EMA/694143/2018

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

Monday 24 September 2018, 13:00 -16:00

Welcome and introductions

- The Chair of the meeting, Noel Wathion, welcomed the participants to this third 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 and veterinary medicinal products. This meeting was organised together with the European Commission.
- Stefan Fuehring, member of the European Commission's Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU, 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 main ongoing work strands currently relate to the Withdrawal agreement ("Article 50 agreement"), the potential transition period which forms part of that agreement and work to define the framework of the future relationship between UK and the EU27.
  - The draft text of the Withdrawal agreement, the purpose of which is to wind down EU membership, has been published on the Commission's website (link). Large parts have been agreed at negotiators' level, however, there are some critical points that are still open. These include some governance aspects, issues related to Ireland/Northern Ireland and some other separation issues. The Withdrawal agreement needs to be ratified by both sides.
  - The transition period, until 31 December 2020 (inclusive), forms part of the draft agreement. As part of a transition period the full Acquis will apply to the UK. However, there will be no UK participation in EU institutions or EU bodies, nor will it have a role as leading authority, meaning UK will not have a role as rapporteur or reference Member State. UK will remain subject to obligations of international agreements concluded by the EU.

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- Industry should not rely on the transition period as there is currently no certainty that it will apply. It is subject to the Withdrawal agreement and outstanding points being negotiated, agreed and ratified by the UK and the EU and this is only expected early in 2019. See further details in the EC Presentation.
- The EC urges all industry stakeholders to prepare now for the consequences of the UK becoming a 'third country' on 30 March 2019. Industry should refer to the procedural guidance and information notices, which have been published by the European Commission and EMA. Stakeholders were reminded of the importance of adapting processes and making the necessary 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.

Operational preparedness for Brexit and next phase of Business Continuity Planning

- Noel Wathion updated the audience on EMA's Brexit preparedness Business Continuity Plan (BCP) and plans for 2019 and 2020.
- EMA's BCP entered into its third phase on 1 October 2018, with the temporary suspension or reduction of additional activities. This includes the scaling back of guideline development and revision, the putting on hold of non-product related working parties, and temporary reductions in international activities and stakeholder interactions. A temporary reduction in clinical data publication has been in place since 1 August 2018.
- The Agency anticipates that phase 3 will be complemented with additional temporary suspensions/reductions as of 1 January 2019, which will be launched as part of phase 4 of the BCP, in order to put in place the necessary arrangements for the physical move to Amsterdam in March 2019. More information is available on EMA's website (link).
- BCP will allow the Agency to safeguard core activities related to the evaluation and supervision of medicines while the Agency prepares for the consequences of Brexit- both in terms of the impact on the Agency's operations, as well as its upcoming relocation to the Netherlands. It will also help the Agency cope with anticipated staff loss.
- Industry stakeholders are encouraged to submit all Brexit related variations prior to Q1 2019 to ensure compliance in due time. With the exception of some delays in processing of EMA certificates, there should be no impact on other EMA procedures (e.g. scientific advice, orphan designation, PIPs, applications for marketing authorisation, post-authorisation activities etc) and industry were advised to proceed as normal.
- Temporary suspension and scaling back of non-product related activities is currently scheduled to last until 30 June 2019, but will be reviewed in April 2019, once the Agency has completed its move to its temporary building in Amsterdam.
- On the basis of current knowledge, 2019 is expected to be a year of transition with the first half of the year focussing on the physical relocation and addressing any staff loss. In the latter half of 2019, EMA will gradually reintroduce previously suspended/reduced activities in line with priorities identified in the Network strategy to 2020. In doing so EMA will take the opportunity to reflect on the most efficient way to achieve certain activities. See further details in EMA presentation.

