

Webinar Q&A -19 May 2022

Renewals

Question 1

If a Repeat use was done before 28-01-2022 and has to be renewed in 2024, does it fall under unlimited licence under art 5.2, so no renewal or has it still to be renewed? How?

Answer

The need for a renewal will depend on the date of issue in each Member State and will be dealt with in accordance with the approach in each Member State. In IE if the MA has an expiry date on or after 28th July 2022 it will be handled by an administrative process. The HPRA will provide the MAH with updated documents with unlimited validity of the MA. As the MA for the repeat use is to expire in 2024 a renewal, processed under the 'old' Directive 2001/82, will not be required.

Question 2

What would be the validity period of parallel import products? Will their licence will be renewed by the HPRA or it will be the responsibility of the PVPA Holder?

Answer

The HPRA will apply the same administrative process for parallel import products as with all MAs with an expiry date, updated documents with unlimited validity of the MA will be provided in accordance with Regulation 2019/6.