EUROPEAN COMMISSION
SECRETARIAT-GENERAL

Directorate E - Single Market & Connectivity
The Director

Brussels,
SG.E/JW/EL

Dear Ms Santos,

On 21 March 2019, you wrote to the European Commission to express your concerns about EU Brexit contingency actions and measures falling short of what was needed to limit major disruptions in case of no deal.

As you will be aware, the date of the withdrawal of the United Kingdom has been postponed to 1 November 2019. In the light of this extension, the Commission has screened all the EU-level measures for Brexit preparedness and contingency to assess whether they are still fit for purpose. Based on this screening, the Commission considers that the measures taken so far continue to meet their intended purpose and that there is thus no need to amend them on substance.

The Commission also does not plan any new measures ahead of the withdrawal date, as it considers that this additional time allows all stakeholders to finalise and fine-tune their preparations for Brexit. There will be no contingency measure to remedy any lack of action[1].

We therefore invite your organisation to encourage its members to arrange for a timely finalisation of their Brexit preparedness efforts in all areas – from financial services, data flows, trade, transport, energy to the agri-food industry. In this context, we would like to highlight the need to finalise preparedness actions for three sectors in particular:

Medicines (human/veterinary)

Marketing authorisation holders (MAHs) are **required to ensure that their marketing authorisations are in compliance with EU legislation by 1 November 2019 and where changes still need to be made submit the appropriate applications to the competent authorities in time**. If this is not done and the marketing authorisations become non-compliant after 1 November, the competent authorities will take action in accordance with Articles 116-118 of Directive 2001/83/EC and Articles 83-85 of

[1] As confirmed in the Commission's Communication 'State of play of preparations of contingency measures for the withdrawal of the United Kingdom from the European Union' of 12 June 2019 (COM(2019) 276 final), no further contingency measures are planned, including in this sector.

Ms Luisa Santos
Chair of the BusinessEurope Brexit Task Force
BusinessEurope
l.santos@businesseurope.eu

Directive 2001/82/EC to suspend or revoke such authorisations and it will not be possible to place these products legally on the EU market[2].

In this context, we would like to emphasise in particular that the **exemptions for the batch testing sites currently located in the United Kingdom** granted by the European Medicines Agency (EMA) and national competent authorities **are valid until the end of 2019 at the latest and conditional on having a plan for transferring these sites to the EU27 by that date. The Commission does not foresee any prolongation of this exemption.**

Finally, MAHs should also assess the potential risk of shortages of their products due to Brexit and if they identify such risk they should notify the competent authorities in accordance with their legal obligations. In this regard, we would call on BusinessEurope's members to particularly assist small Member States, such as Cyprus and Malta, in mitigating the risk of such shortages.

Medical devices

Manufacturers are called upon **to finalise the transfer of their certificates from UK Notified Bodies to EU27 Notified Bodies and to adapt the labels of their medical devices accordingly.** If this is not done, it will not be possible to place these products legally on the EU market as of 1 November[3].

Furthermore, we would like to inform you that the national competent authorities will shortly contact manufacturers who are certified by UK Notified Bodies LRQA and SGS UK using an online questionnaire to identify potential gaps in continued supply of medical devices in a no-deal Brexit. We would appreciate if you could highlight this online survey to your members to ensure active participation of targeted manufacturers.

Chemicals

Stakeholders in the chemicals sector, in particular downstream users, are asked to **check carefully once again based on the below information whether they may be directly or indirectly impacted by the withdrawal of the United Kingdom and called upon to take the necessary action** where appropriate. If this is not done, it will not be possible to place these products legally on the EU market as of 1 November[4].

- UK-based registrants (manufacturers and formulators) either need to appoint an Only Representative in the EU27/EEA or transfer their activity to the EU27/EEA before

---

2 For detailed information, please refer to the notice and the questions and answers document on medicinal products published on the Brexit Preparedness website of the Commission and the European Medicines Agency respectively, provide advice and guidance for stakeholders in this regard (available at: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante and https://www.ema.europa.eu/en/about-us/united-kingdoms-withdrawal-european-union-brexit).

3 For detailed information, please refer to the notice and the questions and answers document on industrial products, including medical devices, published on the Brexit Preparedness website of the Commission, provide advice and guidance for stakeholders in this regard (available at: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#grow).

4 For detailed information, please refer to the notice and the questions and answers document on REACH published on the Brexit Preparedness website of the Commission and of the European Chemicals Agency (ECHA) respectively, provide advice and guidance for stakeholders in this regard (available at: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#envgrow and https://echa.europa.eu/uk-withdrawal-from-the-eu).

1 November 2019. To this end, the European Chemicals Agency (ECHA) has prolonged its "Brexit window" until 31 October 2019;

- UK-based importers need to transfer their importing activity to a company established in the EU27/EEA before 1 November 2019;

- Manufacturers and formulators in third countries supplying the EU27/EEA need to ensure that their Only Representative is established in the EU27/EEA as of 1 November 2019;

- Downstream users need to verify whether the substance supplied to them is registered by an EU27/EEA registrant as of 1 November 2019 and take the necessary action;

- UK-based authorisation holders and applicants for an authorisation can transfer their authorisation or application to a legal entity in the EU27/EEA before 1 November 2019. Such a transfer must be the result of a change of legal entity. In the case of manufacturers and formulators, they can transfer it to an Only Representative in the EU27/EEA before 1 November 2019;

- Authorisation holders and applicants for an authorisation should be aware that any use of their substance by UK-based downstream users will no longer be subject to the REACH Regulation, and any supply of the substance, on its own or in a mixture, by those UK-based companies to their EU27/EEA downstream users will constitute an import into the EU. As a result, the use of that imported substance or mixture in the EU27/EEA will not be covered by their authorisation/application for authorisation. Unless the import is made by the authorisation holder or applicant for authorisation or by another legal entity applying for authorisation jointly with them, the importer of the substance or mixture will need to submit a new application for authorisation in order to be able to use it;

- Downstream users should assess whether the authorisation holder, applicant for authorisation covering their use, but also upstream manufacturer and formulator, are established in the EU27/EEA. Downstream users with a supplier established in the United Kingdom need to verify whether their use of the substance or mixture will be in compliance with the REACH Regulation as of 1 November 2019 and take the necessary action.

The Commission services, the European Medicines Agency and the European Chemicals Agency remain available for further advice.

Yours sincerely,

John WATSON