Brexit Preparedness seminar on Industrial Products

Council Working Party
(Article 50 Format)
12 December 2018

Industrial products

Key issues:

To place industrial products on the EU27 market after the UK becomes a third country…

1. A certificate under the responsibility of an EU27 Notified Body (NB) will be required, manufacturers must:
   - ➢ *Transfer files from UK NB to EU 27 NB; or*
   - ➢ *Get a new certificate by EU27 NB.*

2. EU27 economic operators may need to be re-defined:
   - EU27 distributors become importers for products previously placed on the EU market by UK manufacturers and importers;
     - ➢ *Need to comply with the obligations of the importer, in particular, indicate the name and address on the product;*
   - Authorised representatives or responsible persons in the UK are not recognised anymore;
     - ➢ *Relocation of authorised representative/responsible person may be necessary;*
     - ➢ *Relabelling to indicate authorised representative/responsible person where required.*

European Commission

Industrial products

What has been done:

- *The Commission published a general preparedness notice on industrial products in January 2018;*
- *The Commission also published sector-specific preparedness notices (i.e. cosmetics, fertilisers, pyrotechnics…);*
- *The Commission has disseminated the notices with expert groups of market surveillance authorities and notified body groups;*
- *Member States informed stakeholders;*
- *UK NBs are exploring relocation to EU27;*
- *Member States' notifying authorities have started the processes towards assessment and designation of NBs newly established in the EU27.*

Industrial products

What needs to be done:

- *Continued efforts by Member States' authorities and the Commission to disseminate information and ensure that stakeholders take the necessary steps;*

- *UK NBs relocating and seeking notification in EU27 Member States:*
  - Ensure that the body established in the EU27 is a real entity which:
    - meets the requirements set out in the legislation, in particular in terms of key personnel and facilities, and;
    - has the capacity to fulfil the tasks of NBs;
  - Where the above has been established, ensure the swift accreditation and notification of the EU 27 NB.

Background and reference information

- *Commission preparedness notices*

  https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf
  https://ec.europa.eu/info/sites/info/files/pyrotechnic_articles_en.pdf
  https://ec.europa.eu/info/sites/info/files/explosive_for_civil_uses_en.pdf
  https://ec.europa.eu/info/sites/info/files/law/detergents_en.pdf
  https://ec.europa.eu/info/sites/info/files/fertilisers_en.pdf
  https://ec.europa.eu/info/sites/info/files/cosmetic_products_en.pdf

- *Blue Guide on the implementation of EU product rules*

  https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations/en/renditions/native

European Commission

Brexit Preparedness seminar on Chemicals

Council Working Party
(Article 50 Format)
12 December 2018

Chemicals sector - REACH

Issue

- *UK authority is the "lead" competent authority for a substance:*
  - Substance evaluation under REACH;
  - Substance restriction under REACH.

What is being done

- *Commission/ECHA facilitated reattribution of substances to EU27 competent authorities (plus CH & NO).*

  ⇒ *This measure is also needed in case of a transition period – see Article 128(6) of the Withdrawal Agreement!*

No additional action needed

Chemicals sector - REACH

Key issue

- *Company or subsidiary holding a registration/authorisation for a substance is established in the UK:*
  - Registration under REACH becomes invalid and can no longer be relied on by other companies (from EU27 or third countries);
  - Authorisation becomes invalid and can no longer be relied upon by EU27 downstream users.

What is being done

- *Registration – action by UK companies:*
  - Transfer the registration to EU27 subsidiary or appoint an "only representative" in the EU27;
  - Transfer the "lead" on registration to EU27 based company;
- *Authorisation – action by EU27 downstream users supplied by UK authorisation holders:*
  - Find an EU27/EEA supplier with an authorisation or apply for autorisation;
- *Commission and ECHA informed through preparedness notices, Q&As, technical expert seminars (EU27).*

What else should/can be done

- *A reminder may be sent to companies by the Commission, ECHA and Member States.*

Chemicals sector – Biocides

Key issue

- *UK authority is the "lead" competent authority for the approval of +/- 235 active substances and authorisations of biocidal products;*
- *Reattribution of leading role to EU27 competent authorities.*

  ⇒ This measure is also needed in case of a transition period – see Article 128(6) of the Withdrawal Agreement!

