EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Impact of Brexit on medicines availability and supply for Centrally Authorised Products (CAPs)

Agenda point 5
Industry Stakeholder meeting on Brexit and operation of centralised procedure for Human and Veterinary Medicinal Products

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Introduction

- Based on the assumption that the UK will become a third country as of 30 March 2019 and in order to ensure that companies were ready to take the necessary steps to enable undisrupted supply of their medicines in the EU;
- EMA analysed the potential supply issues for CAPs due to the required changes as a consequence of Brexit;
- The analysis was complemented by a survey to pharmaceutical companies, follow up meetings with MAHs of medicines at risk of supply, and reminder letters sent to MAHs of Brexit-affected medicines;
- A risk matrix was developed to facilitate the risk assessment performed by EMA;
- Medicinal products at risk of supply have been subject to a criticality assessment.

Risk Assessment

- A **risk matrix** was developed which included different elements required to be changed before 30 March 2019
- Risk matrix takes into account the outcome of the survey, including the **timing for submission of the changes** required.
- **Non-respondents** to the survey were considered as non-compliant for the submission of the regulatory changes on time.

Risk level	MAH UK	SME*	Secondary packaging	Quality Control	Batch Release	OMCL	UK: PSMF / QPPV / OD	Local rep.**
A	+	+	UK only	UK only	UK only	UK only	+ / -	+ / -
B1	+		At least one activity in UK only				+ / -	+ / -
B2			At least one activity in UK only				+ / -	+ / -
C	+			UK also	UK also	UK also	+ / -	+ / -
D				UK also	UK also	UK also	+ / -	+ / -
E	+ / -						+ / -	
F								+
G	On time							

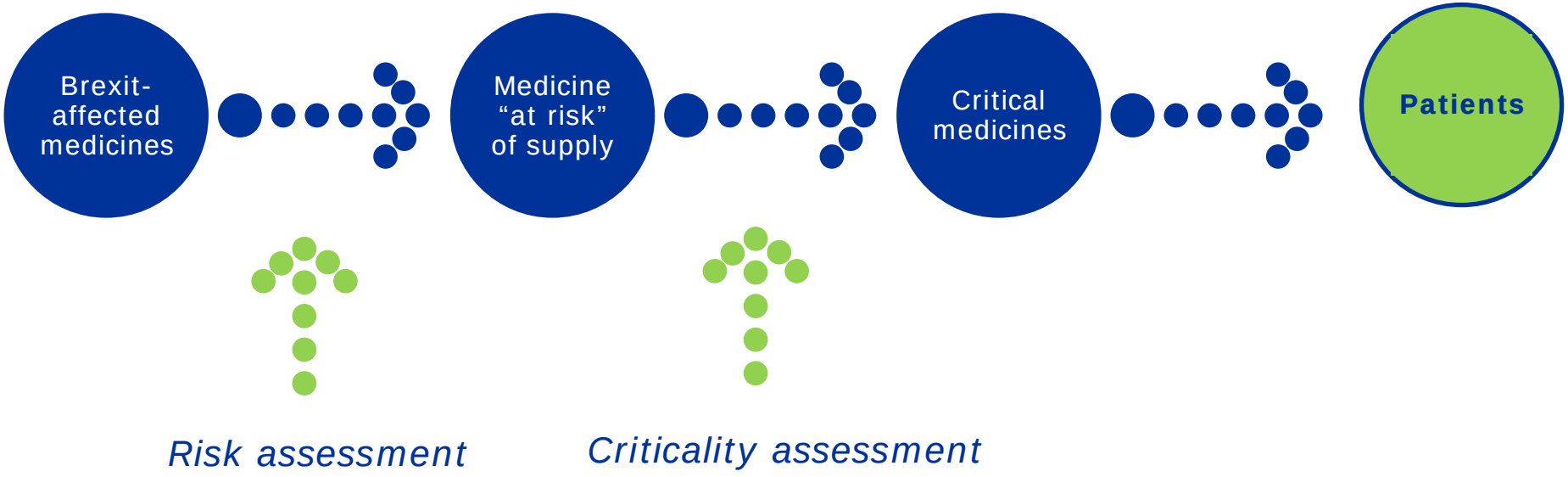
*Small and Medium Enterprise
** Not included in the survey

Criticality Assessment

- All products considered “at risk” and that are marketed in at least one MS of the EU-27 will be subject to a **criticality assessment**
- The methodology is based on the Criteria for classification of critical medicinal products for human and veterinary use, adapted to the context of Brexit, and foresees two parts:

  PART A: CHMP/CVMP with the support of EMA will look at **therapeutic use,** i.e. the medicinal product is an integral part of the treatment for or prevention of a disease, which is life-threatening or irreversibly progressive, or without which the public and animal health could be severely harmed.

  PART B: EMA will liaise with MSs with respect to the **availability of therapeutic alternatives** for each medicinal product, e.g. other products in the same class or even other classes, and generics.


