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Cut-off dates for UK Rapporteurship appointments for pre and post authorisation procedures for centrally authorised products

Human and Veterinary medicinal products

1. Introduction

As stated in the European Commission and EMA Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use "…the United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless a ratified withdrawal agreement[1] establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET)[2]. The United Kingdom will then become a 'third country'[3]…".

As a consequence, the MHRA/VMD will no longer be able to engage as (Co)-Rapporteurs in centralised regulatory procedures which are expected to finalise after 30 March 2019. (Co)-Rapporteurships for centrally authorised human or veterinary medicinal products for which post-authorisation procedures are starting in Q4-2018 and are envisaged to still be ongoing on 30 March 2019, will be assigned for that particular procedure to the newly appointed (Co)-rapporteurs. The MHRA/VMD remains accountable for the medicinal products for which they are (Co)-Rapporteurs until 29 March 2019.

2. Methodology

Based on the nature of the tasks and the average duration of the procedures concerned, cut-off dates have been identified with regards to the participation of MHRA/VMD in the activities identified below. Cut-off dates for each procedure in pre and post authorisation were extrapolated by averaging the length of each procedure from submission to outcome, and by taking into consideration the deadline of 30 March 2019.

[1] Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.
[2] Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.
[3] A third country is a country not member of the Union.

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3. Human medicinal products

3.1. Pre-Authorisation

Pre-Authorisation procedures	*Cut-off date (intended submission)*
PRIME	n/a
Scientific Advice	5 November 2018
PIPs (initial)	July 2018
PIPs (Modification, Waivers and Compliance Check)	December 2018
Orphan Designation (initial)	December 2018
Full MAAs, Hybrids and Biosimilars	February 2018
Generics human medicines and article 58	May 2018

3.2. Post-authorisation

Post-Authorisation procedures	*Cut-off date (intended submission)*
Type IB	16 January 2019
Worksharing (type IB only)	26 October 2018
Type II (Quality)	26 October 2018
Type II (Safety and Efficacy)	26 October 2018
Type II (extension of indication)*	4 July 2018
Renewals	24 October 2018
Annual re-assessment	26 September 2018
PASS	17 September 2018
PAMs	27 November 2018
PSURs (CAPs only)	8 November 2018
PSUSAs - CAPs/NAPs & NAPs/NAPs	24 October 2018
Line extensions*	30 April 2018

*For lines extensions and extensions of indication the cut-off dates have already surpassed and therefore all procedures starting after 1 October 2018 will be allocated to the new (Co)-Rapporteurs.

4. Veterinary medicinal products

4.1. Pre-Authorisation

Pre-Authorisation procedures	*Cut-off date (intended submission)*
Scientific Advice	November 2018
Full MAAs	December 2017
Generics veterinary medicines	March 2018
Article 13(3) - Hybrid	January 2018
Article 13a – Well-established use	November 2017
Article 13b - Fixed combination	September 2017
Article 13c – Informed consent	October2018
Article 13d - Immunologicals (exceptional circumstances)	April 2018
Maximum Residue Limits (MRLs)	April 2018

4.2. Post-authorisation

Post-Authorisation procedures	*Cut-off date (intended submission)*
Type IB	January 2019
Worksharing (type IB only)	November 2018
Type II (Quality)	October 2018
Type II (Safety and Efficacy)	October 2018
Type II (extension of indication)*	July 2018
Renewals	November 2018
Annual re-assessment	December 2018
PAMs	December 2018
PSURs	December 2018
Line extensions*	April 2018

*For lines extensions and extensions of indication the cut-off dates have already surpassed and therefore all procedures starting after 1 October 2018 will be allocated to the new (Co)-Rapporteurs.