30 April 2018
EMA/206502/2018
Corporate Stakeholders Department

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

23 March 2018, 14:00 -16:30

Welcome and introductions

- The Chair of the meeting, Marie-Helene Pinheiro, welcomed the participants to this second face-to-face 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. This meeting was organised together with the European Commission.
- An initial meeting with industry stakeholders was held in Q4 2017 [link] together with a series of Brexit related webinars on specific topics: "MAHs transfers", "Supply and manufacturing" and "pharmacovigilance".
- Ms Olga Salomon from the European Commission (Head of Unit DG SANTE, Directorate B5, Medicines: policy, authorisation and monitoring) opened the meeting and recalled the following points:
  - The United Kingdom notification on 29 March 2017 of its intention to withdraw from the Union means that all Union law ceases to apply to the United Kingdom from 30 March 2019 and the United Kingdom will then become a 'third country' unless a ratified withdrawal agreement establishes another date.
  - The UK withdrawal will have consequences for businesses and for the work of the medicines regulatory network. EMA, the national competent authorities, and the European Commission have been working hand in hand since March 2017, to map out the challenges, both legal and operational, and to put in place and implement mitigating measures.
  - One challenge for the EU 27 as a whole 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).

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- 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 United Kingdom 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" 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 ("nothing is agreed before everything is agreed") and not yet ratified by the concerned parties. In terms of governance, as of 30 March 2019, the United Kingdom 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 Commission, EMA, national competent authorities along with the MAH have a collective responsibility to ensure preparedness of the system so that we can continue to deliver on the expectations and needs of patients for continuous supply of medicines.
  - In view of the considerable uncertainties, industry should not rely on the "transition period". Even if there is commitment to reaching an agreement on the UK's orderly withdrawal, this should not dispense from ensuring 'preparedness'. The Withdrawal agreement needs to be ratified by the UK and the EU and this is only expected early in 2019. Therefore preparedness is a matter of today. See further details in the EC Presentation.

- It was acknowledged that some companies have already established "Brexit" preparedness plans but it was stressed that those who haven't yet, it is time to start as it is a matter of mutual responsibilities to ensure continuous supply of medicines for patients.

Operational preparedness for Brexit and re-allocation of UK product portfolio in the centralised procedure

- Tony Humphreys updated the audience on EMA's preparedness activities. EMA's Operation Relocation Preparedness (ORP) Task Force and its subgroups have been focussing on EMA relocation, Business Continuity Planning (BCP), Scientific procedures and Committees, IT and Communication. Progress has been made regarding the re-distribution of the UK portfolio within the EU-Network based on the discussions within the two EMA working groups on operational preparedness for human and veterinary centralised medicinal products.

- 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.
- Monica Dias provided further details of the methodology which was endorsed by EMA's Management Board in December 2017, taking into consideration the outcome of the survey on capacity building of the EU-27 network. The redistribution plan follows a multifaceted approach and takes into account both the diverse expertise in the European medicines regulatory network and the workload associated with each medicine. It allows Member States to participate in EMA activities according to their individual capacity.
- The methodology used for the reallocation of medicines is based on Member States' current expertise with a specific class of medicines. It also builds on existing knowledge, for example, by transferring medicines to the current co-rapporteur for a particular product, or to the peer reviewer involved in the marketing authorisation application.
- In addition, the reallocation methodology takes into account 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 presentation).
- In terms of the timelines:
  - 1st step of the redistribution commenced in Q1 2018 and will be finalised in April 2018;
  - The new (Co-)Rapporteurs for initial MAAs will be communicated to the Marketing Authorisation Holders (MAHs) on 30th April 2018;
  - Support for knowledge transfer will be provided Q2-Q3 2018. MAHs will also have a role to play to liaise with new Rapporteurs to facilitate the product specific knowledge transfer. Further information will be provided in due course.

Post-meeting note: The methodology for redistribution had now been published [see link].

Industry update on Brexit preparedness activities

- Alan Morrison, representing EBE/EFPIA, provided a joint update on Industry "Brexit" preparedness on behalf of EuropaBio, Medicines for Europe, AESGP, EUCOPE, Vaccines Europe and Eucope SMC.
- He highlighted that legal uncertainties still remain, including around the transition period, and therefore Industry Trade Associations are still advising their Members to prepare for all types of "Brexit" scenarios. The main areas of focus are on regulatory, trade and supply, clinical trials and workforce. Priorities of cross stakeholders were mentioned with reference to the Life Science Industry Coalition Position paper [see link].
- It was noted that for some companies Brexit-related continuity planning and implementation may have implications going beyond the EU and UK, impacting global supply chains and patients access.
- Further to EMA's recent industry Brexit survey, the need for company specific meetings to discuss product related complexities and planning was highlighted as an important next step.
- It was noted that industry would like to have further clarity on the following:

- the implications of the proposed transition period until 31st December 2020 for the Regulatory system and the role of the UK during this period,
- the network resources available at the level of CMDh, EMA and MHRA,
- opportunities for direct and open dialogue with regulators on company's specific portfolio and products,
- post-"Brexit" future arrangements as early as possible, in terms of options for future regulatory and trade relationships between UK and the EU and potential Mutual Recognition Agreements (MRA) in the event of a Free Trade Deal.

