CALLISTO PHARMA GROUP
Technical Expertise from Development to Distribution

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Human Medicine HIGHLIGHTS

Issue 2 December 2023

IN THIS ISSUE

As the Christmas season approaches, we wish to extend our warmest wishes to you and your families. May this festive season bring you joy, peace and lots of cherished moments.

Please note that our office will be closed from 22nd December to 2nd Jan 2024 to allow our team to spend quality time with their families and recharge for the challenges and triumphs that the new year will bring.

Thank you once again for choosing Callisto Pharma Group as your partner. We look forward to working with you in the upcoming year and wish you a Merry Christmas and a Happy New Year.

MHRA International Recognition Procedure (IRP)

Guidance

- From 1 January 2024, the EC Decision Reliance Procedure (ECDRP) will be replaced by the new International Recognition procedure (IRP).
- IRP will be open to applicants that have already received an authorisation from one of MHRA's specified Reference Regulators (RRs) which include the EU, US, Switzerland and Australia.
- The MHRAs IRP guidance has been updated to add guidance on the Eligibility Checker.
- The MHRA have also added updated guidance on Product & eCTD Lifecycle

More information can be found here

- The MHRA have published the fees associated with the IRP.

More information can be found here

UK Change of Ownership applications

Guidance

- The MHRA have updated the guidance on change of ownership applications.
- Changes include a new application form and minor changes to the process.

Current MAH vs Proposed MAH Stock

- Stock in old livery which has been QP released before licence transfer and before end of current licence can continue to be sold.
- Where stock in old livery is on the market following cancellation of the licence, PV procedures should be maintained.
- If there are remaining stocks in old livery that has not been released, the new MAH holder may put in a batch specific variation.

More information can be found here

Human Medicine and Medical Devices HIGHLIGHTS

Issue 2 December 2023

IN THIS ISSUE

Anastrozole to prevent breast cancer

- MHRA authorises enzyme inhibitor Anastrozole to prevent breast cancer in post-menopausal women

More information can be found here

MHRA Developments

Assessors and assessment times

- MHRA is planning to recruit a further 25 new assessors. Training new staff is a significant challenge, more than recruitment as such.
- It is hoped that statutory timelines for new MAAs can be met in 2024.

Scientific Advice Meetings

- SAMs are now being scheduled but the timelines will depend on topic and disciplines needed. SAMs are still being prioritised. By March 2024 it is hoped that SAMs will return to a more predictable timeframe.

GMDP

- GDP Certificates have been extended to 2023. MHRA is currently liaising with other regulators in the EU to determine next steps and further guidance will be published for 2024.

First Electronic Product Information (ePI) for Human Medicines

- The EMA recently announced that the Heads of Medicines Agencies (HMA), the European Commission (EC) and the EMA have published for the first time **electronic product information** (ePI) for selected human medicines harmonized across the European Union (EU).
- The EMA and a group of EU national competent authorities are testing the use of ePI in a one-year pilot project from July 2023.

More information can be found here.

UK transition to UKCA

- In the UK, the transition to requiring UKCA (UK Conformity Assessed) marks for medical devices, initially set for June 2023, has been delayed to July 2024.
- The new UK MDR (Medical Devices Regulation) is anticipated to take effect from July 2024. Additionally, the UK Government plans to release new proposals on international recognition routes in February 2023.

EPSCO (Employment, Social Policy, Health and Consumer Affairs Council) latest meeting

- Discussions included:
  - ✓ Cost and predictability of MDR CE certification and the slow pace at which manufacturers are submitting files
  - ✓ The MDCG (released the 2022-11 Rev 1 Position Paper, urging Notified Bodies to streamline the certification process.
  - ✓ A notable regulatory update is the extension of the DEHP (Di(2-ethylhexyl)phthalate) prohibition in medical devices until July 1, 2030, giving manufacturers longer to comply with the regulation.

More information can be found here

Veterinary Medicine HIGHLIGHTS

Issue 2 December 2023

IN THIS ISSUE

The New VMD Veterinary Medicines Regulations (VMR)

- The VMD are still hoping that the legislation will be laid before Parliament in January 2024, with the legislation applying from April 2024 onwards

VMD Christmas Application Deadlines

MA applications

- The last validation meeting to discuss applications for new Marketing Authorisations (MAs) will take place on 14 December. New applications to be considered for validation must be received on or before 11 December.
- All other applications must be received by 15 December to ensure they are dealt with during the Christmas period

Man A and WDA applications

- The last day for validation of applications for Authorisations for Manufacturers and Wholesale Dealers (new and variations) will be on 15 December.

Specific Batch Control

- Applications must be received by 15 December to ensure it is dealt with during the Christmas period.

Antiparasitic Veterinary Medicinal products

- Similarly to antimicrobial substances, the wide-spread use of antiparasitic substances may lead to the development of resistance, and therefore decreased efficacy of these medicines.
- Antiparasitic VMPs generally have a very 'active' product lifecycle, with a comparatively high number of post-authorisation changes (e.g. the extension of existing indications to allow a wider use, for instance by increasing the range of parasites for which the treatment is indicated (such as a new tick species), or by adding a new target animal species).
- The new EU legislation (Regulation (EU) 2019/6), introduced a number of new measures aiming to reduce the risk of development of antiparasitic resistance
- For instance, data on antiparasitic resistance development was already previously required when applying for authorisation of a new antiparasitic VMP. Under the new legislative requirements, this aspect must also be addressed for generic/hybrid products. In addition, 'antiparasitic resistance' is now stated as a ground for refusal of a marketing authorisation application.
- Regulation (EU) 2019/6 also provides new incentives to marketing authorisation holders in the form of additional data protection (market exclusivity) for certain types of variations (changes to the product) that can demonstrate a reduction in the risk of development of antiparasitic resistance.