HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Questions raised by delegates at the HRPA webinar on the implementation of Regulation 2019/6 on 31 March 2021

Question	HPRA response
Will the slide deck be available after the meeting?	Yes, all slide presentations will be published on the HPRA website after the webinar.
General question: will a recording of the webinar be made available on the HPRA website?	Yes, a recording of the webinar will be published on the HPRA website after the meeting.
Will all veterinary products sold in Ireland now have to be labelled in Irish as well as English?	It is too early to advise if any change to the current system is needed, as the High Court in Dublin has yet to give judgment in the case. Stakeholders can follow developments in this matter in the HPRA's Newsletter.
What kind of availability data needs to be recorded in the UPD - only product shortages?	The availability data required for UPD relates to whether a product is 'marketed' or 'not marketed'. This should be updated by MAH's for all their products at the package level. Notifications of shortages is a separate matter; they should continue to be reported to the national competent authorities using existing procedures.
By what date do MAHs have to have updated the UPD with information regarding the date their product was first placed on the market/information on availability of the products etc?	According to the draft Vet Implementation Guide, for existing veterinary medicinal products that were placed on the market before 28 January 2022, dates for placing on the market and availability should be recorded in UPD by 28 January 2023. However, this is based on information provided in the Implementation guide which is still in draft. The finalised document should be available in May or June. MAH's should review the finalised version for the most up to date information.
Question regarding organisations registering in OMS (in the UPD); am I right to think that this will also include API manufacturers, and organisations in non-EU countries? And to make applications all the companies involved must have an OMS entry?	As we understand it, yes; all manufacturer organisation data should be registered, as well as organisations in non-EU countries. MAHs also need to be registered. For the initial submission of veterinary authorised medicinal products in UPD (i.e. so-called legacy data), this requirement is limited to the provision of information on the MAH and the Manufacturer batch release site as defined in Chapter 4 of the EU Implementation Guide (IG). However, we expect for new product submissions from 28th Jan 2022 this scope will be broadened.
What are the implications for a variation not requiring assessment if it is rejected?	The implications will depend on the reason for rejection. If it is rejected due to missing documentation, it can be resubmitted with the correct documentation via UPD. If it is rejected because it does not meet the conditions for a

	variation not requiring assessment, it can be submitted as a variation requiring assessment under the relevant classification code. A 'z' category can be used, if required.
Could HPRA please expand on their level of preparedness for the challenging target of uploading legacy data in the UPD by 28.01.2022, specifically with respect to the use 'fully FHIR-compatible' messages.	The HPRA is focusing currently on preparing our data for initial upload. We are working to adapt our internal system in order to capture the mandatory data for legacy data upload and for new product data post Jan 2022. We are also working on all the mandatory SPOR referential lists, mapping all our organisations, and working on our substance list. Following updates to our system we need to do further data enrichment. The HPRA has a technical team working on the machine to machine upload (so called 'API') which we will use (a) for initial upload of legacy when ready, and (b) which we will use for synchronisation of data on an ongoing basis.
Has the HPRA considered if fees will be required for variations not requiring assessment?	The HPRA undertakes an annual review of fees. For veterinary medicinal products, changes arising from the implementation of Regulation 2019/6 will be considered in the fee review that will be undertake later this year and again next year. It is not envisaged that fees will be introduced for variations not requiring assessment.
What information will be included in the summary of the PSMF?	The HPRA expects that the information to be included in the summary of the PSMF will be in line with the recommendations from the EMA, namely: PSMF reference number, PSMF location, QPPV details and a signed statement by the MAH and QPPV that the QPPV has the necessary means to fulfil their tasks and responsibilities.
Question to the Pharmacovigilance area: will QPPV-related information be held in the UPD or the PhV Database ?	Art 74.1 suggests that the PhV database will include information on the QPPV. However, as both the UPD and PhV databases are currently being developed and information will be linked between the two, we cannot confirm in which database this information will ultimately be stored.
Will 'signals' be clearly defined in the legislation? At present, each MAH can have a different definition of an [adverse event] signal.	Yes, the HPRA expects that there will be a definition of a signal in the Implementing Act currently being drafted. We also expect that further clarification will be provided on what constitutes a signal in the guidelines currently being drafted by the EMA.
Has the PSMF to be approved by the EMA? by the NCA? or it will not be necessary?	No. Only the summary of the PSMF will be assessed/approved as it will form part of the dossier for new applications from 28th January