Further insight on these points was considered key to manage the challenging year ahead in the run up to 30th March 2019, to minimise impact on resources delays and patients access to medicines. See further details in presentation.

Questions & Answers session

- Further to the receipt of questions from across Industry EU Trade Associations and organisations for human medicines, the topics discussed included:
  - MAH transfer,
  - (on-going) Centralised evaluations and other Brexit-related changes (e.g. labelling and packaging),
  - Manufacturing and supply,
  - GxP inspection requirements,
  - Pharmacovigilance
  - Implications of any transition period, etc.
- Clarifications were provided by EMA and the European Commission based on the currently published EC-EMA Q&A [link] and EMA procedural guidance [link]. For questions related to GMP Certificates, deputy QPPVs, Labelling and packaging etc. It was noted that further information will be published in the next updates by Q2 2018. Updates will be published on the following EMA web page [link].

Close of meeting: next steps

- Marie-Helene Pinheiro closed the meeting and noted that a short report of the meeting will be published by the end of April 2018. The next updates of the EC-EMA Q&A and EMA procedural guidance will be published by Q2 2018 pending European Commission, CMDh and CMDv consultation and finalisation.
- In addition, some high level findings from the EMA Industry survey are expected by end of May 2018.
- As already stated at the October 2017 meeting, Industry was reminded to use the following EMA routes to discuss "Brexit related questions":
  - Product specific - EMA Project Manager as primary Brexit related matters contact;

- Company portfolio discussions – EMA pipeline meeting discussions if planned and agreed in 2018. If not, requests of companies' meetings can be done by sending e-mail to industry@ema.europa.eu. For the latter, Industry should have previously consulted the published European Commission/EMA questions and answers and EMA procedural guidance and include in their requests their details on "Brexit" preparedness plans together with the specific Brexit related question(s) and position(s) ;
- SME office (SME@ema.europa.eu) – for queries from small and medium sized enterprises.
- For more general questions not related to any particular centralised application/product, use **AskEMA** (using the web-form)

- Tentative dates for further Industry Stakeholders meetings on Brexit and the operation of the centralised procedure in 2018 are displayed below. The scope and format of future meetings will be depend on the topics to be addressed with Industry.

- An information-Day with the Veterinary Industry will take place on 20th April 2018 and on 26th October 2018 the SME information Day (for human medicines) will also feature a dedicated "Brexit" session to address SMEs' Questions and Answers. Further details will follow in due course.

List of Participants

European Commission

Name	Role
Olga Solomon	Head of Unit, DG SANTE B5, Medicines: policy, authorisation and monitoring

EMA

Name	Role
Melanie Carr	Head of Stakeholders and Communication, Head of Corporate Stakeholders *ad interim*
Marie-Helene Pinheiro, ***Chair***	Industry Stakeholder Liaison
Christelle Bouygues	Acting Head of Regulatory Affairs *(ad interim)*
Thomas Castelnovo	Head of Evaluation Procedures A, Procedure Management
Ivo Claassen	Head of Veterinary Medicines
Brendan Cuddy	Head of Manufacturing and Quality Compliance, Committees and Inspections
Monica Dias	Policy and Crisis Management
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy
Alberto Jimenez Ganan	Head of Evaluation Procedures D
Evdokia Korakianiti	Head of Procedure Management, Head of Evaluation Procedures B *ad interim*
Sandra Vanlievendael	Head of Long Term and Special Projects Office
Constantinos Ziogas	Head of SME Office
Leonor Enes	SME Office
Julia Lidner	Parallel Distribution and Certificates, Committees and Inspections
Esther Martinez	Manufacturing and Quality Compliance
Zigmar Sebris	Regulatory Affairs

Name	Role
Andrei Spinei Catalin	Manufacturing and Quality Compliance, Committees and Inspections

