# EMA Brexit Interested Parties Meeting
# Joint Industry Presentation – BREXIT

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

January 28, 2019




**This is a joint industry presentation on behalf of the trade associations shown**




# Protecting medicines supply in Europe in a “no deal” scenario

- The current political situation in the UK means that the likelihood of the UK leaving the EU on 30 March 2019 without a deal remains;

- Respecting guidance from the EMA/EC: companies have been preparing for a “no deal” scenario

- Despite this preparation, a “no deal” scenario presents a clear threat of disruption to the supply of medicines throughout the EU (for both CP and MRP/DCP), including:
  - *from transport delays at the border with the UK*
  - *where development, manufacture, packaging, safety testing and regulation of the medicine involves the UK in a manner that is no longer recognized by the EU*
  - *where Notified Body transfers from UK to EU27 for devices associated or co-packaged with medicines cannot be completed by Brexit*

# Measures to avoid delays at the EU/UK border for medicines, clinical trial materials and APIs

- In a 'no deal' the biggest single area outside of the industry's control remains what happens at the borders between the UK and EU.
  - *In the event of 'no deal', customs and other checks at ports and borders causing delays and the possible suspension of air flights, would cause very real disruption to the availability of medicines and time critical supplies of clinical trials and compassionate use/named patient materials to patients.*

- Companies are planning to use different routes to and from the UK where capacity exists, but this is limited.
  - *This includes difficulties with geographic location, suitable secure and refrigerated storage facilities for medicines, and customs checking arrangements.*

- Industry asks EC and Member States to consider possible measures they can take collectively and with the UK to avoid disruption in the movement of medicines and clinical trial materials across the UK and EU borders to protect their supply to patients in Europe, and that they provide clarity as soon as possible to companies for them to be able to take the right measures.

# Measures for the EU recognition of medicines batch testing and release conducted in the UK

- Despite their best endeavors, not all companies will manage to relocate batch release testing to the EU by 30 March 2019.
  - *The EMA has reported that there are currently 18 CP human medicines that are at risk of supply issues after 30 March and CMDh has "many more" medicines authorized through national procedures are at risk.*

- In many cases, Brexit deadline will not be met for reasons outside of companies' control.
  - *There may not be enough laboratory facilities to carry out the necessary quality control testing in EU jurisdictions;*
  - *Shortages of QPs in the EU able to perform batch release onto the EU market;*
  - *The physical replication of the complex testing equipment, processes and technology transfers cannot be completed by the deadline.*

- Industry's proposed solution to mitigate this risk is: the application of the Article 51(2) arrangement under Directive 2001/83 between the EU and UK now as a pragmatic solution to maintain supply of medicinal products until a Mutual Recognition Agreement (MRA) on batch testing and inspections can be agreed

# Proposed way forward

- Continuation of the stakeholders meeting: consider broaden the scope to wider network preparedness (CP, MRP/DCP), including all stakeholders in the regulatory ecosystem should be represented in the discussions i.e. EC, EMA, HMA, CMDh, CTFG.
  - *Acknowledging the progress made for the CP portfolio*

- Case examples have been shared concerning procedural effectiveness of ongoing (regular) procedures - regarding sub-optimal quality and timelines, how can we ensure timely/structured feedback to EMA.

- Discuss opportunities in considering procedural efficiencies, as paused activities will re-start in the 2nd half of 2019, including EMA location, staff retention/recruitment and readiness to operate.

# Thank you