Brexit preparedness activities

- A brief update on EMA committees' operational preparedness was provided by Monica Dias (see presentation) regarding the redistribution of the UK centrally authorised products' portfolio which will be implemented from Q4 2018. The redistribution of the UK portfolio was finalised on 4 April 2018 and the new (Co)-Rapporteurships were communicated to marketing authorisation holders on 30 April 2018. UK's involvement in pre-authorisation procedures (paediatric investigation plans, scientific advice and orphan designations) will also be gradually phased out and cut-off dates have been established to ensure they are finalised before the end of March 2019.
- Alberto Ganan and Beyhan Mustafov presented a summary of the results from the EMA Industry Survey conducted between January to March 2018 to gather information from companies on their Brexit preparedness plans and identify any particular concerns with regard to medicines supply that may impact public or animal health. Industry stakeholders were reminded of their legal obligations to inform EMA on supply issues and product withdrawals. Furthermore, marketing authorisation holders are requested to also inform EMA of any changes in their plans (see presentation).
- Aimad Torqui presented the views of the (human medicines) trade associations on behalf of EFPIA, EBE, Vaccines Europe, AESGP, EUCOPE, EuropaBio, and Medicines for Europe. The importance of continued dialogue to minimise the resources impact of Brexit was emphasised. In addition, the need for company specific product portfolio dialogue with both EMA and CMD(h). In general, it was noted that companies are taking into account EC/EMA guidance to prepare for a "no deal" in due time. The challenges industry face in completing all required activities in time for all products and the need for solutions to minimise the impact on continuity of supply of medicines to patients were also highlighted (see Joint human medicines industry presentation).
- Rick Clayton presented the main concerns of the (veterinary medicines) trade associations on behalf of AnimalhealthEurope, EGGVP and AVC. The areas highlighted related to continuity of supply, multi country packaging (particularly for UK and Irish pack), replication of testing, validity of UK reference products and UK field trials for ongoing procedures , the economic impact and the need for a transition period (see Joint veterinary medicines industry presentation).

Questions & Answers session

- Further to the receipt of questions from across the EU industry organisations in advance of the meeting, the topics discussed included:
  - Ongoing negotiations, Withdrawal agreement and transitional period,
  - EMA preparedness and upcoming relocation,
  - Regulatory and procedural management (timing of Type A submissions, labelling and packaging, reference medicinal products and medical devices),
  - Manufacturing and inspection related matters (UK certificates validity, batch importation testing and release requirements),
  - Parallel distribution,
- Answers were provided during course of the meeting and will be addressed in future Q&As and EMA procedural updates, which are expected to be published by end of 2018 (tbc).

Close of meeting: next steps

- Noel Wathion closed the meeting thanking the audience and speakers for their participation and fruitful discussions.
- The next Industry stakeholder meetings on Brexit have been tentatively scheduled for 22 November 2018 and 28 January 2019 (EMA, London). This is subject to confirmation also in terms of scope and format.

  Post-meeting: The meeting tentatively scheduled for 22 November 2018 has been cancelled.

List of Participants

European Commission

Name	Role
Martin Dorazil	Directorate General, Health and Food Safety, Unit B5 – Medicines – policy, authorisation and monitoring
Stefan Fuehring, *via* ***VC***	Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU
Eveline Lecoq, *via* ***VC***	Secretariat General, Brexit Preparedness Group
Jerome Boehm, *via* ***VC***	Directorate General, Health and Food Safety, Unit B5 – Medicines – policy, authorisation and monitoring
Marilena Lungu, *via* ***VC***	Directorate General, Health and Food Safety, Unit B5 – Medicines – policy, authorisation and monitoring
Christian Siebert, *via* ***VC***	Directorate General, Health and Food Safety, Unit E5 – Animal nutrition, veterinary medicines
Josa Nicole Preuss, *via* ***VC***	Directorate General, Health and Food Safety, Unit E5 – Animal nutrition, veterinary medicines
Julie Sainz, *via* ***VC***	Directorate General, Health and Food Safety, Unit E5 – Animal nutrition, veterinary medicines
Luben Goranov, *via* ***VC***	Directorate General, Health and Food Safety, Unit E5 – Animal nutrition, veterinary medicines

