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Human Medicines

COVID-19: Queries and Updates

- If you have any regulatory queries specific to COVID-19, please e-mail covid19@hpra.ie.
- For further information on the HPRA response to COVID-19, see our dedicated webpage: hpra.ie/covid19.
- Queries to Receipts and Validation:
  We continue to operate our standard service for the receipt and validation of applications with all mailboxes closely monitored. To ensure the efficient processing of your query, please provide:
  - PA number
  - Procedure Number
  - CESP submission number
  within the body of your query to facilitate our prompt follow up.

COVID-19 Related Human Research – Expedited Regulatory and Ethical Review

Expedited Review

The HPRA, in conjunction with the Department of Health, the National Office for Research Ethics Committees and the Health Research Declaration Committee (HRCDC), have agreed an expedited review process for human health research related to COVID-19 (SARS-CoV-2, coronavirus).

A key development is the establishment of a dedicated COVID-19 national research ethics committee (NREC-COV19) by the Minister for Health. In the interests of time and resource efficiency, applications for ethical review of all human health research studies related to COVID-19 should be submitted to the NREC-COV19.

Applications for clinical trials of human medicines, or clinical investigations of medical devices, will be given a priority and expedited review by the HPRA. The NREC-COV19 will review applications concurrently with regulatory review processes and will endeavour to facilitate an expedited ethical review.
Submitting applications

Applications for clinical trials or clinical investigations should be marked ‘COVID-19’, and this should be included in the research title.

Applications can be sent in parallel to HPRA and the COV19-REC to obtain an expedited national decision. Please copy the HPRA clinical trials (clinicaltrials@hpra.ie) or medical devices (devices@hpra.ie) mailbox when making an application.

Please also contact us as early as possible in advance of the submission, to ensure that we can prioritise the application.

HPRA contacts

Clinical trials should be submitted through the usual CESP route, and copied to submissions@hpra.ie.

NREC-COV19 contacts

All applications for ethical review should be submitted to nationaloffice@nrec.ie. This will be the central contact point for both the NREC-COV19 and Health Research Consent Declaration Committee (HRCDC).

Regulatory Expectations and Flexibilities – COVID-19

Guidance on the Management of Clinical Trials during COVID-19

The HPRA acknowledges the potential impact of COVID-19 on the health system and broader society, and the impact it may have on clinical trials and subjects. The HPRA appreciates that the situation is evolving, and pragmatic actions may be required to deal with the challenges of conducting research, and in ensuring the rights, safety and wellbeing of subjects. Please reference our website for guidance and considerations during this time for investigators and site staff, sponsors and contract research organisations (CRO).

Variation Implementation Times for Labelling and Leaflet Updates to Human Medicines: Update on Regulatory Flexibility during the COVID-19 Pandemic

The HPRA has agreed to extend the permitted implementation time from six months to nine months for labelling and/or package leaflet updates following variation approval for the duration of the COVID-19 pandemic. This is a temporary measure only and it will be kept under review. The HPRA has taken this decision to help maintain medicines availability in Ireland during this exceptional time.

It is important to highlight that this extension to nine months does not apply to the implementation of significant safety updates to the labelling and/or package leaflet. Significant safety updates will still need to be implemented within the six-month timeframe. The marketing authorisation holder (MAH) is therefore advised to carry out an evaluation of the specific nature of the updates to the labelling and/or package leaflet before allowing the extended implementation period.

In general, the standard implementation period will still apply to significant safety updates to sections 4.1, 4.2, 4.3 and 4.4 of the SmPC which have implications for the labelling and/or package leaflet. The addition of new safety information to other sections of the labelling and/or package leaflet, such as interactions, driving information, pregnancy/breastfeeding advice, adverse events or overdose information also requires implementation within the six-month timeframe in cases where new significant safety information has been added to the labelling and/or package leaflet as a result of the variation.

The implementation of all other variations can be extended to nine months without the need for a batch-specific request, provided that the MAH is satisfied that the update is not concerned with significant safety-related changes.

For queries related to product-specific concerns, please e-mail Customer Services at info@hpra.ie inserting COVID-19 into the subject line.
Excipients in the Labelling and Packaging Leaflet of Medicinal Products for Human Use

The updated ‘Annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use EMA/CHMP/302620/2017 Rev 1’ is effective from 22 November 2019. It contains the information which should appear in the package leaflet for the excipients known to have a recognised action or effect.

For already authorised medicines, MAHs should use the first opportunity to implement the wording in compliance with the revised Annex. For medicines with no foreseeable regulatory submissions, MAHs should submit a type IB variation within three years after the publication of the revised Annex.

