15 November 2017
EMA/686513/2017

Report of Industry Stakeholder Meeting on Brexit and operation of the centralised procedure for veterinary medicinal products

Friday 13 October 2017, 15:00 - 16:30

Welcome and introductions

- Fia Westerholm welcomed the participants to this teleconference with Industry Stakeholders to discuss the United Kingdom's withdrawal from the European Union ("Brexit") and operation of the centralised procedure for veterinary medicinal products.
- It is important that industry stakeholders work together, with the European Medicines Regulatory Network, to prepare for the UK's withdrawal from the EU and the possible impact this may have on the industry and the availability of medicines in Europe.
- It was recognised that the impact will vary from one company to another depending on their product portfolio and organisation. The industry associations have raised a number of questions on areas that they would like further clarification on.
- EMA and the European Commission have provided some initial guidance in the form of Questions and Answers (Q&As) to help companies to prepare for Brexit and are engaging in regular dialogue with industry stakeholders.
- This teleconference has been organised as the first in a series of planned stakeholder meetings on Brexit and operation of the centralised procedure for veterinary medicinal products, to update the industry on EMA's preparedness activities and to discuss plans and next steps.

Background:

- EMA established an Operation Relocation Preparedness (ORP) Task Force the day after the UK referendum results were announced on 24 June 2016.
- EMA and EC are working on the assumption that the UK will leave the EU as of 30 March 2019 and will become a 'third country' thereafter (see Notice to MAHs published on 2nd May 2017).
- EMA is affected by the UK's withdrawal from the EU in two major ways:

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- Firstly, the UK will no longer participate in the work of the Agency. This means that the assessment work currently carried out by the UK will have to be redistributed to experts from the national regulatory agencies in other 27 EU Member States.
- Secondly, the Agency will have to relocate and move to one of the EU Member States who have indicated that they would like to host EMA.

1. EMA update on "Brexit" preparedness activities

- Tony Humphreys, Head of Scientific Committees Regulatory Science Strategy and a member of EMA's Brexit ORP task force, provided an update on the scope of activities of the task force and its work streams: 'relocation', 'operation and financial preparedness', 'human resource related matters' and 'communication actions'.
- It was noted that important progress has been made in several areas, including: finalisation of a first draft impact assessment and the launch of phase 1 of a dedicated Brexit preparedness Business Continuity Plan (BCP) - see presentation and further information published on EMA website (link).
- The next phase of EMA's Brexit preparedness BCP which will be launched as of 1 January 2018, is currently under discussion and further information is expected to be released after the Agency's Management Board meeting in December.
- To maintain EMA's operability, clearly staff retention is a key concern followed by accessibility of the new premises for experts and delegates, and the new building.
- Over recent months, the Agency has conducted a number of staff surveys to inform its recruitment strategy to compensate for any staff loss. It is clear that the level of staff retention and the ability to address staff loss will depend on where the Agency is located (see "EMA business continuity planning and impact of staff retention scenarios from the EMA staff survey"). The Council decision on EMA's new seat is expected on 20 November 2017.

2. EMA working group on committees' operational preparedness for veterinary medicines

- Monica Dias provided an update on the EMA working group on Committee's operational preparedness for veterinary medicines, outlining the composition of the group, its mandate and objectives, the general principles for workload redistribution, the working methodology, the timelines and next steps (see presentation). It was noted that a similar working group exists for medicines for human use.
- The VMD and UK experts are currently engaged in EMA activities and will continue to do so until the UK withdraws from the EU. There is regular communication with VMD around Brexit preparedness activities.
- Work is ongoing to prepare for the scenario that as of 30 March 2019 the UK will be a third country. EMA is working with the 27 Member States now to ensure that the resources and capacity required are available to guarantee an orderly redistribution of the work.
- To support capacity building and map available expertise within the EU27 Member State network, a mapping exercise/survey has been undertaken. This will be used within the network to inform work on redistribution of UK workload. It is reassuring to see that several NCAs are already planning to take on additional workload.

- With regard to Rapporteur appointments, EMA clarified that for initial Marketing Authorisation Applications (MAAs), those appointments are proceeding in line with current EMA Committees Rules of procedure. Rapporteurs are appointed on the basis of objective criteria, which will allow the use of the best and available expertise in the EU in the relevant scientific area. In the current context, "available" is interpreted as being available also beyond 30th March 2019. As the average length of a centralised evaluation for initial MAAs is more than 1 year, it was noted that this is already starting to take effect with regards to UK Rapporteur appointments for new medicines.
- Regarding post-authorisation workload, it was clarified that a step by step approach is envisaged. The working groups will meet again in November to discuss various redistribution scenarios for legacy products and will make a recommendation for agreement within the Network and by the Agency's Management Board (currently expected for December). Once finalised the plan for reallocation of Rapporteurships will be communicated to MAHs. The changes are not expected to come into effect before Q3 2018 with adequate time foreseen for knowledge transfer. To facilitate product transfer, the MAH should also play an important role e.g. in meeting with the new Rapporteurs team.
- The importance of transparency around the planned approach with clear communication to Industry Stakeholders, and Q&As around the practical aspects to ensure smooth roll out was emphasised.
- It will be key for industry to keep EMA well informed of any foreseen changes to the timing of initial MAA submissions and to better share post-authorisation lifecycle submission planning. This is particularly important for those with UK Rapporteurs.

