Information on batch testing of medicinal products in the context of withdrawal of the United Kingdom from the Union

Following a request by the United Kingdom, the European Council (Article 50) agreed on 11 April 2019 to extend further the period provided for in Article 50(3) TEU until 31 October 2019. Unless the United Kingdom ratifies the Withdrawal Agreement by 31 October 2019 or requests a third extension, to which the European Council (Article 50) agrees by unanimity, the period under Article 50(3) TEU will end then. The United Kingdom will then be a third country as of 1 February 2020.

On 21 February 2019 Commission services set out in a note on the "Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products", the conditions for marketing authorisation holders to continue relying on quality control testing performed in the United Kingdom for a limited period of time after the UK becomes a third country. A key condition for this exemption is that "all necessary steps have been taken to prepare the transfer of the quality control testing site to the EU27". Furthermore, "marketing authorisation holders must confirm and set out their precise timetable for transfer of the quality control testing site (which should allow the process to be completed quickly and in principle by the end of 2019 at the latest)".

It is essential that marketing authorisation holders use the remaining time to complete their preparations so that by 1 January 2020 all batch testing facilities are fully transferred to the EU27/EEA and the necessary regulatory submissions are completed.

For further details please see the relevant communication