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Corporate Stakeholders Department

Report of Industry Stakeholder meeting on "Brexit" and operation of the centralised procedure for human medicinal products

4th October 2017, 16:30 -18:30

Welcome and introductions

- Guido Rasi welcomed the participants to this first meeting with Industry Stakeholders to discuss the United Kingdom's withdrawal from the European Union ("Brexit") and operation of the centralised procedure for human 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 identified a number of areas that require urgent impact assessments by companies so that they can take appropriate actions to ensure their marketing authorisations remain valid, once the United Kingdom has left the Union.
- EMA and the European Commission are providing guidance in the form of Questions and Answers (Q&As) to help companies in this task and are engaging in regular dialogue with industry stakeholders.
- This meeting, chaired by Noel Wathion, has been organised, as the first in a series of planned stakeholder meetings, to update the industry on EMA's preparedness activities and to discuss plans and next steps. The meeting also coincided with the October meeting of the Working Group on Committees operational preparedness to discuss Brexit, hence, members of the Working Group were invited to attend this meeting with industry stakeholders.

Background:

- EMA established an Operation Relocation Preparedness (ORP) Task Force the day after the UK referendum results were announced on 24 June 2016.
- EMA is affected by the UK's withdrawal from the EU in two major ways:

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  - Firstly, depending on the outcome of the withdrawal negotiations, the UK may 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.

- 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. This being without prejudice to the ongoing negotiations (see Notice to MAHs published on 1 May 2017). Depending on the outcome of the negotiations, the approach may need to be adapted accordingly.

1. EMA update on "Brexit" preparedness activities

- Noel Wathion, chair of EMA's internal ORP, 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 human medicines

- Tony Humphreys and Monica Dias provided an update on the EMA working group on Committee's operational preparedness for human 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 veterinary medicines.
- The MHRA and UK experts are currently still engaged in EMA activities and will continue to do so until the UK withdraws from the EU. There is regular high level communication with MHRA 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. Industry update on "Brexit" preparedness activities

- Alan Morrison, representing EBE/EFPIA, provided a joint update also on behalf of EuropaBio, Medicines for Europe, AESGP, EUCOPE and Vaccines Europe. Reference was made to the Joint trade association letter of 13 July 2017 on Brexit as background to the industry position.
- It was highlighted that a "hard-Brexit" scenario is clearly not the preferred option. Industry voiced their concerns around business continuity and disruption in the medicines supply chain. In the current climate of uncertainty, industry stakeholders believe that an early decision on the future relationship and a long transition period are needed to mitigate manufacturing supply issues and ensure uninterrupted availability of medicines. Industry stakeholders emphasised the need to agree on a transition period beyond March 2019, to ensure that the necessary changes (e.g. technology transfers) can be undertaken.
- In the short term, it was acknowledged that companies need to be in a position to make decisions on required changes on a per product level. 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.

- With reference to the EC-EMA-CMD "Q&A" released on 31st May 2017, and in light of the required regulatory submissions (high volume) and the short timeframe, coupled with EMA impending re-location, industry calls for simplification and flexibility where at all possible.
- EMA noted that an update of the Q&A is currently under finalisation by EC/EMA and CMD(h+v) and publication is expected by the end of October 2017.

  Post-meeting note: publication of the Q&A is now foreseen later in 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 companies' structure and may affect individual companies differently. A list of detailed questions was compiled by industry stakeholders in advance of the meeting, to highlight some of the areas where clarification is needed. As this meeting was not the appropriate forum to work through these and provide detailed feedback, it was agreed to organise follow-up discussion starting with the following topic groups:

