Practical guidance of the CMDv for facilitating the handling of processes during the COVID-19 crisis

This document is prepared by CMDv in line with and in addition to the EC/EMA/HMA “Notice to stakeholders: Questions and answers on regulatory expectations during a pandemic”. It is intended to give further explanations and practical guidance how to address, apply and implement the provisions given by this notice for MR/DCP products.

1. **We have to submit a renewal application in order to meet the deadline. However, due to COVID-19 situation we are not able to prepare the complete renewal application in time. Can we submit the application later?**

MAHs are requested to submit the renewal application on time. However in the situation above, in order to meet the legal deadline, it is acceptable to submit only the renewal application form (without annexes) and renewal cover letter to the RMS and CMS, stating in the cover letter that the complete dossier is delayed due to COVID-19 and will be submitted as soon as possible but at the latest within 6 months. The MAH should use the usual submission route. The RMS should already include the procedure in CTS and use the annotation field to inform the CMS of the delay in the procedure due to COVID-19.

Once the complete renewal application is submitted as additional documentation the usual submission route, the applicant should indicate in the cover letter that an incomplete application has been submitted previously due to COVID-19.

2. **Will the Covid-19 pandemic affect the timelines for the assessment of marketing authorisation application or post-authorisation procedures?**

In certain cases, the RMS, in consultation with the CMSs, may decide to delay the procedure start or re-start, if this is in the interest of the applicant and/or the RMS/CMSs.

Furthermore, it is exceptionally agreed for DCP/MRP/RUP, renewal and type II variation procedures to allow a “freezing” (holding the timetable at the same procedure Day and restarting it as soon as the response is received or as soon as the RMS AR is finalised) in the clock stop) of the procedure timetable due to unexpected and COVID-19-related capacity issues within the RMS, or when it is not possible for applicants to submit responses due to the COVID-19 pandemic. The applicant
should inform the RMS timely enough of a necessary interruption of the procedure and justify that
the reason for not being able to respond is related to the pandemic.

In these cases applicant/MAH and RMS should closely communicate the necessary steps and the
RMS will decide the solution considered most suitable in the specific situation.

The RMS will inform the applicant/MAH and CMS by e-mail about any changes in the time-lines.
The RMS will also update CTS accordingly and use an annotation field to note how the timeline
has been changed.

For centrally authorised products, notification should be made to the EMA.

3. **I would like a full or partial exemption to certain labelling and packaging requirements for an authorised veterinary medicinal product in order to avoid a shortage due to the Covid 19 situation. What can I do?**

Article 61(1) of the Directive 2001/82/EC, as amended, mentions: « Competent authorities may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of the Member State in which the product is placed on the market, when the product is intended to be administered only by a veterinarian.»

So a flexible approach is legally possible. However, the MAH should send an email to the relevant national competent authorities with the subject title “COVID-19” next to the national product number in the email heading (see link to national contact points: https://www.hma.eu/530.html?&L=0).

4. **Due to the Covid 19 situation I would like to add CMS to my marketing authorisation (MRP/DCP) in an accelerated way. How should I communicate that?**

The CMDv has agreed to perform accelerated repeat use procedure via a fast-track timetable (shortened TT). The choice of the procedure depends on the criticality of the product as well as the decision of the RMS and the proposed new CMS. In the first instance the MAH should liaise with the proposed CMS in order to agree on their acceptance for an accelerated procedure. The MAH should confirm that the product is ready to be marketed immediately after receipt of the MA. Details have to be discussed case by case with the RMS and CMS. All requests for such procedures should be addressed to the RMS and CMS by email notification with the subject “COVID-19 accelerated RUP”. Furthermore, all agreements between MAH and MS in communication beforehand should be summarized clearly in the cover letter of the application.

5. **Due to the Covid 19 situation I have to submit/pending urgent variation procedures for veterinary medicinal products. Is it possible to expedite these variations?**

According to the Regulation 1234/2008/EC and the CMDv Best Practice Guide for Variations it is generally possible to speed up variations if necessary. In this case, the MAH should contact the RMS in by sending an email notification to the RMS with the subject “COVID-19 – shortened variation TT”. In this notification it should be sufficiently described why the TT needs to be shortened. The request will be evaluated by the RMS in consultation with the CMS promptly. If there is an agreement before the submission of the variation this should be summarized in the cover letter and also stated in the section “background/scope” as
“accelerated timetable”. A shortening of the timetable is only possible for type IB and type II variations. The timetable will be agreed by RMS and CMS on a case by case basis dependent on the urgency of the matter, for example for type II variations this may also be shorter than the 30-day timetable.

6. **If there are urgent variations due to the Covid 19 situation, would it be possible to handle the grouping possibilities in a more flexible way?**

Yes, a more flexible handling of the grouping activities is possible in this specific situation. It should be discussed with the RMS before submission.

7. **In case a medicinal product would be needed in the EU due to the Covid 19 situation but would not be available, is it possible to apply for an MRP based on a third country MA?**

No, it is not possible to apply for such an MRP based on a third country MA. However, it is possible to import such products. The prerequisites for import should be discussed with the relevant national authorities beforehand.