Pharmacovigilance: Prioritisation of ICSRs during the COVID-19 Pandemic

The European Commission, the Heads of Medicines Agencies and the European Medicines Agency have published Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the COVID-19 Pandemic (revision 1, 17 April 2020), which details regulatory expectations and flexibilities available to MAHs to maintain medicines on the EU market during the COVID-19 pandemic.

To interpret the practical aspects of the document for MR/DCP products, CMDh has published practical guidance for facilitating the handling of processes during the COVID-19 response. It provides further direction on how to request and apply the provisions described in the EU Commission document.

The Q&A introduces a new regulatory procedure called the ‘Exceptional Change Management Process’ (ECMP), to allow applicants to quickly implement new manufacturing or control sites for crucial medicines for the treatment of COVID-19 patients. Applicants are also reminded of existing regulatory routes to maintain supply of all medicines, such as batch-specific requests, exempt medicinal products and zero-day mutual recognition/repeat use procedures. Guidance is available on the HPRA website on these routes, and we remain available for further discussion as necessary. Applicants who consider that they have a need for regulatory flexibility in relation to the COVID-19 pandemic should carefully consult these documents.

Requests for ECMP should be sent to ecmp@hpra.ie stating “COVID-19 ECMP” in the heading. Requests for other regulatory flexibilities should be sent to the usual procedural contact points, ensuring the prescribed headings for MR/DCP applications as per CMDh practical guidance are included where relevant. A full list of these contact points is available on the COVID-19 Regulatory Expectations and Flexibilities page of the HPRA website.

Exceptional Change Management Process

The Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the COVID-19 Pandemic document published by the European Commission, Heads of Medicines Agencies and the European Medicines Agency has been updated to include clarification regarding the potential impact of the pandemic on reporting of Individual Case Safety Reports (ICSRs) to EudraVigilance.

It is recognised that during the current pandemic, the reporting of suspected adverse reactions related to the widespread use of medicinal products for the treatment or prevention of the pathogen causing the pandemic may increase. At the same time, there is a risk that workforces in industry may be reduced due to high levels of employee absenteeism. These exceptional circumstances may force MAHs to activate business continuity plans and prioritise activities. Where such incidences arise, MAHs may temporarily implement prioritisation of ICSR reporting based on case type. Further details are provided in the questions and answers document (linked above).

MAHs are reminded to regularly consult the HPRA, EMA and HMA websites for further updates in this regard. Should you wish to notify the HPRA of the need to activate business continuity plans relating to pharmacovigilance, please email medsafety@hpra.ie.
Revision of National Legislation on Veterinary Medicinal Products

The HPRA has been informed by the Department of Agriculture, Food and the Marine that a public consultation on the revision of SI No. 786 of 2007 is planned for the coming period. The revision is necessary to complement Regulation 2019/6, as aspects of the current national legislation will be redundant or in conflict with it. The Regulation will apply on 28 January 2022. The national legislation is expected to significantly impact on how veterinary medicinal products are regulated and monitored in Ireland. The new legislation is also expected to provide for the regulation of autogenous vaccines in Ireland, as well as the regulation of borderline products and products that are used in certain categories of pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits. More information on the consultation will be available on the DAFM website.

A consequence of the HPRA initiative on the method of supply of antiparasitic veterinary medicinal products for use in food-producing animals is that the substances concerned will be restricted to veterinary prescription. This means that from January 2022, any such substances that are used in certain categories of pets — aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits — will no longer meet the relevant criteria for exemption from the requirements for supply without a marketing authorisation.

Strategic and Operational Planning for Veterinary Medicines

The HPRA is currently preparing its Strategic Plan for the period to 2025. For veterinary medicines, the backdrop to the plan is the implementation of Regulation 2019/6, the so-called new veterinary regulation, which will apply on 28 January 2022. The changes in the legislation will require the HPRA to simplify and make changes to certain business processes (e.g. variations and pharmacovigilance), as well as providing for increased resources for real-time surveillance of the safety and use of products. We face additional challenges from Brexit, in terms of its effects on the availability of veterinary medicinal products and its impact on the economy, particularly the agricultural sector. The HPRA is required under statute to ensure that service costs are recovered from the regulated sector. Since 2019, the Veterinary Medicines Department has increased our personnel resources to meet expected demands on the service due to the UK’s departure from the network. Accordingly, the HPRA will need to plan carefully over the coming period to ensure that the business model is agile but capable. The HPRA looks forward to working with marketing authorisation holders to better understand their expected needs for HPRA services over the coming years. If you would like to contact us with ideas on this topic, please do so by emailing Ms Elaine Hynes, Elaine.Hynes@hpра.ie.

