23 May 2018
EMA/271499/2018
Stakeholders and Communication Division

Report of EMA Info Day on Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure

20 April 2018, 9:00-12:00

Welcome and introduction

- The chair of the meeting, Ivo Claassen, welcomed participants to this event to update pharmaceutical companies, including small and medium-sized enterprises (SMEs), and stakeholders working in the veterinary field, on EMA "Brexit" preparedness activities. It also provided an opportunity to clarify the impact of the United Kingdom's withdrawal from the Union on centralised veterinary applications/marketing authorisations. The event was organised together with the European Commission (EC). The proceedings were broadcast and recorded for publication.
- This is the second meeting on Brexit organised for Veterinary Industry stakeholders. The previous one took place on the 13th October 2017 (see corresponding report). Two joint Human and Veterinary Industry Stakeholder webinars were also organised to address Marketing Authorisation Holder (MAH) transfers and manufacturing and supply at the end of 2017.
- Ivo Claassen reminded the audience that the focus of the meeting was on the centralised procedure and, therefore, EMA/EC was not in a position to address any question relating to MRP/DCP/National procedures as part of this meeting.
- Christian Siebert from the European Commission (Head of Animal Nutrition and Veterinary Medicines Unit, European Commission, DG SANTE (E5)) opened the meeting and underlined the following aspects:
  - The UK notification on 29 March 2017 of its intention to withdraw from the Union means that all Union law ceases to apply to the UK from 30 March 2019 and the UK will become a 'third country' unless a ratified withdrawal agreement establishes another date.
  - The UK withdrawal will have consequences on businesses and on the work of the veterinary medicines regulatory network. EMA, the national competent authorities (NCAs) and the EC have been working together since March 2017, to map out the legal and operational challenges and to put in place and implement mitigating measures.

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- One challenge for the EU 27 is to take over the workload and expertise currently carried out by the UK. This is also an opportunity for all Member States (MSs) to increase their level of expertise and contribute further to the EU regulatory network. Some MSs have already started investing in extra resources. A methodology for redistributing the work for centrally authorised medicines has been developed (further details below).
- Pharmaceutical associations and companies have been actively informed about the necessity to adapt processes and to consider changes to the terms of the marketing authorisations in due time to ensure their continuous validity and exploitation, once the UK has left the Union.
- The European Commission and EMA have published information notices and procedural guidance to raise awareness of stakeholders about the consequences of the UK becoming a "third country" [Link] and to facilitate Brexit related changes for centrally authorised medicinal products. It was highlighted by the Commission that similar notices were also published by CMDh/v.

- Although the purpose of this meeting was not to discuss political aspects or speculate on the outcome of negotiations, the following facts were noted to emphasise the importance of companies taking prompt action:
  - The Draft text of the **Withdrawal agreement** of the UK and Northern Ireland from the European Union and the European Atomic Energy Community was published on 19th March 2018. The EU and the UK have agreed, at negotiators' level, on the colour-coded text, indicating areas of agreement, disagreement or where further clarifications are needed. The withdrawal agreement needs to be ratified by both sides.
  - The "**Transition period**" until 31st December 2020 (inclusive) is part of the Withdrawal agreement. This Withdrawal agreement is still not agreed upon and not yet ratified by the concerned parties. In terms of governance, as of 30 March 2019, the UK is no longer going to take part in the decision-making of EU institutions and bodies, nor will it have a role as a leading authority, meaning that the UK will not have a role as rapporteur or reference Member State.
  - The EC, EMA, NCAs along with the MAHs have a collective responsibility to ensure preparedness of the system for continuous supply of medicines for the benefit of animal health.
- In view of the considerable uncertainties, companies should not rely on the "transition period". Even if there is a commitment to reach an agreement on the UK's orderly withdrawal, this should not dispense from ensuring 'preparedness'. Indeed, the Withdrawal agreement needs to be ratified by the UK and the EU and this is only expected early 2019. It was acknowledged that some companies have already established "Brexit" preparedness plans. For those who have not yet done so need to start now was stressed (See further details in the EC Presentation).

