

CMDv - call for early submission QRDv.9 (Apr 2024)

Please find the call for submitting the variation to update the product information according to QRDv.9 and the current statistics on these variations from the CMDv here:

Dear Marketing Authorisation Holders,

According to article 152 of the Regulation (EU) 2019/6, all marketing authorisation of VMPs granted according to the Directive 2001/82/EC, as amended, require an update of the product information in line with the QRD template version 9. The MAs should be updated before the 30th of January 2027, after which all products on the market should have product information compliant with QRDv9.

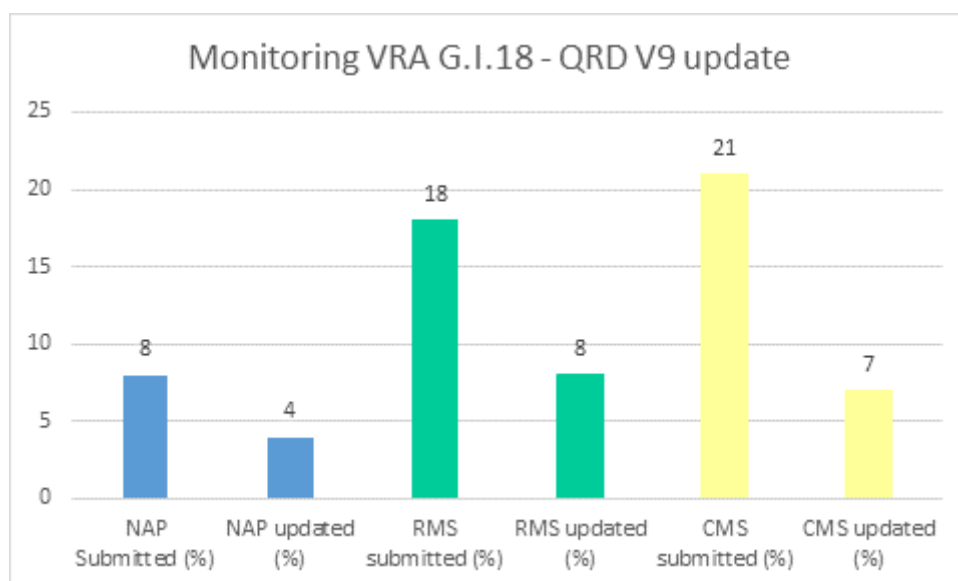
With reference to the tabulated data below, the % of currently updated MAs is not sufficient to guarantee that all VMPs will have an updated marketing authorisation before the 30th of January 2027.

The % of G.I.18 VRAs submitted (currently awaiting or under review) is also critically low. This low number of VRA applications submitted in the Member States will not allow for all changes to be implemented in the EU market before the 30th of January 2027.

As a matter of urgency MAHs are kindly invited to plan for and start submitting the required G.I.18 VRAs to the NCA/RMS as soon as possible, to guarantee compliance with Article 152 of Regulation 2019/6 by the required deadline. To speed up submission and processing time for these variations the MAHs are furthermore encouraged to submit the VRA G.I.18 as stand-alone applications.

In addition, MAHs are kindly recommended to provide, as far as possible, their schedules for remaining submissions to the relevant national competent authorities to support the timely allocation of necessary resources.

Consequently, I kindly invite you to circulate this e-mail amongst the members of your associations.



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Further information:

<https://www.hma.eu/veterinary-medicines/cmdv>