Update on Implementation of the Report of the Task Force on the Method of Supply of Antiparasitic Veterinary Medicinal Products that are Intended for Food-producing Species

The Report of the Task Force on the Method of Supply of Antiparasitic Veterinary Medicinal Products that are Intended for Food-producing Species was published in December 2019. The Report states that the available scientific evidence shows that antiparasitic veterinary medicines that are intended for use in food-producing species do not comply with the criteria for derogation from veterinary prescription specified in Regulation (EU) 2019/6. Following publication, the HPRA held a public consultation on implementation of the report findings.

Details of the consultation and a subsequent meeting with stakeholders on 27 April 2020 are available on the HPRA website.

In line with the report, and in order to allow stakeholders the necessary time to make adjustments to their businesses, the HPRA wishes to give maximum flexibility to implement the findings of the report. This means that existing antiparasitic products may continue to bear the LM supply route for the present, pending a concerted initiative to review and approve all affected products in the period May to July 2021. The HPRA clarified the detailed steps and timeframe for changing products from Licensed Merchant (LM) to Prescription Only Medicines (POM) as follows:

- In respect of existing products, variation applications should be submitted to the HPRA before 30 April 2021. The HPRA hopes to approve all products concerned by 28 July 2021.
- In respect of new products that are authorised up to 30 April 2021, they
may, at the request of the Marketing Authorisation Holder, be allocated an LM status on the basis that an application to vary the method of supply will be submitted before 30 April 2021 to change to LM. If no such request is made, the products concerned will be assigned POM status upon authorisation and can thereafter only be supplied under prescription.

In respect of new products that are authorised from 30 April 2021, they will be assigned POM status.

As has been advised in the report, and clarified during the consultation, antiparasitic veterinary medicinal products for bees may continue to be marketed without a veterinary prescription, as is also the case for such products that have been authorised under the centralised procedure.

In respect of the products that require a change of the method of supply, the application is classified as a Type 1B C.II.6 variation. The HPRA will not charge a fee for these variations, provided that the applications are submitted before 30 April 2021, with a view to processing and approving all such variations for all MAHs within a short timeframe just before 28 July 2021. All such applications must be clearly identified as ‘Change of supply of antiparasitic veterinary medicine in line with HPRA policy’. Applications submitted after 30 April 2021 will be charged a fee in line with fee code 591 (currently €595 but subject to annual change) per application.

Applications can be grouped if submitted at the same time. Mock-ups are not required to be included in the variation application provided that the changes to the mock-ups relate only to the information on the method of supply and no other change is being made to the product labelling or leaflet. A declaration to this effect should be included within the supporting documentation.

The HPRA will follow the policy outlined in the HPRA Guide to Implementation of Packaging Changes to Authorised Veterinary Medicinal Products in implementing the changes to the labelling (specified as ‘other safety restrictions – item 3.2 of that policy). This means that marketing authorisation holders should:

- Co-ordinate the supply/importation of stock to ensure the introduction of the amended product labelling and literature as soon as possible and in any case, within six months of the approval of the variation. Products in old livery containing the LM supply designation should not be QP released after six months from the date of approval of the variation (i.e. the labelling of all products released for the Irish market must be compliant with the prescription requirement at the latest by 28 January 2022).

- Plan to avoid having large quantities of product in old livery in the marketplace in the second half of 2021. Where they exist, MAHs should place notices in the farming press and/or professional journals as appropriate, alerting users to the changes.

- Inform retailers of the changes.

Separately, the HPRA stands ready to contribute to a multi-stakeholder approach in a national initiative to address the wider issue of antiparasitic resistance.

Compliance

Automatic Extension of Periods of Validity of GMP and GDP Certificates due to Restrictions Linked to the COVID-19 Pandemic

The European Commission, the Heads of Medicines Agencies and the European Medicines Agency have published Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the COVID-19 Pandemic. The document includes information about measures taken in relation to Good Manufacturing Practice (GMP) certificates and Good Distribution Practice (GDP) certificates.

Travel restrictions and risk to public health posed by the COVID-19 pandemic are preventing the conduct of on-site GMP and GDP inspections. Measures have been taken at EU level to maintain the validity of GMP and GDP certificates to avoid disruptions in the availability of medicines. The period of validity of GMP and GDP certificates in the EudraGMDP database has been extended until the end of 2021.