What is being done

- *Commission facilitated reattribution of files to EU27 competent authorities (plus NO & CH): 81 active substances and 124 cases for biocidal products;*
- *Commission and ECHA informed the affected companies through specific Q&As;*
- *Commission sent letters to competent authorities for further capacity building.*

What else should/can be done

- *Encourage competent authorities to take over some more product files (+/- 30).*

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Chemicals sector – Biocides

Key issue

- *Companies need to transfer an authorisation for biocidal products to an EU27-based company and to have an EU27-based representative to be included as suppliers in Article 95 list;*
  - Holders of product authorisations: only 250 transfers requested so far (out of 650);
  - Suppliers in the Article 95 list: only 3 transfers requested so far (out of 112).

What is being done

- *The Commission and ECHA informed stakeholders through preparedness notices, specific Q&As and technical expert seminars of the need to have an EU27-based representative/holder.*

What else should/can be done

- *An individual reminder could be sent to the relevant companies by ECHA and Member States.*

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Chemicals sector – Plant Protection Products

Key issue

- *UK authority is the "lead" competent authority for approvals of active substances, authorisations of plant protection products and evaluations of Maximum Residue Levels (MRL);*
- *This lead role has to be reattributed to EU27 Member States.*
  ⇒ This measure is also needed in case of a transition period – see Article 128(6) of the Withdrawal Agreement!

What is being done

- *Commission facilitated reattribution of active substances and MRL assessments to EU27 competent authorities (plus NO) – 97 cases;*
- *Central zonal steering committee reattributes ongoing authorisation evaluations to competent authorities in other Member States in the zone;*
- *The Commission and ECHA informed stakeholders through preparedness notices and specific Q&As.*

No additional action needed

European Commission

Background and reference information

Commission and ECHA preparedness notices, Q&As, additional information material :

- *REACH:*
  - https://echa.europa.eu/uk-withdrawal-from-the-eu
  - https://echa.europa.eu/advice-to-companies-q-as/reach
- *Biocides:*
  - https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante
  - https://echa.europa.eu/advice-to-companies-q-as/bpr
- *Plant protection products:*
  - https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante

European Commission

Brexit Preparedness seminar on Medicinal Products (including clinical trials and substances of human origin)

Council Working Party

(Article 50 Format)

12 December 2018

Medicinal products (human/veterinary)

Key issue 1 - Replace UK competent authority within the network / capacity building:

- *Centrally authorised products (CAPs) - redistribution of work in EMA committees;*
- *Nationally authorised products (NAPs) - change of reference Member State in decentralised and mutual recognition procedures (DCP/MRP).*

  ⇒ This measure is also needed in case of a transition period – see Article 128(6) of the Withdrawal Agreement!

What has been done

- *Redistribution of UK CAPs portfolio by EMA to EU27 completed (370 products);*
- *Switches of reference Member State (RMS) for NAPs to EU27 on-going (new RMS identified for 2849 out of 4327 products by 12/2018).*

What remains to be done

- *Continue building capacities and working arrangements in EU27 to take up UK portfolio as of 30 March 2019.*
- *Finalise pending switches of RMS by 30 March 2019.*

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Medicinal products (human/veterinary)

Key issue 2 – Compliance with EU law requirements and adaptations of Marketing authorisations (CAPs and NAPs):

- ***Industry**: to implement Brexit-related changes required by legislation and submit corresponding amendments of marketing authorisations to regulators;*
- ***Regulators** (EU and national): to process increased number of regulatory submissions (transfers, variations) efficiently and in a timely manner.*
- *For example:*
  - *Marketing authorisation holders need to be established in EU27;*
  - *Testing and batch release sites need to be located in EU27;*
  - *Qualified persons need to be established in EU27;*
  - *Brexit-related changes need to be made to clinical trials;*
  - *Labelling needs to be adapted;*
  - *Etc.*

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Medicinal products (human/veterinary)

What has been done

- *CAPs:*
  - Early publication of Commission preparedness notice and Q&As (3 updates), EMA practical guidance documents;
  - Meetings with industry, two technical expert seminars (EU27);
  - Flow of Commission implementing acts amending marketing authorisations (Brexit-related changes).
- *NAPs*
  - Early publication of CMDh/v notice and Q&As (3 updates) and practical guidance documents;
  - Meetings with industry associations;
  - National competent authorities processing Brexit-related changes.

What remains to be done

- EMA and Member States to urge industry to comply with regulatory requirements and change remaining marketing authorisations on time.
- Another technical expert seminar (EU27) for national authorities, if needed.