Brexit-affected medicines
Medicine "at risk" of supply
Critical medicines
Patients
Risk assessment
Criticality assessment

Survey to MAHs of Brexit-affected medicines

- The European Medicines Agency launched a **survey** in **January 2018** to identify the CAPs potentially "at risk" of supply shortages and to obtain information on the timelines for submission of the necessary regulatory changes.
  - Scope: **694 centrally authorised medicinal products** where either:
    - Marketing Authorisation Holder (MAH) is located is the UK, or a Batch control (QC) site, a Batch release (BR) site and/or an Importation site is located in the UK, or the Qualified Person for Pharmacovigilance (QPPV) or the Pharmacovigilance System Master File (PSMF) is located in the UK.
- Based on the results of the survey and taking into consideration the risk matrix, medicines under categories A, B1 and B2 were considered at risk of supply.

Risk assessment

108
medicines
"at risk" of supply

Follow-up meetings with MAHs of medicines “at risk” of supply

- Follow-up meetings for **108 medicines** at risk of supply were organised with 54 MAHs (45 human and 9 veterinary) during **July-September 2018** (these included MAHs that did not reply to the survey);
- The feedback provided showed that many companies had changed their plans and stated that they would make the necessary changes before 30 March 2019;
- On 26 October 2018, the number of medicines “at risk” of supply was **revised** to **31 medicines** (19 human and 12 veterinary.

Risk assessment

31*
medicines
“at risk” of supply

as of 24 January 2019 this number has been further revised and it is now 19 (7 veterinary and 12 human medicines)

Criticality assessment – October 2018

- In October 2018, **31 medicines** (19 human and 12 veterinary) were considered “at risk” of supply since all, or a major part of, the manufacturing steps were carried out in the UK only and changes were unlikely to be submitted in time, according to companies’ plans.
- These 31 medicines were subject to a criticality assessment.
  - Outcome of Part A was sent to all HoAs in December 2018
  - Part B is currently ongoing and will be finalised on **15 February 2019**

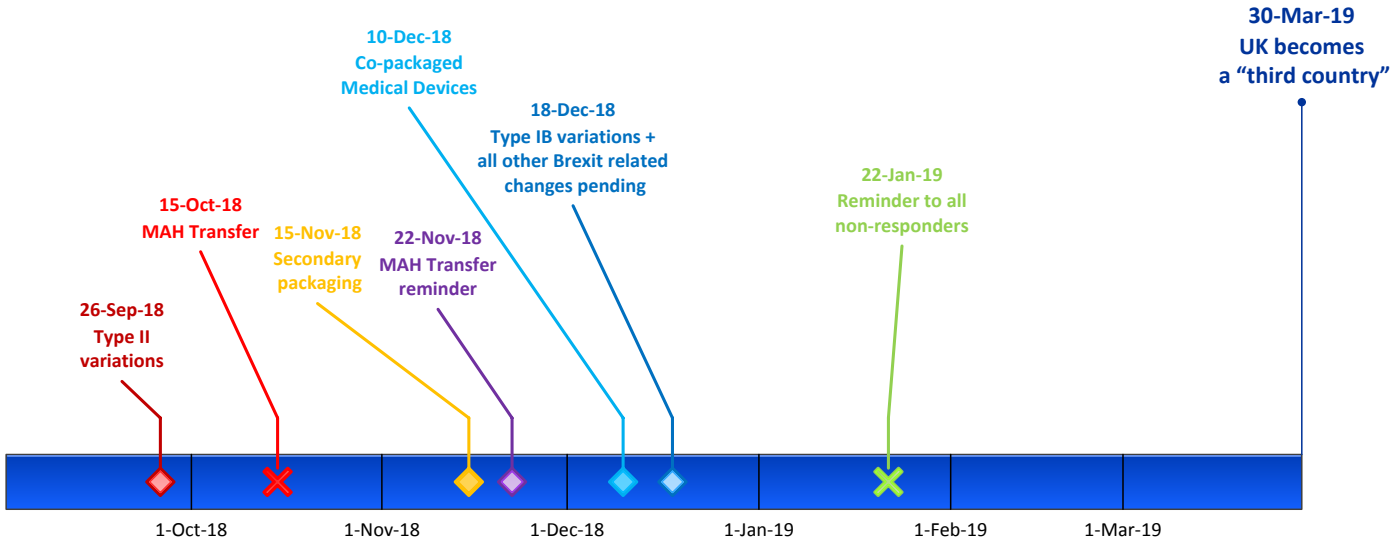
Criticality assessment
(October 2018 – batch 1)

tbc* **critical medicines in the EU**

***after 15 February 2019**

Reminders sent to MAHs of Brexit-affected medicines

- EMA sent letters to MAHs of Brexit-affected medicines, at least one month before the cut-off date of the procedure, reminding them of the requirement to submit the necessary regulatory procedures in a timely manner.



Next steps

- EMA and the EC will continue providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the UK's withdrawal from the EU;
- MAHs are urged to make the necessary changes in order to comply EU legal requirements after 29 March 2019.
- MAHs are advised to inform EMA of any potential disruption in the supply of their medicinal products and the measures being considered to prevent medicinal product shortages.

Thank you for your attention

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