  - Regulatory MAH transfer (transfer versus variation, timelines etc.)
  - Manufacturing and supply chain (GMP status, batch testing, acceptance beyond 30th March 2019 of UK QP testing)
  - Pharmacovigilance (QPPV changes, access etc.)
  - Cross projects activities i.e. telematics etc.
- Procedurally industry would like to see flexibility around the timelines and administrative requirements for Brexit related changes (e.g. for MAH transfers). It was noted that the industry trade associations are working together on transfers. There are also issues they would like to discuss in more detail around batch release.
- It was agreed that a follow-up discussion on this will be organised in the context of procedural guidance that EMA is working on. In addition, EMA will shortly communicate a plan to address the questions raised by industry in advance of this meeting, and specific teleconferences will be set up to consult with industry also on the other topic areas mentioned above.
- It was noted that an industry wide survey, across the industry trade associations, is currently ongoing to collect insights into short- and long- term company impact and timing of decision making.
- Depending on the information that is forthcoming from these surveys, EMA is considering conducting its own survey of MAHs on "Brexit" related activities to gather detailed information on product, e.g. supply/availability concerns. In the meantime, companies are urged to contact EMA to flag any specific concerns regarding medicinal product supply shortages as early as possible.

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. 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 Project Manager as primary Brexit related matters contact
  - Company portfolio discussions – EMA pipeline meeting discussions
  - 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 (tbc). The objective will be to obtain companies and/or product specific "Brexit" preparedness activities in order to 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 trade associations for sharing the list of questions which will be used for drafting updates of procedural Q&As/guidance on practical aspects to manage changes resulting from Brexit.
- 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.

Network

EMA WG on Committees' operational preparedness for human medicines:

Name	Affiliation	
Catarina Andersson Forsman	MPA	Member, Management Board
Martina Schussler-Lenz	PEI	Chair, CAT
Mette Aaboe Hansen	DKMA	Alternate, Management Board
Michiel Hendrix	MEB	Medicines Evaluation Board
Hugo Hurts	MEB	Member, Heads of Medicines Agencies Member, Management Board
Wiebke Loebker	BFARM	Alternate member, EU Innovation Network
Outi Maki-Ikola	FIMEA	Alternate, CHMP
Lorraine Nolan	HPRA	Member, Heads of Medicines Agencies Member, Management Board
Jean-Pierre Orand	ANSES	Alternate, Management Board
Tomas Salmonson	MPA	Chair, CHMP
Almath Spooner	HPRA	Vice Chair, PRAC

EMA

Name	Role
Guido Rasi	Executive Director
Noel Wathion	Deputy Executive Director
Melanie Carr	Head of Stakeholders and Communication *ad interim*, Head of Corporate Stakeholders
Marie-Helene Pinheiro	Industry Stakeholder Liaison
Michael Berntgen	Head of Product Development Scientific Support
Christelle Bouygues	Acting Head of Regulatory Affairs
Radhouane Cherif	Head of Telematics Office
Patrick Costello	Manufacturing and Quality Compliance
Brendan Cuddy	Head of Manufacturing and Quality Compliance
Monica Dias	Policy and Crisis Management
Leonor Enes	Scientific Administrator, SME Office
Georgy Genov	Head of Signal and Incident Management
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy
Evdokia Korakianiti	Head of Procedure Management
Anabela Marcal	Head of Committees & Inspections Department
Alexios Skarlatos	Head of Labeling Review and Standards Office
Sandra Vanlievendael	Head of Long Term and Special Projects Office

Industry

Name	EU Trade Association
Emma Du Four	EBE
Simon Bennett	EBE
Alan Morrison	EBE
Lucile de Champs	EBE
Stephane Callewaert	Vaccines Europe
Kate Beaujeux	Vaccines Europe
Monica Pagni	Vaccines Europe
Katharina Duchardt	Vaccines Europe
Susan Sandler	Vaccines Europe
Susanne Heiland-Kunath	Vaccines Europe
David Jefferys	EFPIA
Aimad Torquai	EFPIA
Nick Sykes	EFPIA
Matthias Jauslin	EFPIA
Mike Murray	EFPIA
Rose-Marie Swallow	EFPIA
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Pär Tellner	EFPIA
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Britt Vermeij	Medicines for Europe
Vanda Misović	Medicines for Europe
Janet Lewis	Medicines for Europe
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Davide Marchi	EuropaBio
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Barbara Bovy	Eucope

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Mairéad Duke	Eucope
Steve Hayes	Eucope
Bettina Doepner	Eucope
Louise Peacock	Eucope
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