EMA update on Brexit preparedness activities

Tony Humphreys and Isaura Duarte updated the audience on the following:

- EMA's Operation Relocation Preparedness (ORP) Task Force and its subgroups composition and objectives, namely the EMA relocation, Business Continuity Plan (BCP), scientific procedures and Committees, IT and Communication aspects.
- EMA Working Groups on committees' operational preparedness for human and veterinary medicines were established to explore options for a reasonable and robust allocation of the

workload related to human and veterinary medicines across the network. The objectives of the working groups for veterinary medicines are to redistribute the UK portfolio and to distribute the workload for initial marketing authorisation applications, maximum residue limits (MRLs) and scientific advice requests within the EU-27 Network.

- General principles guiding the redistribution of the UK portfolio were to ensure business continuity, knowledge retention, compliance with legally required timelines and maintenance of the quality of outputs, to be as easy as possible to implement and to be sustainable, and to strive to allow all NCAs to participate in EMA activities as per the capacity and capability of each NCA.
- Details were provided on the methodology for the redistribution of the UK portfolio (See further details in the published document) :
  - It takes into account the expertise available in the EU-27 network and the workload associated with each medicine. It allows MSs to participate in EMA activities according to their individual capacity, taking into consideration the outcome of the survey on capacity building of the EU-27 network.
  - It builds on existing knowledge. For example, by allocating a medicine to the current co-rapporteur for this specific product, or to the peer reviewer involved in the marketing authorisation application.
  - It also takes in consideration the type of product. Clusters of products with the same international non-proprietary name (INN) and/or belonging to the same MAH have been allocated to a single rapporteur in order to facilitate review of post-authorisation procedures and ultimately improve efficiency within the Network (See further details in the presentation).
- In terms of timelines:
  - 1st step of the redistribution was finalised in April 2018;
  - EMA published the methodology for redistribution of UK products on 11th April 2018 [Link];
  - The new (Co-)Rapporteurs for initial MAAs have been communicated to the Marketing Authorisation Holders (MAHs) on 30th April 2018; please note that although the process started this year to ensure timely preparedness of the European Medicines Regulatory Network for the upcoming additional workload, the new (Co)-Rapporteurs will only take full responsibility for their re-allocated products as of 30 March 2019, when the UK withdraws from the Union and becomes a third country;
  - EMA will provide a knowledge transfer package to the new (co)-rapporteurs in September 2018. The knowledge transfer package builds on existing information repurposed for the redistribution of UK (Co)-Rapporteurships to adequately enhance the transfer of knowledge. Although information on upcoming post-authorisation procedures (type II variations and line extensions) is also included in the package, MAHs are encouraged to provide any additional or updated information also to the new (Co)-Rapporteurs notwithstanding the fact that the process of EMA knowledge transfer will only begin in September 2018. Further information will be provided in due course.

Impact of Brexit on veterinary applications / marketing authorisations

- Sandra Vanlievendael presented the requirements as outlined in the EC/EMA questions and answers document which provides the legal interpretation of the principles to be applied consistently across the pharmaceutical network, for both human and veterinary medicines.

- She highlighted in particular the impact of Brexit on the establishment location requirements for UK based entities (e.g. marketing authorisation holder/applicant, companies with EMA SME status, companies with minor use/minor species (MUMS) for a medicinal product, Qualified Person for Pharmacovigilance (QPPV), local representative, manufacturing site, batch release site and batch control site), stressing the importance for companies to plan all these changes in advance in order to avoid negative impact on the supply of veterinary medicines in the EU/EEA. She also clarified the requirements for generic and hybrid marketing authorisations (See presentation for further details).
- Beyhan Mustafov and Andrei Spinei presented the practical aspects for submission of Brexit-related changes for centrally authorised veterinary medicinal products as detailed in the EMA practical guidance [link] such as : transfers of marketing authorisations, update of local representatives in the product information, changes of QPPV, transfer of MUMS/limited market classification and changes to manufacturing and supply (See presentation for further details).
- Practical questions on how to proceed can be raised directly to the EMA Veterinary division via vet.applications@ema.europa.eu. See further details on contacts with EMA on Brexit related queries below.

