Webinar Q&A -19 May 2022

Transitioning existing MAs to meet the requirements of Regulation 2019/6

Question 1
When will a full alternative/comparable product list be available for use on DAFM new NVPS?

Answer
The development of the new system is being undertaken under the aegis of DAFM. From contacts with DAFM, the HPRA understands that the system will be integrated within the new electronic prescribing system, which DAFM expects to be ready by 1 December 2022.

Question 2
With regards to classification of VMPs, will the HPRA be retaining the POM(E), LM and CAM distribution categories?

Answer
Legislation on veterinary medicinal products is the remit of the Department of Agriculture, Food and the Marine (DAFM) and not the HPRA. From contacts with DAFM, the HPRA understands that a new SI is being prepared which restores the national methods of supply (CAM, LM, PS, POM(e)), which had been abolished in January when SI No 786 of 2007 was revoked. This new legislation is expected imminently.

Question 3
For QRD variation, if we submitted and variation was approved, should be implemented on printed packaging component after 6 months of approval or we can implement within the allowed time period before 2027?

Answer
In line with the Best Practice Guide for Variations Requiring Assessment, for variations that affect the SPC/LAB/PL the common earliest implementation date will be 60 days after the EoP. The timing of submission should ensure that the variation is finalised and implemented on the printed labelling and package leaflet before 27 January 2027.

Question 4
QRD template, if a generic company updated their QRD template and then the reference company updated differently for the same product, should the generic company update again as per the reference product?

Answer

It cannot be excluded that changes subsequently made to the SPC of the reference product may also need to be made to the SPC of the generic product, although it is expected that the need for such changes would be determined by the significance of any potential differences between SPCs of the generic and reference products.

Question 5

Can the changes that are related for update QRD template (v.9) be implemented on the printed packaging material (Mockups) within one year from the approval date of the Variation??
How long can we use the old inventory (old mockups)?

Answer

In line with the Best Practice Guide for Variations Requiring Assessment, for variations that affect the SPC/LAB/PL the common earliest implementation date will be 60 days after the EoP. With respect to the use of old livery, the HPRA will adopt a relatively flexible approach, where required, but do encourage marketing authorisation holders to try co-ordinate their transition from old to new product livery within a reasonable time period.

Question 6

Before starting a new repeat use procedure, generic MA holders are being requested to update the SPC/QRD text to bring it in line with the new veterinary legislation before the reference product.
As you know the generic SPC/QRD text is a copy of the reference product so by updating the text, generic SPC/QRD would not be consistent with the reference product anymore. So, our question is - will HPRA request the MAH for reference product to copy the generic product in this instance?

Answer

For the situation as outlined above, the reference product will be independently reviewed to ensure compliance with the latest version of the annotated QRD texts ahead of the submission of an application for a subsequent recognition procedure.