EU Network

Name	Role
Laetitia Le Letty	Chair of the CMDv

European Medicines Agency

Name	Role
Noel Wathion	Deputy Executive Director
Melanie Carr	Head of Stakeholders and Communication
Marie-Helene Pinheiro	EMA Industry Stakeholder Liaison
Hilde Boone	Head of EU Institutional Liaison
Brendan Cuddy	Head of Manufacturing and Quality Compliance
Monica Dias	Policy and Crisis Management
Nicholas Jarrett	Head of Veterinary Pharmaceuticals

Name	Role
Alberto Jimenez Ganan	Head of Evaluation Procedures D
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy
Evdokia Korakianiti	Head of Procedure Management
Beyhan Mustafov	Veterinary Regulatory and Organisational Support
Zigmars Sebris	Regulatory Affairs
Sandra Vanlievendael	Head of Long Term and Special Projects
Apolline Lambert	Policy and Crisis Management
Liv Weingartz	Parallel Distribution & Certificates

Industry

Name	Company	EU Trade Association
AnimalhealthEurope		
Rick Clayton	AnimalhealthEurope	AnimalhealthEurope
Alexander Boettner	MSD	AnimalhealthEurope
Donal Murphy	NOAH	AnimalhealthEurope
Eamon Flahive	Elanco	AnimalhealthEurope
Erik Waterdrinker	Virbac	AnimalhealthEurope
Victoria Marshall	B-I	AnimalhealthEurope
Andrew Gubb, *via* ***web connection***	Zoetis	AnimalhealthEurope
AESGP		
Katy Slater, ***spokesperson***, *via* ***web connection***	RB	AESGP
AVC		
Paul Cooper, *via* ***web connection***	AVC	AVC
Birgit Roser, *via* ***web connection***	Dr. med. vet. Birgit Roser	AVC
Helen Edwards, *via* ***web connection***	Cyton	AVC
Declan O'Rourke, *via* ***web connection***	Ortec	AVC

Name	Company	EU Trade Association
Klaus Helmann, *via* ***web connection***	Klifovet	AVC
EBE		
Lucile de Champs, ***spokesperson***, *via* ***web connection***	Roche	EBE
Lisa Howel, *via* ***web connection***	Lilly	EBE
Pedro Franco	Merck	EBE
Fiona Reekie	UCB	EBE
Louise Gill	GSK	EBE
Janet Lewis	Sanofi	EBE
Angelika Hoenlinger	Novartis	EBE
Tom Denorme	MSD	EBE
EFPIA		
Rose-Marie-Swallow, ***spokesperson***, *via* ***web connection***	Bayer	EFPIA
Angela Walker, *via* ***web connection***	LEO	EFPIA
Giovanna Lasagna, *via* ***web connection***	Chiesi	EFPIA
Tracey Atkins, *via* ***web connection***	B-I	EFPIA
Aimad Torqui	MSD	EFPIA
Victoria Kitcatt	Pfizer	EFPIA
David Jefferys	Eisai	EFPIA
Eszter Telekı	BMS	EFPIA
Tim Stonehouse	Celgene	EFPIA
Pär Tellner	EFPIA	EFPIA
EGGVP		
Helen Hall	Dechra UK	EGGVP
Leo Aerden, *via* ***web connection***	Inovet	EGGVP
Xavier Molins, *via* ***web connection***	Bimeda	EGGVP