The following footnote appears on all certificates viewed on the EudraGMDP database:

‘Due to the restrictions caused by COVID-19, the period of validity of MIAs, WDAs, GMP and GDP certificates in effect at the time of declaration of the pandemic by WHO is automatically extended until the end of 2021. On-site inspections will resume as soon as there is a consensus that the period of the public health crisis has passed. The clarifying remark section of individual MIAs, WDAs, GMP and GDP certificates will indicate any exceptions. Competent authorities reserve the right to inspect a manufacturing site should the need arise.’

This automatic extension applies only to the period of validity and does not cover changes in the scope of the certificates (e.g. type of medicinal products/dosage forms or authorised operations).

For new sites/facilities that have never been authorised, a remote inspection/distant assessment may be conducted in order to evaluate if the site could be authorised without a pre-authorisation on-site inspection.

The obligation of manufacturers (active substance and finished product), importers and wholesalers to comply with GMP and GDP is not waived and it is incumbent upon all holders of authorisations and/or certificates to ensure continued compliance with the applicable legislation and guidelines.
Remote GxP Inspections

In light of the current travel restrictions and risk to public health posed by the COVID-19 pandemic, the HPRA has initiated a process to enable us to conduct inspections remotely. Alignment of this process is underway in association with EU working groups coordinated by the European Medicines Agency.

The requirement to conduct a remote inspection will be determined on a case-by-case basis. Notifications will be sent in advance of the remote inspection in the same manner as that which exists for an on-site inspection. The remote inspection process will, in general, follow a similar format to that for an on-site inspection and will commence with an opening meeting and conclude with a closing meeting via teleconference or alternative remote communication platform. The communication platform used will be particularly important to facilitate the smooth running of the inspection.

Those subject to inspection will be requested to propose a suitable telecommunications method and this will be agreed with the Inspector in advance of the inspection. The process will require electronic copies of documents and other information to be provided to the Inspector for review. Consideration should be given to the use of platforms which provide for live sharing of documents and videos, in addition to the use of cameras to allow for a virtual review of physical facilities and equipment, where applicable.

To avoid delays during remote inspection, companies will be requested to make certain documentation available prior to the commencement of the inspection. Documentation requirements will be specified in the pre-inspection notification.

In certain circumstances, a remote inspection on its own may not be sufficient to enable a decision to be made regarding the level of compliance with GxP requirements and, as such, an on-site inspection may be performed at the earliest possible time. It is envisaged that this would generally focus on areas of the site that could not be inspected remotely and/or areas requiring further follow-up resulting from the remote inspection.

For remote Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) inspections (also referred to as distant assessments), further information may be accessed in Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use during the COVID-19 Pandemic, which was recently published by the European Commission, Heads of Medicines Agencies and the European Medicines Agency.

Provision for Remote Qualified Person (QP) Certification during the COVID-19 Pandemic

The holder of a Manufacturer’s Authorisation (MIA) shall have permanently and continuously at his disposal the services of at least one qualified person (QP). The relevant legislation (human and veterinary) also permits the use of alternative premises, from time to time, if approved in writing by the HPRA.

Due to the extenuating circumstances presented by the COVID-19 pandemic, the HPRA communicated with QPs by email on the 12 March 2020, to advise them of a provision allowing for remote QP certification.

If seeking to avail of that provision, the MIA holder is required to submit its proposal for a remote QP certification arrangement, in writing, to the HPRA for review and approval.

Any such proposal should be addressed to compliance@hpra.ie with the subject line of Request for Remote QP Certification. The HPRA will endeavour to respond to these requests within two working days.

Approval will be conditional on implementation of the following arrangements, and confirmation of these should be provided with the proposal:

- The certifying QP would need to have access to all information necessary to enable them to perform the batch certification steps;
- The address where batch certification takes place will be recorded as part of the certification documentation;
- Any batches certified under this process would be documented within the non-conformance/deviation management system if the relevant Standard Operating Procedures (SOPs) have not been updated to reflect this change;
- The recording of the batch certification in the register (or equivalent document) would be contemporaneous. The following provisions should be defined;
  - If the register remains at the site, responsibility for keeping it up to date when the QP has remotely certified a batch;
  - If the register stays with the QP, the arrangements for returning it to the site.
Variations to a Manufacturer’s Authorisation (MIA)

Timelines for assessment and approval of variations are detailed in HPRA guidance document AUT-G0140: Guide to New Applications and Variations to Manufacturer’s Authorisations.

