Human Medicine HIGHLIGHTS

Issue 1 November 2023

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In November 2003, Jo Bunyan and Andrew Burbage saw that there was a potential gap in the market for consultancy services for MA holders particularly in the generics market. With Jo's background in Regulatory affairs and Andrew's in GMP manufacturing and also a qualified QP, together they could provide a wide range of services to their clients. And so, Callisto Regulatory Consulting Ltd was founded. The early years saw steady growth and a loyal client base, and in 2012 in response to their clients' needs, Elara Pharmaservices Ltd was founded to facilitate an MIA and ManA, to expand services to include batch importation and release. In 2018, Elara Pharmaservices Europe Ltd, based in Dublin, was added to the group to ensure continuity of service post-Brexit in Europe.

Today the companies are integrated under the Callisto Pharma Group portfolio and currently has an amazing team of 35 employees providing expertise across Regulatory Affairs, Pharmacovigilance, Medical Devices and GMDP services.

As we celebrate 20 years of diligently serving our clients, we are not only reminiscing about our journey, but also looking to the future. The industry is dynamic and ever evolving, with new challenges and opportunities. In the years ahead, we are committed to staying at the forefront of these changes, ensuring that our clients continue to receive the highest level of support and expertise. Our future plans include expanding our services to embrace emerging trends in the industry. Our journey has been incredible so far, and our vision for the future is equally exciting. We look forward to sharing this new chapter with our valued clients and our exceptional team.

Current MD Jo Bunyan commented, "20 years ago I would not have envisaged the company that now exists, with so many great people and such loyal clients. It is a testament to our work to see our clients' businesses growing as well and hopefully our input has helped their journey in some small way as well"

DCP/MRP timelines

- CMDh has adopted updated guidance documents with the timetables for MRP/DCP applications to be submitted in 2024.
- The overview of timetable can be found here
- Competent Authority, should do so as a matter of priority, including any updates to previous notifications.

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Nitrosamines

- An amended version of the Questions and Answers document regarding nitrosamine impurities has been published
- Any MAHs that have not reported identified Nitrosamine impurities to the relevant Competent Authority, should do so as a matter of priority, including any updates to previous notifications.
  - The updated document can be found here

Safety warnings to be provided to all patients with every valproate-containing medicine

- Following a government consultation, this change to legislation has been made to ensure that patients always receive specific safety warnings and pictograms, including a patient card and the Patient Information Leaflet, which are contained in the manufacturer's original full pack.

More information can be found here

GMP Chain of Contracts

- The European Medicine Agency EMA has updated its Questions and Answers and discusses the "Chain of Contracts", a "setup where one or more parties (sites/companies) are acting as signatory in a chain of contracts that links them together.
- More information can be found here

EU GMP Annex 1

- On 25 Aug 2023 the updated EU GMP Annex 1 became effective, all except paragraph 8.123 relating to lyophilizers and associated product transfer and loading/unloading areas, although the expectation is to be compliant as soon as possible and not wait until next year's deadline.
- More information can be found here

EU GMP and GDP guidelines

- The EMA published updates to the frequently asked questions discussed and agreed by the GMP/GDP Inspectors Working Group to provide additional interpretation of the EU GMP and GDP guidelines.
- The FAQs can be found here

Treatment with isotretinoin for patients under 18 must be approved by two prescribers, under new MHRA rules

- New measures strengthen the safe use of the acne drug isotretinoin for patients across the UK, following a patient-focused expert review
- In response to these concerns, a patient-focused independent expert review of suspected mental health and sexual side effects of isotretinoin has been carried out, leading to new safety measures introduced today.

More information can be found here

Veterinary Medicine HIGHLIGHTS

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GB Veterinary Medicines Regulations transition

Local representatives

- MAHs without an existing UK entity will need to engage with potential individuals/entities to identify an appropriate local representative prior to varying all their licences.

Prequalification of veterinary vaccines and medicines

- The prequalification scheme initiated by the WHO in 1987 for human vaccines and extended in 2001 to medicinal for establishing lists of prequalified products for use by procuring organisations through independent evaluation has been successful in assuring the pharmaceutical quality, safety and efficacy of procured medicines in humanitarian assistance programmes without the need of repeated and resource demanding evaluations with possibly uncertain reliability.
- The European Commission is working to create a similar scheme for veterinary medicines and vaccines.
- The PQv scheme has been established in the first instance for Food and mouth disease (FMD) vaccines but may be extended to other Foot-and-Mouth and Similar Transboundary (FAST) diseases once experience has been gained with FMD.

Veterinary EU Regulations

Product information

- The use of QRD v.9 has been mandatory since 28 January 2022 for all new marketing authorisations.
- MAHs can continue to place VMPs compliant with the old QRD template on the marketed until the 29th January 2027.
- MAHs should Consider production runs to avoid destruction of existing packaging
- The European Commission is working to create a similar scheme for veterinary medicines and vaccines.