Name	Company	EU Trade Association
Elsa Vecino, *via* ***web connection***	EGGVP	EGGVP
EUCOPE		
Maren Von Fritschen	EUCOPE	EUCOPE
Dawn Spark, *via* ***web connection***	Kyowa kirin	EUCOPE
Mohan Ganapathy, *via* ***web connection***	MSD Europe	EUCOPE
Astrid Cornee, *via* ***web connection***	Vertex	EUCOPE
Minesh Vaidya, *via* ***web connection***	Nordic pharma	EUCOPE
EuropaBio		
Bernard Grimm	EuropaBio	EuropaBio
Darren Kinsella	EuropaBio	EuropaBio
Emma du Four	AbbVie	EuropaBio
Christiane Abouzeid	BIA	EuropaBio
Astrid Cornee, *via* ***web connection***	Vertex	EuropaBio
Clothilde Barlet, *via* ***web connection***	BioMarin	EuropaBio
Medicines for Europe		
Geraldine Moore	Mylan	Medicines for Europe
Michael Banks	TEVA	Medicines for Europe
Beata Stepniewska	Medicines for Europe	Medicines for Europe
Corinne Barra, *via* ***web connection***	Fresenius Kabi	Medicines for Europe
Britt Vermeij, *via* ***web connection***	TEVA	Medicines for Europe
Sanyukta Kher, *via* ***web connection***	Apobiologix	Medicines for Europe
Lepczyńska Ewa, *via* ***web connection***	Polpharma	Medicines for Europe
Špelca Jenko, *via* ***web connection***	KRKA	Medicines for Europe
Caroline Kleinjan, *via* ***web connection***	Sandoz	Medicines for Europe
Paul Fleming, *via* ***web connection***	BGMA	Medicines for Europe

Name	Company	EU Trade Association
Vaccines Europe		
Monica Pagni, ***spokesperson***, *via* ***web connection***	Seqirus	Vaccines Europe
Stephane Calewaert	GSK	Vaccines Europe
Hazel-Anne Griffiths	SEqirus	Vaccines Europe
Susanne Heiland-Kunath, *via* ***web connection***	Takeda	Vaccines Europe
Susan Sandler	Janssen	Vaccines Europe
Pam Smith	Astra Zeneca	Vaccines Europe
ACRO		
Fiona Maini, ***spokesperson***, *via* ***web connection***	Medidata	
Parastoo Karoon	Parexel	ACRO
Jo Maywhort, *via* ***web connection***	Syneos	ACRO
AIPES		
Helen Barker	Blue Earth Diagnostics	AIPES
EAEPC		
Richard Freudenberg	EAEPC	EAEPC
EIPG		
Luigi Martini	King's College London	EIPG
Claude Farrugia, *via* ***web connection***	University of Malta	EIPG
Quinh Lee, *via* ***web connection***	Havlandet Research laboratory	EIPG
EQPA		
Ulrich Kissel, *via* ***web connection***	EQPA	EQPA
MedTech Europe		
Dario Pirovano, *via* ***web connection***	MedTech Europe	MedTech Europe
Oliver Bisazza, *via* ***web connection***	MedTech Europe	MedTech Europe

Invited Industry Stakeholder Associations

1. AnimalhealthEurope
2. Association of Clinical Research Organizations (ACRO)
3. Association of the European Self-Medication Industry (AESGP)
4. Association of Imaging Producers & Equipment Suppliers (AIPES)
5. Association of Veterinary Consultants (AVC)
6. European Association for Bioindustries (EuropaBio)
7. European Association of Euro-Pharmaceutical Companies (EAEPC)
8. European Biopharmaceuticals Enterprises (EBE)
9. European Chemical Industry Council (CEFIC)
10. European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
11. European CRO Federation (EUCROF)
12. European Federation of Pharmaceutical Industries and Associations (EFPIA)
13. European Group for Generic Veterinary Products (EGGVP)
14. European Healthcare Distribution Association (GIRP)
15. European Industrial Pharmacists Group (EIPG)
16. European QP Association (EQPA)
17. Medicines for Europe
18. MedTech Europe
19. Parenteral Drug Association (PDA)
20. Small to medium-sized pharmaceutical companies across Europe (Europharm SMC)
21. The International Society for Pharmaceutical Engineering (ISPE)
22. Vaccines Europe