# Impact of Brexit on medicines availability Centrally Authorised Products (CAPs)

HMA/EMA workshop on availability of authorised medicines, 9 November 2018

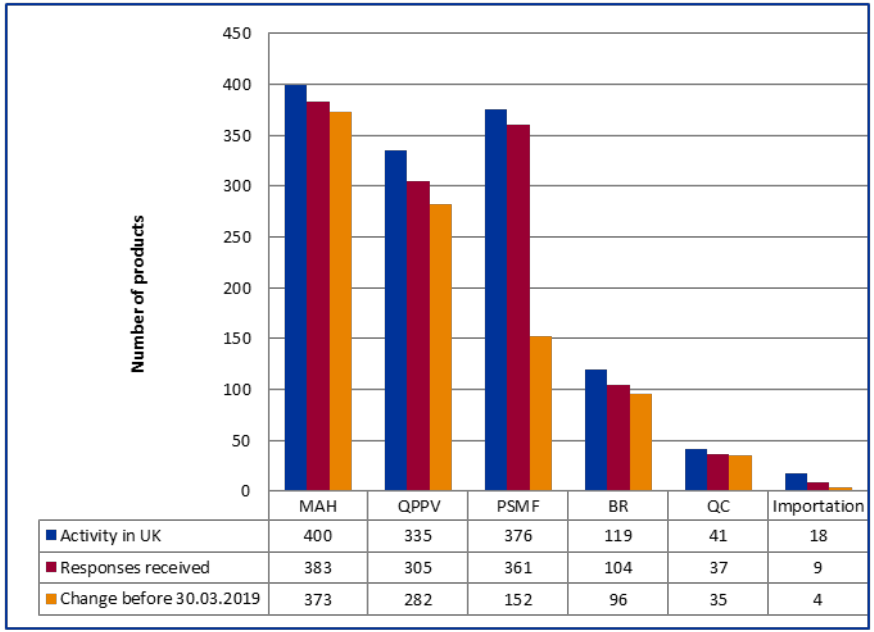
Monica Dias, PhD
Policy and Crisis Coordinating Officer, Office of the Deputy Executive Director
Ivo Claassen, PhD
Head of Division, Veterinary Medicines

# Impact of Brexit on medicines availability (CAPs) Survey to MAHs

- The European Medicines Agency launched a **survey** (22 January to 19 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.
- The aim of the survey was 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.

# Impact of Brexit on medicines availability (CAPs) Results of the Survey

- High response rate: 91%
- The results of the survey showed that **58% of the 694 CAPs were "on track" with their regulatory planning** to ensure that the marketing authorisations remain valid once the UK becomes a third country
- Based on the survey results, EMA was concerned about potential supply shortages for **108 medicines (88 human and 20 veterinary)** which had one or more manufacturing sites located in the UK only without any other current alternatives, hence these medicines were considered to be **"at risk" of supply** disruption or shortages in the EU, if changes were not submitted and implemented in due time




| | MAH | QPPV | PSMF | BR | QC | Importation |
|---|---|---|---|---|---|---|
| Activity in UK | 400 | 335 | 376 | 119 | 41 | 18 |
| Responses received | 383 | 305 | 361 | 104 | 37 | 9 |
| Change before 30.03.2019 | 373 | 282 | 152 | 96 | 35 | 4 |

# Impact of Brexit on medicines availability (CAPs)
# 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 is UK only | | | | +/- | +/- |
| B2 | | | At least one activity is 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

# Impact of Brexit on medicines availability (CAPs)
# Outcome of the Risk Assessment

Based on the survey results, EMA contacted MAHs of the 108 medicines to address any potential medicines supply disruptions.

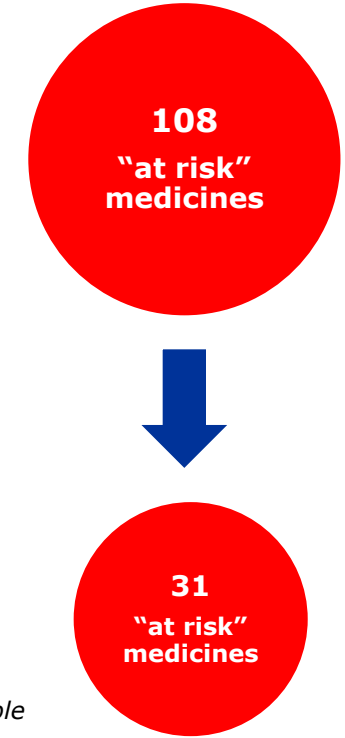
| Risk level | Human Medicines Submissions after 30 March 2019 | Vet Medicines Submissions after 30 March 2019 |
|---|---|---|
| A-B2 | 88 | 20 |
| C | 35 | 3 |
| D | 68 | 0 |
| E | 73 | 8 |
| F | 3 | 28 |
| **Risk level** | **Submission before 30 March 2019** | **Submission before 30 March 2019** |
| G | 388 | 3 |

EMA is monitoring the submissions of changes to marketing authorisation, where necessary.

# Impact of Brexit on medicines availability (CAPs)
# Revised number of CAPs "at risk" of supply

- Follow-up meetings with MAHs of the "at risk" medicines:
  - **Follow-up meetings** for **108** medicines were organised with 54 MAHs (45 human and 9 veterinary) during July-September 2018. These included MAHs that did not reply to the survey.
  - Plans are changing for a number of companies since the launch of the survey; many companies have stated that they will make the necessary changes **before 30 March 2019**
  - **31*** medicines (19 human and 12 veterinary) are currently considered "at risk" and may have potential supply issues

**as of 26 October 2018. This number is likely to change when updated information from MAHs becomes available*



# Impact of Brexit on medicines availability (CAPs) Criticality Assessment

- All products considered as "at risk" will undergo 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.

→ EMA is closely monitoring the medicines considered critical and evaluating potential mitigation measures to minimise any disruptions in supply

# Any questions?

## Further information

AAMTFSecretariat@ema.europa.eu

**See websites for contact details**

**European Medicines Agency** www.ema.europa.eu

**Heads of Medicines Agencies** www.hma.eu

Follow us on **@EMA_News**