	2022. However, the PSMF itself will be subject to review at the time of PhV inspections.
Will sales data for 2021 be required to be included in database or will it be from 2022 onwards?	At this time, the HPRA cannot provide a definitive response to this question. However, given that the regulation applies from the 28 January 2022, the HRPA expects that sales data submission requirements would apply only from then. For further clarification, we would suggest sending this question to vetchange.programme@ema.europa.eu
Given the changes to pharmacovigilance does HPRA envisage an increase in the number of PV Inspections?	There are currently no plans to increase the number of PhV inspections. However, as PhV inspections are to be primarily scheduled using a risk-based approach and the introduction of the new legislation may increase the risk of non-compliance, it is possible that there may be a need to inspect more MAHs.
It was stated that existing products will remain jointly labelled [with the UK] subject to alignment. Will joint labelling still be available for newly authorised products post January 2022?	The HPRA is committed to continue to support joint labelling for newly authorised products post-January 2022 with the UK (GB) subject to the UK and EU operating an equivalent regulatory framework and opinions align. Joint labelling between IE and UK (NI) will be feasible given that the UK (NI) may act as a concerned member state in EU regulatory procedures in line with the Northern Ireland Protocol.
Is it expected that there will be provisions for joint labelling for products approved post implementation of 2019/6?	The HPRA is committed to continue to support joint labelling for newly authorised products with the UK subject to the UK and EU operating an equivalent regulatory framework and opinions align. Those product that were joint-labelled prior to 28th January 2022 will remain joint-labelled (as long as the product information remains identical in both the UK and IE).
In terms of joint labelling, if the UK requires the licence to be held by a UK MAH in future will this no longer be possible?	Joint labelling should still remain a possibility for VMPs authorised by way of national/decentralised/mutual recognition procedures if the UK MAH is placed in the country-specific "box" which houses administrative information. All other information on the labels must remain identical in order to avail of joint labelling.
Will the name and logo of distributor still be allowed to mentioned on outer packaging and in Product information?	The subject of name and logo of distributor has been discussed in recent CMDv-Interested Parties meetings with no common approach agreed at an EU level. Applicants are advised that the spirit of the

	Regulation 2019/6 is that a minimum set of information is allowed on the packaging. If the applicant requires, more information can be allowed by Member States, but this will not facilitate multi-country packaging.
The summary of the PSMF for new registration should be the same?	As the summary of the PSMF is specific for each PSMF, the information to be included in the summary of the PSMF for each marketing authorisation application from the same applicant may differ as it is possible to have a different PSMF for each product. However, there can only be one summary for each PSMF.
Do we need to submit application to the DAFM to obtain GDP certificate?	Requirements relating to the regulation of wholesale distribution of veterinary medicinal products are set by the Department of Agriculture, Food and the Marine (DAFM). It is recommended that any holder of an existing wholesale distribution authorisation or intending applicant contact the DAFM - https://www.gov.ie/en/service/641c4-veterinary-medicines-form/ The HPRA expects that the DAFM will conduct inspections of wholesalers of veterinary medicines. If there is a satisfactory outcome to the inspection of a wholesaler then the DAFM will issue a certificate of Good Distribution Practice which will be uploaded to the EU database. The inspection may be triggered by receipt of an application for a Wholesale Distribution Authorisation for veterinary medicines, or on the basis of factors as decided by DAFM under its programme for inspection of wholesalers.
Can you elaborate on 'novel therapies for vet use	Novel therapies are therapies entirely new to veterinary medicine either because they are genuinely novel and have not been previously used in the context of a medicine, or new only to the veterinary domain, although well known in terms of research, and possibly in the context of human medicine. Novel therapies include products such as stem cell products intended for veterinary use. Further information on novel therapies may be accessed on the EMA website through the following link: https://www.ema.europa.eu/en/veterinary-regulatory/research-development/scientific-guidelines/novel-therapies