Perspective from EU Industry Trade associations

- Rick Clayton, representing AnimalhealthEurope, gave a joint presentation on behalf of AnimalhealthEurope and European Group for Generic Veterinary Products (EGGVP) on their views on the implications of “Brexit” for veterinary companies.
- He started by acknowledging the European Commission’s introductory statement that companies cannot rely on a “transition period”, and therefore, timely preparedness for Brexit is critical for the veterinary industry in Europe.
- The outcome of a survey conducted amongst AnimalhealthEurope’s members to gather feedback on the impact of Brexit showed that the main concern was the capacity for a company to bring or maintain veterinary medicinal product(s) on the UK market in a “hard” Brexit scenario and, more generally, the impact that Brexit will have on trade relationships between UK and the EU.
- Other aspects such as the impact of Brexit on UK research and development, on manufacturing and on new and existing products were also presented. Full details are available in the presentation.
- Declan O’Rourke, representing the Association of Veterinary Consultants (AVC), described the particular challenges faced by SMEs in the context of Brexit. He explained that many SMEs were taking the risk of a “wait and see” approach as Brexit preparedness generates extra costs and increased workload, which cannot be borne by the majority of this industry. He emphasised the importance to involve these stakeholders in Brexit preparedness discussions (Link).

Questions & Answers session

- Marie-Hélène Pinheiro moderated the Q&A session and recalled that the focus was on the centralised procedure. Any questions relating to MRP/DCP/National procedures would, however, be forwarded to the network as appropriate (e.g. CMDv) for follow-up. For questions relating purely to UK national post-Brexit implementation, industry should raise these directly with VMD.

- Questions raised by participants were received in advance of the meeting. Topics discussed included:
  - Transition period and the future EU-UK relationship;
  - EMA operations;
  - Packaging and Labelling;
  - Pharmacovigilance (QPPV);
  - Manufacturing and Supply (Qualified Person, batch release/quality control/testing site locations, GxP inspections);
  - EMA procedural and regulatory management of Brexit related changes.
- Clarifications were provided by EMA and the European Commission based on the currently published EC-EMA Q&A and EMA procedural guidance. For questions related to labelling and packaging requirements in particular, it was noted that these are currently being discussed by EC and clarifications are expected in the next update of the guidance documents by Q2 2018. Industry Stakeholders were advised to regularly consult EMA's dedicated webpage where all Brexit-related Industry guidance is published.

Interaction with Industry Stakeholders - Next steps

- Marie-Hélène Pinheiro summarised recent EMA-Industry Stakeholder interactions on Brexit-related topics and future plans. Tentative dates for 2018 Industry Stakeholders meetings on Brexit and the operation of the centralised procedure were presented (See details in the enclosed presentation). Whether these meetings will take place will depend on the specific needs identified by stakeholders and the timing of future updates. The scope of the meetings (Human and/or Veterinary), the format (face-to-face meeting or webinar) will also be decided closer to the event.
- The next updates of the EC-EMA Q&A and EMA procedural guidance is expected to be published by Q2 2018 pending European Commission, CMDh and CMDv consultation.
- Some high level findings from the EMA Brexit Industry survey on Brexit preparedness are expected by end of Q2 2018.
- Industry was reminded to consult the published EC-EMA Q&A and EMA procedural guidance and, if there are any questions, these can be raised as follows:
  - on product specific Brexit-related aspects via e-mail to vet.applications@ema.europa.eu
  - on more general Brexit-related questions to AskEMA (using the web-form).

Close of meeting

Ivo Claassen closed the meeting and thanked all participants for their attendance and the fruitful discussions.

List of Participants

European Commission

Name	Role
Christian Siebert via TC	Head of Animal Nutrition and Veterinary Medicines Unit, European Commission, DG SANTE (E5)
Ariane Vander-Stappen via TC	Policy officer, Veterinary medicines, European Commission, DG SANTE (E5)
Josa Nicole Preuss	National Expert on Secondment, European Commission, DG SANTE (E5)

