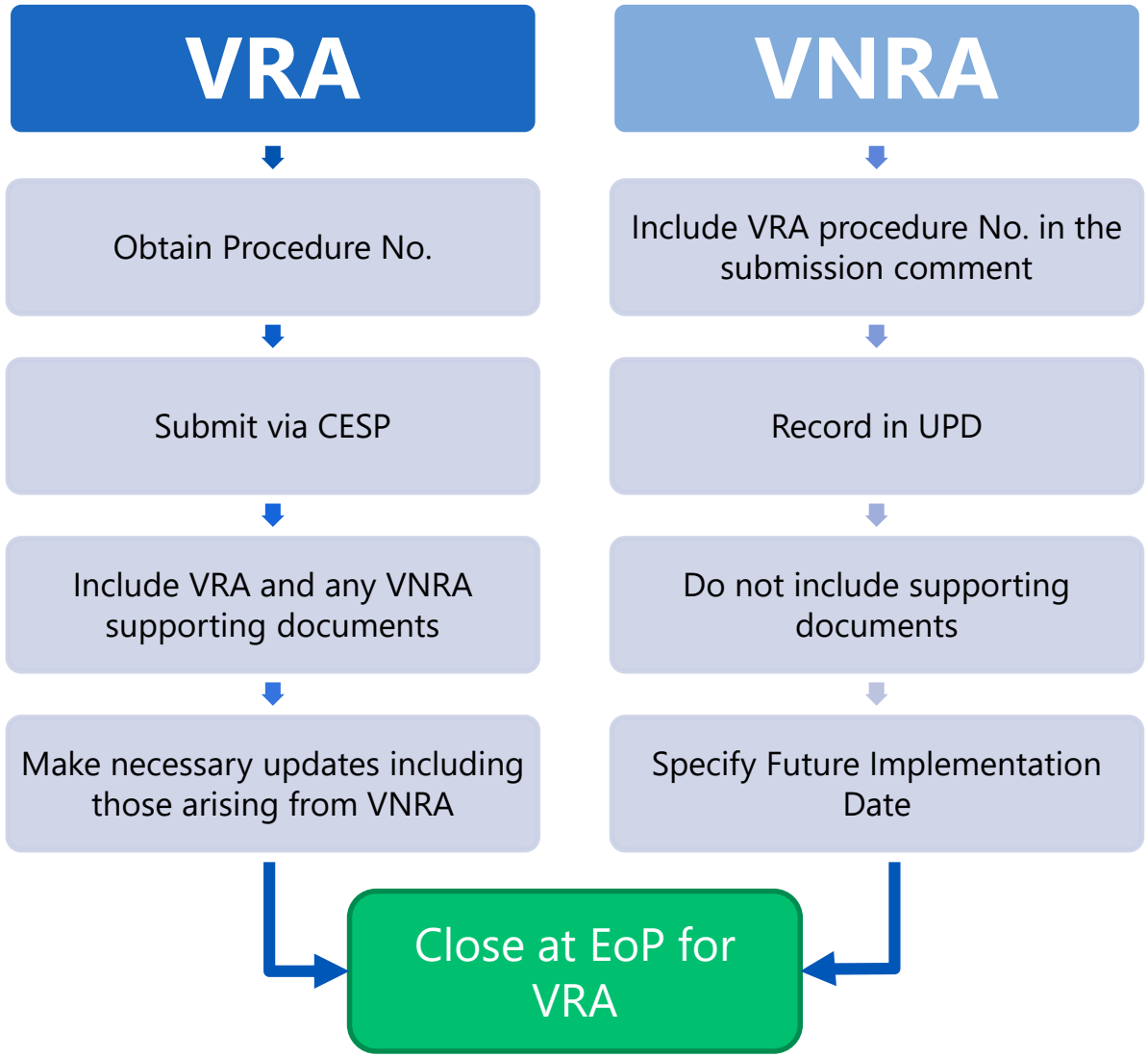
- The VNRAs can be recorded in UPD at the same time that the VRA is submitted via CESP
- VRA procedure number should be included in the submission comment in UPD.
- VNRA change(s) should be clearly identified in the submission comment
- The VNRA submission in UPD should have no supporting documentation uploaded to UPD
- The VNRA should be submitted as "empty" documentation (No provision for amending documents in a VNRA).
- VNRA should refer to an implementation date in the future or “to be implemented together with the VRA <nº VRA>).

Consequential VRAs and VNRAs

- The VRA is submitted via CESP with the VRA(s) change(s) detailed.
- Consequential VNRA changes can be included with the VRA submission package once they are clearly identified.
- The VNRA documents should be included in the VRA submission, clearly identified as relating to the VNRA.
- Separate tables of the VRA(s) and VNRA(s) changes should be included.
- If required, changes can be requested during the VRA assessment .....to the VNRA documents without causing rejection of the VNRA.

Consequential VRAs and VNRAs

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority



Consequential VRAs and VNRAs & Worksharing

Letter of Intent Section b) "Description of the changes"

Only a table of the proposed **VRAs** should be listed. A separate table can be included listing any proposed VNRAs and should be introduced with the following explanatory text:

*The following variation(s) are **not** intended to be part of the worksharing procedure, and have been identified as consequential VNRA(s), but are shared here for information only:*

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Consequential VRAs and VNRAs & Worksharing

- The timetable for WS variations have been agreed by the CMDv and they will follow the Standard timetable (S).
- The eAF does not default to “S” for a WS variation
- When filling out the eAF “S” should be ticked unless one of the variations in the application has an extended TT or an extended TT was agreed with the RMS in advance.

For details see CMDv Best Practice Guide for worksharing.

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you

vetinfo@hpra.ie

www.hpra.ie

Follow @TheHPRA