Industry

Name	Company	EU Trade Association
In person		
EBE		
Fiona Reekie	UCB	EBE
Alan Morrison	MSD	EBE
EFPIA		
Aimad Torqui	MSD	EFPIA
Victoria Kitcatt	Pfizer	EFPIA
David Jefferys	Eisai	EFPIA
Janet Lewis	Sanofi	EFPIA
Craig Johnson	GSK	EFPIA
Nick Sykes	Pfizer	EFPIA
EUCOPE		
Megann Looker	Jazz pharma	EUCOPE
Susanne Hastrup	Bio Products Laboratories	EUCOPE
Mairéad Duke	BioMarin	EUCOPE
Louise Peacock	Aimmune	EUCOPE
EuropaBio		
Christiane Abouzeid	BIA	EuropaBio
Emma Du Four	AbbVie	EuropaBio
Pedro Franco	Merck	EuropaBio
Robert Morgan	Shire	EuropaBio
Peter Embley	VCLS	EuropaBio
Medicines for Europe		
Geraldine Moore	Mylan	Medicines for Europe
Dora Halmai	Mylan	Medicines for Europe

Name	Company	EU Trade Association
Kunal More	Accord Healthcare	Medicines for Europe
Pradip Karmarkar	Accord Healthcare	Medicines for Europe
Vaccines Europe		
Susan Sandler	Janssen Vaccines	Vaccines Europe
Stephane Callewaert	GSK	Vaccines Europe
ACRO		
Parastoo Karoon	Parexel	ACRO
Alok Patel	IQVIA Ltd	ACRO
EAEPC		
Richard Freudenberg	EAEPC	EAEPC
EIPG		
Luigi Martini	KCL	EIPG
Jane Nicholson	EIPG	EIPG
EQPA		
David Cockburn	EQPA	EQPA
Lance Smallshaw	UCB	EQPA

Name	Company	EU Trade Association
Web connection		
AESGP		
Christelle Anquez	AESGP	AESGP
Katy Slater	RB	AESGP
EBE		
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Ross Carroll	UCB	EBE
EFPIA		
Rachel Adams	Janssen	EFPIA
Rose-Marie-Swallow	Bayer	EFPIA
Morgana Sebenello Wolf	B-I	EFPIA
Jessica Luppus	Grunenthal	EFPIA
Lucile de Champs	Roche	EFPIA
Lisa Howell	Lilly	EFPIA
Angelika Hoenlinger	Novartis	EFPIA
Eszter Teleki	BMS	EFPIA
EUCOPE		
Jörg Plessl, ***spokesperson***	Norgine	EUCOPE
Maren von Fritschen	EUCOPE	EUCOPE
Bettina Doepner	CSL Behring	EUCOPE
Dan Hood	Intercept	EUCOPE
Tony Bratt	Nordic Pharma	EUCOPE
Dawn Spark	Kyowa Kirin	EUCOPE
Leslie Dowling	Real Regulatory	EUCOPE
EuropaBio		
Stephanie Lane	MSD	EuropaBio
Daria Mari	GMBH	EuropaBio
Ian Thomas	Vertex	EuropaBio
Medicines for Europe		
Britt Vermeij, ***spokesperson***	TEVA	Medicines for Europe

Name	Company	EU Trade Association
Beata	Stepniewska	Medicines for Europe
Gabriele Schaefer	Sandoz	Medicines for Europe
Caroline Kleinjan	Sandoz	Medicines for Europe
David Jaugh	Fresenius Kabi	Medicines for Europe
Sanyukta Kher	Apobiologix	Medicines for Europe
Ana Esteban Nunez	Apotex	Medicines for Europe
Matthias Baus	Fresenius Kabi	Medicines for Europe
Vaccines Europe		
Anna Czwarno	Vaccines Europe	Vaccines Europe
Monica Pagni, ***spokesperson***	Seqirus	Vaccines Europe
Kate Beaujeux	AstraZeneca	Vaccines Europe
ACRO		
Ilse-Maria Nolan, ***spokesperson***	ICON	ACRO
John Poland	ACRO	ACRO
GIRP		
Martin FitzGerald	GIRP	GIRP
Martin Sawer, ***spokesperson***	HAD	GIRP
Ronan Brett	McKesson Europe	GIRP
Gavrilo Nikolic	McKesson Europe	GIRP
Johnny Pring	McKesson Europe	GIRP
EIPG		
Claude Farrugia	The University of Malat	EIPG
EQPA		
Ulrich Kissel	EQPA	EQPA

Invited Industry Stakeholder Associations

Association of Clinical Research Organizations (ACRO)

Association of the European Self-Medication Industry (AESGP)

European Association for Bioindustries (EuropaBio)

European Association of Euro-Pharmaceutical Companies (EAEPC)

European Biopharmaceuticals Enterprises (EBE)

European Chemical Industry Council (CEFIC)

European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

European CRO Federation (EUCROF)

European Federation of Pharmaceutical Industries and Associations (EFPIA)

European Healthcare Distribution Association (GIRP)

European Industrial Pharmacists Group (EIPG)

European QP Association (EQPA)

Medicines for Europe

Parenteral Drug Association (PDA)

Small to medium-sized pharmaceutical companies across Europe (Europharm SMC)

The International Society for Pharmaceutical Engineering (ISPE)

Vaccines Europe