EMA

Name	Role
Ivo Claassen	Head of Veterinary Medicines (Chairperson)
Marie-Helene Pinheiro	Industry Stakeholder Liaison
Helene Casaert	SME Office
Patrick Costello	Head of Parallel Distribution and Certificates
Monica Dias	Policy and Crisis Management
Emily Drury	Head of Veterinary Regulatory & Organisational Support
Isaura Duarte	Head of Veterinary Medicines Department ad interim
Alberto Ganan Jimenez	Head of Evaluation Procedures D
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy
Anne-Christine Lantin	Veterinary Regulatory & Organisational Support
Beyhan Mustafov	Veterinary Regulatory & Organisational Support
Wendy Parker	Veterinary Regulatory & Organisational Support
Zigmars Sebris	Regulatory Affairs Officer
Andrei Spinei	Manufacturing & Quality Compliance
Sandra Vanlievendael	Head of Long Term and Special Projects
Marlena Zarnecka	Long Term and Special Projects Office

Some members of CMD(v) and CVMP also participated in this event as observers.

Industry

Name	Company / Trade Association
Attendance in person	
Leo Aerden	EGGVP
Guillaume Agede	Ceva Santé Animale
Miriam Alemany Usón	Labiana Life Sciences, S.A.
Irene Antypas	Ashurst LLP
Jackie Atkinson	Bayer
Eleonora Bastino	Zoetis Belgium
Laura Bennett	Boehringer Ingelheim Ltd
Steve Bertram	Boehringer Ingelheim Vetmedica GmbH
Brigitte Boenisch	Boehringer Ingelheim
Alexander Boettner	MSD AH Innovation GmbH
Julian Braidwood	Triveritas
Maria Dolores Cainzos Fernandez	Laboratorios Maymo, S.A.
Cesar Carnicer	Laboratorios Svya S.A.U.
Rodney Cartmill	Norbrook Laboratories
Kristel Ceyssens	Dopharma Research B.V.
Richard Clayton	AnimalhealthEurope
Brigitte Colin	Vetoquinol
Jaume Colomer	AnimalhealthEurope
Paul Cooper	Assentra Limited
Bob Cornez	Huvepharma NV
Nicolas Cousseau	Ceva Animal Health Limited
María Jesús Crespo Domínguez	Labiana Life Sciences, S.A.
Tracy Critchley	Elanco
Santiago De Andrés	Veterindustria (Spanish Animal Health Industry Association)
Maria Luisa de Arriba	Laboratorios Svya S.A.U.
Erik De Ridder	Elanco Animal Health
Zoltán Esztergomi	Ceva-Phylaxia Co. Ltd.
Roxane Feller	AnimalhealthEurope
Eamon Flahive	Elanco
Louise Foster	Bayer Animal Health GmbH

Name	Company / Trade Association
Daniel Freudl	Federal Office of Consumer Protection and Food Safety (BVL)
Rosa Gil	Elanco
Puñet Gironès	SP Veterinaria SA
Kate Gittins	Dechra Limited
Clara Gobbe	AnimalhealthEurope
Susanne Goebel-Lauth	MSD AH Innovation GmbH
Marc Guàrdia	Laboratorios HIPRA, S.A.
Valérie Guiral-Treuil	SIMV (Syndicat de l'industrie de la santé animale)
Helen Hall	Dechra Limited
Pablo Hervás	Veterindustria (Spanish Animal Health Industry Association)
Anja Holm	Panion Animal Health AB
Dawn Howard	NOAH Limited
Marco Hoyer	MSD Animal Health Innovation GmbH
Mirja Huhtinen	Orion Corporation
Edith Huland	Immunservice GmbH
Despoina Iatridou	FVE
David John	AnimalhealthEurope
Patrick Kaumanns	Boehringer Ingelheim Vetmedica GmbH
John Keogh	Animal and Plant Health Association
Eva Kickstein	ERAvet
Beate Kohl	Boehringer Ingelheim Vetmedica GmbH
Marie-Paul Lachaud	Aratana Therapeutics Inc.
Michael Lammers	ERAvet
Iñigo Lusarreta	EquiCord-YMAS
Nikolina Mahovlić	Genera Inc., Dechra Pharmaceuticals PLC
Victoria Marshall	Boehringer Ingelheim Ltd
Deborah McGeown	Norbrook Laboratories
Jaana Mero	Orion Corporation
Natalie Miller	Elanco Animal Health
Marc Molkenboer	Elanco
Eva-Maria Möllenhoff	Boehringer Ingelheim Vetmedica GmbH

