# Human Medicine HIGHLIGHTS

Issue 3 January 2024

**IN THIS ISSUE**


| | |
|---|---|
| Windsor Framework | 1 |
| International Recognition Procedure | 2 |
| EC-HMA-EMA Union List of Critical Medicines | 2 |
| MA Suspension- Contract Research Organisation | 2 |
| GMP and GDP Certificates | 2 |
| MHRA Consultation on product safety | 2 |
| Medical Device Coordination Group (MDCG) of the European Commission | 3 |
| MHRA Devices- Regulatory framework | 2 |
| New Veterinary Regulation Updates | 3 |
| Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin | 3 |


Welcome to our first newsletter of 2024. We are looking forward to an exciting year of continued growth and to providing tailored solutions and expertise to help enable your businesses to realise their potential.

At the end of last year, and as part of our continued growth, we moved to new larger offices in the UK with space to accommodate our 30+ employees and room for further expansion. We have also recently moved offices in Dublin as our EU based operations increase. Existing Clients will have been contacted separately regarding any implications of the address change on their operations but if you have any questions please talk to your normal contact or email info@callistopharmagroup.com.

Our new address in the UK is, Callisto Pharma Group, Garden Court, Lockington Hall, Main Street, Lockington, DE74 RH2, UK.

Our new address in the EU is, Callisto Pharma Group, Office 107, Regus Block 1, Blanchardstown Corporate Park, Dublin, D15AKK1, Ireland

Finally, we would like to wish you a prosperous year and hope that you find our monthly newsletter useful.

## Windsor Framework

### HPRA

- The HPRA have published a Q&A document relating to the impact of the Windsor Framework on the regulation of human medicines. The document is based on questions the HPRA has received from companies.

More information can be found here.

### MHRA

- Update to the labelling and packaging Windsor framework guidance include:
  - the decision to allow the early release to the GB market of PLGB products that have had 'UK Only' added, before 1 January 2025
  - the addition of a third option for initially submitting new artwork changes without an eCTD
  - Updated section 7 to provide clarity on where existing stock packs can be supplied.
  - Any stock in existing packaging already placed on the marketed in NI and GB can continue to be supplied until the date of their expiry.

# Human Medicine and Medical Device HIGHLIGHTS

Issue 3 January 2024

**IN THIS ISSUE**


| | |
|---|---|
| Windsor Framework | 1 |
| International Recognition Procedure | 2 |
| EC-HMA-EMA Union List of Critical Medicines | 2 |
| MA Suspension- Contract Research Organisation | 2 |
| GMP and GDP Certificates | 2 |
| MHRA Consultation on product safety | 2 |
| Medical Device Coordination Group (MDCG) of the European Commission | 3 |
| MHRA Devices- Regulatory framework | 2 |
| New Veterinary Regulation Updates | 3 |
| Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin | 3 |


## MA Suspension- Contract Research Organisation

- EMA has recommended the suspension of the marketing authorisations of a number of generic medicines tested by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Pune, India.

## GMP and GDP Certificates

- GMP & GDP Certificates: Validity Period Extended- The MHRA has decided to continue the extension of the validity date until 2024

## MHRA Consultation on product safety

- The MHRA have published a consultation on how MHRA communicate with healthcare professionals to improve medicines and medical devices' safety.
- The consultation outcomes will underpin the MHRA's risk and safety three-year communications strategy, shaping the MHRA safety communication output and ongoing engagement with HCPs and ensuring that the MHRA supports HCPs and organisations across the medicines, devices, and patient safety landscape.
- There are 13 key recommendations, which fall into 4 main themes:
    1. communications
    2. websites
    3. awareness and education
    4. engagement.

More information can be found here

## International Recognition Procedure (IRP)

### Submission dates

- MHRA has updated the guidance on the IRP to add submission dates for Recognition B which align with Commission on Human Medicines (CHM) dates for New Active Substances (NAS). More information can be found here

## EC-HMA-EMA Union List of Critical Medicines

- The European Commission (EC), The Heads of Medicines Agencies (HMA) and The EMA have published the first version of the Union list of critical medicines. The list contains more than 200 active substances considered critical for healthcare systems across the EU/EEA, for which continuity of supply is a priority and shortages should be avoided.

More information can be found here

## MHRA Devices- Regulatory framework

- The UK government is working on a substantial reform of the current regulatory framework for medical devices and aim to implement core aspects of this new regime from July 1, 2025.
- Legislation planned for later in 2023 will introduce strengthened Post-Market Surveillance requirements as part of the future regulatory regime, emphasising improved patient safety.

# Medical Device and Veterinary Medicine HIGHLIGHTS

Issue 3 January 2024

**IN THIS ISSUE**


| | |
|---|---|
| Windsor Framework | 1 |
| International Recognition Procedure | 2 |
| EC-HMA-EMA Union List of Critical Medicines | 2 |
| MA Suspension- Contract Research Organisation | 2 |
| GMP and GDP Certificates | 2 |
| MHRA Consultation on product safety | 2 |
| Medical Device Coordination Group (MDCG) of the European Commission | 3 |
| MHRA Devices- Regulatory framework | 2 |
| New Veterinary Regulation Updates | 3 |
| Ectoparasiticide Veterinary Medicinal Products Containing Fipronil, Imidacloprid, and Permethrin | 3 |


## Medical Device Coordination Group (MDCG) of the European Commission

- At the end of 2023, the Medical Device Coordination Group (MDCG) of the European Commission released several guidance documents, including the following:
  - Guidance on Clinical Investigation Exemptions. It specifically addresses situations where clinical investigations may not be necessary, outlining criteria and processes for these exemptions, focussing specifically on Class III and implantable devices
  - Q&A on Regulation Articles 13. & 14; covering aspects related to the identification and traceability of devices, including the Unique Device Identification (UDI) system
  - Guidance on Demonstration of Equivalence for Annex XVI Products (medical devices without an intended medical purpose, e.g. contact lenses)
  - Guidance on Qualification and Classification of Annex XVI Products.

More information can be found here

## New Veterinary Regulation Updates

### UPD- Volume of sales

- Regarding the Union Product Database (UPD), Marketing Authorisation Holders (MAHs) are reminded that information on the volume of sales in 2023 for each product should be submitted before 29 February 2024.

### QR Codes on packaging

- The EMA published a document outlining general principles of acceptability and procedure in respect of Quick Response (QR) codes in the labelling and package leaflets of veterinary medicinal products. The document applies to all veterinary medicines whether authorised centrally or nationally. More information can be found here

## Ectoparasiticide Veterinary Medicinal Products

- The VMD have published an awareness piece in response to increased action group interest regarding banned pesticides (Fipronil, Imidicloprid, Permethrin) still being used in veterinary medicines for cats, dogs and other companion animals.
- The VMD recognise the concerns regarding the potential contribution being detected in UK surface waters.
- The VMD has commissioned research and has formed a cross-governmental Pharmaceuticals in the Environment (PiE) Group. This group is chaired independently of Government and provides a platform for discussion and knowledge exchange relating to pharmaceuticals in the environment. The aim is to develop a co-ordinated strategy to reduce the impacts of pharmaceuticals on the environment.