EMA/521851/2018

Meeting Notes [taken by Emma Du Four] – Industry Stakeholder meeting on Brexit and operation of centralised procedure for Human and Veterinary Medicinal Products

24 September 2018, 13:00 -16:00, meeting room 02-A

Chair: Noel Wathion, EMA

Item	Agenda	Time
1.	**Welcome by the Chair and introductions** – Stefan Fuehring (SF), *presentation via **VC** (additional EC colleagues also present on VC)* SF is a representative of the Article 50 TF led by Barnier. Withdrawal agreement; transition period (part of withdrawal agreement) and future relationship all addressed in his comments. UK will be a third country on 30 March 2019. Purpose of withdrawal agreement is to wind down the UK membership of the EU – large parts agreed but some critical points remain open. Products already placed on the market (already in the distribution chain and a transfer/sale completed –definition unclear) can continue to be sold. EU unitary trademarks have to be grandfathered into UK system. How pharmaceuticals are dealt with at customs if in transit at point of UK withdrawal still under discussion. Citizen's rights and financial settlement agreed. Dispute settlement and NI border remain unresolved. Transition period (if it comes into effect) will continue to apply the entire pharmaceutical acquis to the UK, but the UK becomes third country regarding decision-making; UK will therefore not participate in any EU bodies (parliament, commission, member state meetings e.g. EMA management Board or expert committee meetings. Exception is where the chair considers it relevant and in EU interests for UK to participate in part of the meeting. UK cannot act as leading authority e.g. RMS, Rapporteur. During a transition period (if agreed) UK will be treated as a Member State without being a	13:00-13:15 *(15')*

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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	Member State. Transition period is part of withdrawal agreement and so if no agreement on outstanding points on withdrawal agreement then no transition period. This is why EC continues to state that MAHs should continue to prepare for no agreement. EC Brexit preparedness notices have been published – these assume no deal. Notice on industrial products applies to medical devices. Also relevant are notices on customs, trademarks, personal data protection, professional qualifications (system of mutual recognition for pharmacy and medical qualifications finishes – persons with UK qualifications will need to seek EU27 recognition of the qualification), pharmaceuticals and clinical trials. International agreements of the EU – bilateral EU agreements cease to apply to the UK at Brexit 30 March 2019. Multilateral agreements with EU also cease, however multilateral agreements with mixed partners is more complex as UK will not be a Member State – while the obligations under agreements with third countries (eg MRAs for batch testing) will continue to apply to the UK, there is no guarantee that the benefits of such agreements will continue to apply to the UK during transition period. UK is currently working with third countries to carry over obligations of MRAs. EU can only guarantee that UK applies EU acquis during a transition period. Future possible partnership framework communicated by political declaration (not agreement) being developed: covers free trade agreement (some sectorial specifics), socio-economic cooperation, police & judicial, foreign security. Oct 2018 European Council intends to adopt withdrawal agreement and then move to ratification by EU (not each individual Member State National Parliament) and UK Parliament. Will not know until Feb 2019 for certain if there will be a transition period and so EC urge MAHs to prepare by 30 March 2019 as in any case these changes will need to be completed by end of the transition period. If withdrawal agreement is agreed and ratified, then EC may issue Q&A on transitional period but not before as EC believe this will send the wrong signal. EC does not see any legal uncertainty; the applicable EU rules having been in place for 30 years.	
2.	**Operational preparedness for Brexit and next phase of Business Continuity Planning (BCP)** – *Noel Wathion, EMA* – *Q&A session* There will be a discussion at EMA Management Board meeting on 4 October to endorse the next phase of the BCP implementation (details below).	13:15-13:45 *(30')*

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	EMA Brexit BCP – activities grouped into 3 categories: category 1 (highest priority) core scientific activities and legal obligations; category 2 (medium priority) strategic activities; category 3 (lowest priority) non-strategic activities. Since January 2018 category 3 activities have been scaled back and some category 2 activities have been temporarily placed on hold. 1st August publication of clinical data suspended. Dutch employment law is different to UK and so approx. 180 FTE staff cannot transfer; additional category 2B activities are therefore to be suspended. EMA will transfer staff to support category 1 activities. International activities e.g. ICH will shift from leading role to reactive or supportive role. Guideline development will be suspended temporarily from end of October 2018, except where necessary for implementation of legislation or Brexit or urgent public health need – 5 ICH guidelines will continue e.g. Q12 where EU has a leading role. Where consultations are on-going they will be completed and may be extended if needed on a case by case basis. Product related working parties will continue, but there will be a reduction in activities for other working parties. Stakeholder interaction will be primarily focused on Brexit related activities and category 1 and 2A related activities (Centralised procedures, PV and R&D support). Policy 70 Clinical data publication team will complete redacted document procedures already submitted (Policy 43 access to documents will continue as this is a legal obligation). ***Relocation to Amsterdam*** – several uncertainties remain that may impact EMA ability to maintain business continuity. All current short term contract staff will cease at end of Feb 2019. EMA will move by end of Feb 2019It is possible to find adequate replacement contract staff in Amsterdam and recruitment is progressing. The number of permanent staff that will relocate remains uncertain; some have changed their minds. Teleworking will be used for staff staying in the UK but uncertain for how long. Number of staff on parental leave/unpaid leave throughout 2019 remains unclear. Disruption and settling in to new location will have some impact. Possible second wave of staff resigning at a later stage. EU budgetary authority's decision as regards the EMA request for additional resource not yet known. Short to mid term focus on business continuity balanced with long term aim of fostering scientific excellence. 2019 will be a year of transition and 2020 will pave the way for the future. Jan-June 2019 focus on temporary staff loss and physical relocation (all staff leave current building at the end of Feb 2019). First week of March 2019 will be a transition (not in new building and left current building) –. Special arrangements to apply during critical	