Medicinal products (human/veterinary)

Key issue 3 - Ensure continuous supply:

- CAPs, NAPs;
- Investigational medicinal products (products used in clinical trials – also see key issue 5);
- Specific challenges for smaller markets (for both human and veterinary products).

What has been done

- CAPs: EMA closely monitors situation, survey to concerned MAHs, criticality assessment, follow up actions; From initially identified 694 products only 24 human and 12 veterinary remain of concern (12/2018);
- NAPs: More complex. Member States preparedness measures, information exchanges at CMDh/v and HMA.

What remains to be done

- CAPs: EMA continues to monitor "products at risk" and informs the network;
- NAPs:
  - Member States continue to survey and follow-up on NAPs (including criticality assessment and direct communication with the companies concerned);
  - Further exchanges of information and coordination at CMDh/v and HMA level.

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Medicinal products (human/veterinary)

Residual issues 4:

- *Marketing authorisation applications - dossier requirements*
  - **GMP certificates issued by UK**: EU legislation does not require an EU GMP certificate (Article 8(3)(ha) of Directive 2001/83/EC). GMP certificate issued by the UK pre-Brexit can be submitted as supporting document for GMP compliance. Assessing NCAs apply a risk-based approach).
- *Marketing authorisation applications - studies submitted*
  - Bioequivalence studies with UK-sourced comparator generally not acceptable but certain limited flexibility already allowed to avoid unnecessary repetition of studies in humans and animals (see published Q&A document).

Medicinal products (human/veterinary)

- *Labelling*
  - Multi-country packs in practice possible if the product information in third country (UK) is exactly the same and the additional (administrative) information related to the third country complies with the requirements for inclusion in the so-called "Blue box" (Articles 57 and 62 of Directive 2001/83/EC);
  - This is by its very nature only a temporary solution;
  - Industry has to move to multi-country packs with EU27 Member State markets.
- *Changes of Reference Member State*
  - Procedural requirements based on CMDh/v regulatory guidance.
- *National authorisations based on Article 126a of Directive 2001/83/EC*
  - Authorisations issued pre-Brexit on the basis of Article 126a are not affected by Brexit;
  - Nevertheless, in view of future authorisations on the basis of Article 126a, affected Member States need to act;
  - Support and assistance provided by the Network including the Commission.

Clinical trials and investigational medicinal products (IMP)

Key issue 5 – Ensuring continuity for on-going clinical trials:

- The import of IMPs for clinical trials into the EU is subject to **holding an authorisation**;
- EU27 authorisation holders need at least **one qualified person located in the EU27** to conduct a batch release, no need for retesting if already tested in the UK;
- For clinical trials conducted in the EU27, the sponsor or a legal representative needs to be established in the EU27.

What has been done

- Commission informed through a preparedness notice and a technical expert seminar (EU27).

What remains to be done

- Sponsors are urged to submit the appropriate amendments as soon as possible.

Substances of human origin (blood, tissues and cells)

Key issue 6 – UK substances of human origin subject to third country regime:

- Blood rarely exchanged. UK is not collecting plasma since CJD and organ-exchange is subject to bilateral agreements;
- Replacement tissues (e.g., bone, heart-valves, cornea, skin) need to be imported from third countries in EU by authorised importing tissue establishments;
  - Need to organise UK import through EU27 importing tissue establishments;
  - Need to reorganise some US imports into EU;
  - Some direct imports for immediate use can be authorised directly by national authorities (e.g. for bone marrow straight to a patient in a clinic).

What has been done

- Commission informed through a preparedness notice.

What remains to be done

- Continue awareness raising.

Background and reference information

- *Commission preparedness notices and Q&As:*
  https://ec.europa.eu/health/sites/health/files/files/documents/ec_ema_notice_communication_brexit.pdf
  https://ec.europa.eu/health/sites/health/files/files/documents/qa_on_brexit.pdf
  https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_brexit_clinical_trials_final.pdf
  https://ec.europa.eu/info/sites/info/files/file_import/substances_of_human_origin_en.pdf

- *EMA Website related to UK's withdrawal from the EU :*
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/general/general_content_001707.jsp&mid=WC0b01ac0580a809a7

- *CMDh Website related to UK's withdrawal from the EU :*
  http://www.hma.eu/535.html

- *CMDv Website related to UK's withdrawal from the EU:*
  http://www.hma.eu/542.html

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