3. Veterinary Industry update on "Brexit" preparedness activities and priorities

- Representatives of AnimalhealthEurope (previously known as IFAH-Europe), noted that veterinary companies would like guidance on how to proceed with redistribution of their UK portfolios, for nationally authorised products as well as centrally authorised products. The question has also been raised to CMD(v). Industry highlighted the importance of providing a co-ordinated approach based on the results of the mapping exercise undertaken by EMA.
- Industry voiced their concerns around business continuity and disruption in the medicines supply chain. Industry stakeholders considered that there should be a transition period beyond March 2019, to ensure adequate time for transfer of MAH and necessary changes to batch release sites to be undertaken where applicable. EMA reiterated the timelines communicated in the EMA/EC Notice of 2nd May 2017 and emphasised the importance for industry to take the appropriate action.
- It was acknowledged that companies are in the planning phase. This means looking at MAH transfers, and the administrative requirements and timelines to action Brexit related changes. Furthermore, making the necessary legal and regulatory arrangements for batch testing, certification and release of products.
- EMA noted that an update of the Q&A is currently under finalisation by EC/EMA and CMD(h+v). Publication is expected by the end of 2017.
- EMA emphasised that Industry should be "proactive" in preparing for the Brexit related regulatory changes. Acknowledging that this will of course depend on each company's structure and may affect individual companies differently. A list of questions was compiled by industry stakeholders in advance of the meeting, to highlight some of the areas where clarification is needed.

- European Group for Generic Veterinary Products (EGGVP) asked how the loss of UK expertise in the EU regulatory network is planned to be addressed. It was reiterated that the Agency has been reassured to see that NCAs are already implementing plans to expand their capacity and capability to deal with the workload after the UK leaves the EU on 30th March 2019. In addition, EMA will be looking to use the EU Network Training Centre for competency development where needed.
- The Association of Veterinary Consultants (AVC) raised a question on the fees payable to action Brexit related changes. EMA noted that fee reductions are not foreseen, but will flag the industry request to ORP. In response to a question about the future working language of EMA, it was noted that this will continue to be English.
- All questions raised by industry will be picked up as part of relevant updates of Q&As or in the context of procedural guidance that EMA is working on and their updates thereof.

4. EMA stakeholders interaction and dialogue: next steps

- In terms of next steps, Marie-Helene Pinheiro highlighted the following:
    - Industry Stakeholders meetings/TC or webinars (tbc) will be scheduled every two to three months to discuss all "Brexit" related matters;
    - Regular Q&A updates and EMA procedural guidance to be released shortly. For the latter, there will be industry consultation, where and as appropriate;
    - Companies are asked to inform EMA of any changes in intended submissions at centralised level across pre- and post- activities;
    - Pro-active and early dialogue with industry is encouraged, through the following routes:
        - Product specific - EMA Scientific lead (previously also known as Project Manager) as primary Brexit related matters contact
        - Ask-EMA – for general Brexit-related questions
        - Industry stakeholders liaison – for requests particularly *via* trade associations
        - SME office – for queries from small and medium sized enterprises.
- An industry survey and/or mailing to gather information for CAPs is under discussion and may be launched before year end however this still needs to be confirmed. The objective will be to obtain companies and/or product specific "Brexit" related activities status update. This will provide clarity on the "workload" and submission schedule forecast for 2018.

Close of meeting

- Both the regulators and industry stakeholders present welcomed the transparency, openness and constructive dialogue.
- EMA thanked the industry stakeholder associations for sharing a list of questions for discussion prior to the meeting.
- Moving forward we will continue to engage in timely, open, two-way dialogue, as we work to transition to a new way of working with the UK.

List of participants

EMA

Name	Role
Fia Westerhom	Head of Veterinary Medicines Division a.i.
Melanie Carr	Head of Stakeholders and Communication ad interim, Head of Corporate Stakeholders
Marie-Helene Pinheiro	Industry Stakeholder Liaison
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy
Isaura Duarte	Head of Veterinary Medicines Department a.i.
Monica Dias	Policy and Crisis Management
Beyhan Mustafov	Veterinary Regulatory and Organisational Support
Patrick Costello	Scientific Administrator
Helene Casaert	Scientific Administrator, SME Office
Sandra Vanlievendael	Head of Long Term and Special Projects Office

Name	Affiliation
Rick Clayton	AnimalhealthEurope
Donal Murphy (NOAH, UK)	Representing AnimalHealthEurope Brexit Task Force
Xavier Molins	EGGVP, Bimeda, Ireland
Vladislav Kurtev	EGGVP, Richter Pharma, Austria
Alessandro Agostini	AVC, Association of Veterinary Consultant
Birgit Roser	AVC, Association of Veterinary Consultant