Name	Company / Trade Association
Emmanuelle Motte	Virbac
Donal Murphy	NOAH Limited
Ben Myring	Royal College of Veterinary Surgeons
Michael O'Gorman	Elanco
Catherine O'Leary	MSD Animal Health Ireland
Declan O'Rourke	Nexcyon Pharmaceuticals
Patrizia Oelker	Boehringer Ingelheim Vetmedica GmbH
Loubna Ouriaghli	MSD Animal Health
Luisa Pachés Samblás	Cyton Biosciences Ltd
Almudena Pradera	EquiCord-YMAS
Teresa Prat	Laboratorios HIPRA, S.A.
Jean-Marie Préaud	IABS (International Alliance for Biological Standardization)
Anne-Lise Saint-Gerand	Boehringer-Ingelheim
David Sapp	MSD Animal Health UK
Cornelia Schleutner	MSD AH Innovation GmbH
Pieter-Jan Serreyn	Huvepharma
Claudia Sigge	Bundesverband für Tiergesundheit e.V. (BfT)
Lovorka Špirić	Genera Inc., Dechra Pharmaceuticals PLC
Catrina Stirling	Zoetis
Gábor Szőnyi	Ceva-Phylaxia Co. Ltd.
Pablo Tejero Muñoz	Labiana Life Sciences, S.A.
Andrew Thornley	The Organisation for Professionals in Regulatory Affairs (TOPRA)
George Tice	Eli Lilly & Co Ltd/Elanco Animal Health
Irma Van Deurzen	Dopharma Research B.V.
Rens van Dobbenburgh	FVE
Gijs Van Rijn	Kernfarm BV
Johan Vanlerberghe	Zoetis
Frank Verheijen	Medicines Evaluation Board
Robert Vrancken	ViroVet NV
James E. Ward	Boehringer Ingelheim
Erik Waterdrinker	Virbac

Name	Company / Trade Association
Inka Weingaertner	MSD AH Innovation GmbH
Nicole Wirtherle	Dechra
Regina Wolf	Klifovet AG
Web connection	
Melanie Anderson	Triveritas Ltd
Mónica Blanco	Laboratorios Svya S.A.U.
Marc Civit	SP Veterinaria SA
Chloé Coste	Laboratoire TVM
Reyes De la Calcada	SP Veterinaria SA
Juana María Doce Cebreiro	CZ Veterinaria, S.A.
Jan Embrechts	Emdoka bvba
Edward Ferguson	Zoetis UK Limited
Andy Forsyth	Ceva Animal Health Ltd
Ilona Frank	Immunservice GmbH
Hedi Goerg	Klifovet AG
Alazne Goldaraz	SP Veterinaria SA
Kelly Gomm	Pharmacosmos UK
Stephan Grundke	MSD Animal Health
Rachel Harte	Chanelle Pharmaceuticals Manufacturing Ltd
Richard Hunter	Triveritas
Richard Hunter	Triveritas
Gerhard Jordaan	Fulvi Doc
Imelda Jordaan	Fulvidoc (PTY) Ltd
Olivier Legros	Emdoka bvba
Benjamin Masia	Ceva Animal Health Ltd
Sabine Menges	B. Braun Melsungen AG
Anna Obiol	SP Veterinaria SA
Esther Peñaranda	Labiana Life Sciences, S.A.
Vera Popova	Primavet-Sofia Ltd.
Scott Price	Zoetis UK Limited
Johannes Prox	Immunservice GmbH
Birgit Roser	Consultant (AVC Member)

Name	Company / Trade Association
Sonia Serrano	SP Veterinaria SA
Amarinder Singh	Vita (Europe) Ltd.
Jyoti Soni-Gupta	ZIVA Health Consultancy
Dubravka Špoljarić	Krka, d.d., Novo mesto
David Tibbles	Zoetis UK Limited
Lindsey Toon	Benchmark Animal Health
Edward Wood	Sinclair Animal and Household Care Ltd
Annegret Wünsch	Klifovet AG