

# Important Information for applicants of marketing authorisations: New Applications

News story

Submission opportunities that are now available to applicants of marketing authorisations.



Five months have passed since the end of the transition period and our Exit from the European Union and we are embedding the submission opportunities that are now available to applicants.

It is important, however, for the VMD to be able to plan its resources to ensure that we can continue to provide you with the predictability of the authorisation process; and to ensure we have assessor availability during the traditional busy periods. This will include the Summer months and the Christmas period, especially as the pandemic lockdown procedures ease and life begins to return to something resembling normality.

The VMD will therefore be introducing the following measures:

- As a temporary measure until the end of the year, submission slots will be introduced for biological and bio-pharm products. Submissions will need to be agreed in advance with the Regulatory Affairs Team who will liaise with the Biologicals Team.
- Applicants should arrange to meet with us at least three months in advance to discuss your applications. This would be in respect of GB and NI national only procedures and those being submitted to NI under the mutual recognition and decentralised procedures. This is in line with the CMDv Best Practice Guide on Decentralised procedures (CMDv BPG-002) and would help to facilitate submission under parallel procedures in GB. This would not be a Scientific Advice meeting, but one in which you outline your product, cover the regulatory aspects, outline the data you

plan to submit and to also discuss the timing of the submission.

- Likewise, we would like to meet with you to discuss applications you plan to submit in parallel with the Centralised Procedure around the same time as you meet with the EMA which would be about seven months in advance of the planned submission.

One of the new ways of working arising from the pandemic lockdown measures, is use of virtual meetings. These open up attendance more widely and more easily facilitates meetings between the VMD and companies. Virtual meetings may be as short as 10 minutes or as long as two hours.

Please contact Chris Abbott [c.abbott@vmd.gov.uk](mailto:c.abbott@vmd.gov.uk) to arrange a meeting. You would need to provide a meeting agenda to ensure we can invite the appropriate VMD personnel.

Should you wish to discuss these measures in more detail, then please contact Gavin Hall [g.hall@vmd.gov.uk](mailto:g.hall@vmd.gov.uk) or telephone 01932 338431.

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