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	period around relocation from London to Amsterdam for period 11 Feb -15 March 19 inclusive. Most staff will be teleworking but there will be a small core group available on site for critical issues. CHMP meeting in March 2019 will be in Amsterdam. SAWP meeting Feb 2019 will be a pilot in Amsterdam. ***July-Dec 2019*** aim to restart some of the temporarily paused activities. Careful thought will be given as to whether this is an opportunity to restart in a more efficient way and make fit for the future. Prepare for 2020-2025 strategy jointly with HMA focusing on Regulatory Science Strategy (meeting on 24 Oct 2018) and Corporate ICT strategy. ***Phase 4 of BCP Jan 2019 – July 2019*** existing category 1 activities but no new activities (no optimising, but all submission procedures will be maintained); only critical 2A and 2B activities to be maintained. Category 1A is all procedures (covers all pre- & post authorisation and scientific advice, orphan designations). Pre-submission meetings will move to TC rather than face to face. Category 1B includes some IT procedures and access to documents Temporary staff retention measures have helped to maintain some staff; some early movers to Amsterdam have provided positive feedback e.g. Monica Dias. Procedures are 1A, other core activities are 1B – if the worst case arises then 1B would be temporarily paused and 1A would be protected. Interchangeable staff and critical staff identified. Recruitment procedures being launched. 250+ people left (this includes the contract staff who could not be relocated). Training of new staff and Brexit-related training is protected. Training of network to replace expertise of UK will be maintained.	
3.	**Brexit preparedness activities** • **Update on EMA Brexit committees' operational preparedness** – *Monica Dias, EMA* Redistribution of UK centrally authorised products portfolio was finalised in April 2018; for planned MAAs UK also now reassigned (new bidding process) and this will be communicated soon. New rapporteurs only take on responsibility from 30 March 2019, however new rapporteurs will from Q4 start taking on procedures which will likely be on-going as of 30 March 2019 e.g. line extension procedures starting after 1 Oct 2018; Q,S,E type II variations submitted after 26 Oct 2018 and renewals submitted after 24 Oct	13:45-15:05 *(80')*

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	2018, PSURs for CAPs after 6 Nov 2018. Knowledge transfer package (KTP) provided to new rapporteur on the regulatory and evaluation history of each product – includes highlighting of safety concerns, product overview and most recent benefit/risk assessment. KTP also includes details of EMA product team, regulatory information, assessment history and workload forecast. UK is no longer being appointed as Rap or Co-Rap for new marketing authorisation applications. UK's involvement in PIP, SA, ODD will gradually be phased out e.g. no more SA coordination from Dec 2018, no more ODD from Jan 2019. PIPs already reassigned. • ***EMA Industry Survey summary results*** – *Alberto Ganan and Beyhan Mustafov, EMA* Survey launched in January 2018; 91% response rate. 360 CAPs have Pharmacovigilance System Mater File (PSMF) and QPPV currently located in UK and so will change, 89 to Germany, 44 to Belgium a few to France, Ireland, Netherlands (208 not yet known at time of survey) – update reported via Art 57 database so can occur closer to Brexit date. MAH Transfer – 365 MAH were in UK; 74% of MAH of transfers have now been received. Required Brexit related manufacturing changes are estimated to be 441 Type 1As, 12 1Bs, 45 Type IIs, mainly to be submitted in Q4 2018 and Q1 2019. QC and batch release site new locations spread across EU Member States but 50% not yet known at time of survey. EMA have undertaken a risk assessment of products that have an operation in the UK and followed up with companies to understand plan to make changes. 39 CAP products (25 human, 14 vet) are currently considered at risk and may have potential supply issues. Press release issued today regarding 39 medicines at risk of supply challenges - Companies stepping up efforts to ensure medicine supply post Brexit. Regulatory changes to MA are needed even if not marketed and including products exempted from the sunset clause. UK sites for QC, import and batch release must be deleted from the MA.	

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	• ***Industry preparedness update*** – *Industry Speaker Aimad Torqui, on behalf of EFPIA, EBE, Vaccines Europe, AESGP, EUCOPE, EuropaBio, Medicines for Europe (Human Medicines)* Please see industry slides – *Industry Speaker Rick Clayton on behalf of AnimalhealthEurope, EGGVP, AVC (Veterinary Medicines)* Similar priorities and areas of concern as for human medicinal products	
4.	**Questions & Answers session** – *Moderator: Marie-Helene Pinheiro* – *Panel discussion, All* *Please see separate word document listing questions from industry and responses from EMA*	15:05-*15:55 (50')*
5.	**Close of meeting**: **next steps** – *Noel Wathion, EMA* These stakeholder discussions will continue over the coming months.	15:55-16:00 *(5')*