	Specific guidelines for manufacture of novel therapies are not yet drafted but are planned.
Will HPRA develop guidance for extemporaneous substances, autologous stem cells and autogenous vaccines?	The HPRA will use the guidance developed at EU level in relation to regulation of manufacturers of novel therapies and autogenous vaccines. The Department of Agriculture, Food and the Marine will oversee autogenous vaccines with assistance from the HPRA. The HPRA is not planning to develop guidance on extemporaneous compounding/manufacture, as this practice relates to one-off product compounding by veterinary practitioners and this practice is outside the remit of the HPRA (which relates to authorised veterinary medicines).
Is Regulation 2019/6 immediately implemented by HPRA with no transition period for PSUR?	As and from 28th January 2022, there is no requirement to submit PSURs and therefore the HPRA will not be requesting or assessing them after 28th January 2022.
For PSURs where the data lock point (DLP) was in 2018, 2019 or 2020 how will HPRA obtain details of non serious reports that occurred during this period.	This matter is currently under discussion within the regulatory network as the signal management required from 28th January 2022 will depend upon the availability of PhV data (including non-serious reports). It is currently possible for MAHs to submit non-serious adverse event reports to EV-VET so that these reports are available for signal management purposes. Once discussion of this issue has been finalised, the HPRA expects to provide an update on the HPRA website.
What will happen the renewals for existing products where the MA expires after 28.1.2022?	Individual decisions granting the marketing authorisations concerned must be amended to make their duration unlimited in order to comply with Regulation 2019/6. A mechanism to effect the change will be required and the topic is still under discussion at the level of CMDv. The HPRA will be advocating for a solution that is a simple administrative procedure. Once a decision is taken, the HPRA expects to provide an update on the HPRA website.
Are PSURs with DLP 30 Nov 2021 the last PSURs that MAHs need to submit – i.e. submission date 28 January 2022. Or will the submission of PSURs for products with later DLP (28 January 2022 latest) be required?	The HPRA has sought and is currently awaiting clarification on this particular question from the EMA as the HPRA's preference is that a harmonised approach to cessation of PSUR assessment is adopted across the regulatory network. We will provide an update on the HPRA's website once the requested clarifications have been received and a decision has been made.

Can the PSMF be held on server in Northern Ireland but accessible in EU?	The recommendations sent from the EMA to the Commission states: *'where the pharmacovigilance system master file is held in electronic form, the location stated must be a site in the EU, where the data stored can be directly accessed, also for inspection or audit.'* It is the understanding of the HPRA that if the pharmacovigilance system master file is kept in electronic form (e.g. on a server located in Northern Ireland) it should be sufficient that the data stored in electronic form are directly accessible/available from the site where the PSMF is located. However, we cannot provide a definitive answer as the Implementing Act has yet to be adopted and we would encourage you to provide any comments/submissions to the Commission when the Implementing Act is published for public consultation if this question is not adequately addressed in the Implementing Act.
Will there be a timeline for accepting or rejecting the VNRAs?	The CMDv Best Practice Guide (BPG) for variations not requiring assessment is not yet finalised. The timeframe will be detailed within that BPG and is currently proposed to be 30 days.
How will duplication/triplication of sales data for all products (not AM only) be avoided in practice?	The responsibility for uploading sales data to the UPD rests with the Marketing Authorisation Holders. Final decisions on the approach to uploading sales data have yet to defined by the EMA. Further clarification of this matter should be directed to the EMA.