Assessment timelines are based on the receipt of a variation application. A variation application is one that includes a correctly completed application form AUT-F0211, ‘Application Form for Variation to a Manufacturer’s Authorisation’ and all the required supporting documentation, as detailed in the guidance document referenced above.

Receipt of incorrect or incomplete applications leads to longer assessment timelines and delays in approval of variations.

A process exists for the expedited assessment of variations and immediate notification of variations to Annex 3/Annex 4 of a manufacturer’s authorisation related to Investigational Medicinal Products (IMPs). This process is described in the guide referenced above and was covered in Issue 60 of the HPRA Medicinal Products Newsletter.

Some examples of common errors in applications received, which have required further correspondence with the applicant, are detailed below:

– Selection of ‘Other’ for manufacturing or importation operations: In circumstances where manufacturing or importation operations do not fall into one of the specified operations on the form, the applicant must specify the detail to which ‘other’ relates, as this information is required to be captured on the MIA. For example, if an applicant selects ‘1.2.1.17 Other non-sterile medicinal product’ is to be manufactured, a description of the dosage form must be provided, e.g. ‘Breath-activated metered-dose inhaler’.

– Batch certification: Applications have incorrectly detailed ‘batch certification’ as an activity performed at a contract manufacturer listed in Annex 3. Batch certification, as an operation, is applicable to the holder of the MIA only. If a contract manufacturing site performs batch certification, it does so under its own MIA. The site at which batch certification is conducted must be in accordance with that specified in the Marketing Authorisation for the product.

– 1.3.1.5 Biotechnology products: As outlined in the guide, this operation is applicable to products manufactured using biotechnology. The applicant is instructed to provide information describing the operations to be conducted to enable this detail to be included as a clarifying remark on the MIA. An example of the detail required of the applicant is as follows: ‘Section 1.3.1.5 Biotechnology products relates to the manufacture of a biological active substance using mammalian cell culture, its isolation/purification, formulation of a low bioburden bulk intermediate and manufacture of the finished dosage form.’

– 1.4.2 Sterilisation of active substances/excipients/finished product: As described in the guide, this section should only be used when sterilisation is not performed as part of the manufacture of the finished dosage form (e.g. when a site conducts contract sterilisation operations such as gamma irradiation of products not manufactured onsite).

– 1.4.3 Other: This section should be primarily used to indicate storage sites or sites of physical importation operations.

– Storage: This should be recorded under section 1.4.3, as outlined above. Storage is only required to be specified when the site does not conduct other manufacturing operations. For a site conducting manufacturing operations, it is automatically assumed to be capable of product storage.

– Primary packaging/filling of sterile medicinal products: Primary packaging of sterile medicinal products is considered intrinsic to the manufacture of the dosage form. Therefore, ‘primary packaging operations’ under section 1.5.1 is not required to be selected for sterile dosage forms.

– Annexes 3, 4 and 5 of the application form:
- Provision of a copy of the manufacturer’s authorisation for the contract manufacturer instead of the GMP certificate.
- Name and address on the application form not aligned with the details on the GMP certificate.
- The proposed manufacturing operation for the relevant dosage form outsourced to the contract manufacturer not included in the scope of the GMP certificate provided.

- Annex 3 of the application form completed instead of Annex 4 for a contract laboratory performing laboratory operations only.
- Applicant incorrectly selected all operations a contract facility is authorised to perform, instead of only those operations to be performed under contract to the MIA holder.

- Addition of a proposed Qualified Person (QP):
- Applicants submit evidence of relevant QP qualification which do not state the name of the course completed. The certificate issued by a University for a QP qualifying course may not detail the name of the course completed. In these cases, a formal record from the university (an official letter or a copy of the course transcript) that details the name of the course completed should also be provided in the application pack.

- The summary of training of the QP in the company’s pharmaceutical quality system does not include the signature of the applicant QP and/or their supervisor.

– Annex 8 ‘Product Authorised for Import’: The names of the contract manufacturers of the imported products must be included.
Manufacturing/Importation Arrangements during the Post-Brexit Transition Period

The UK formally left the EU on 31 January 2020 and became a third country. A transition period began on 1 February 2020, during which EU pharmaceutical law remains applicable to the UK and, unless agreed otherwise, this is due to end on 31 December 2020.

1. Batch Certification in the UK during the Transition Period

Qualified Person (QP) certification of batches intended for EU markets may continue at UK sites during the transition period. Third country importation requirements will not be applied until the end of the transition period, i.e. there is no requirement for additional certification by a QP in the EU following importation of a batch from the UK during the transition period.

In order to facilitate continuity of supply from 2021 onwards, marketing authorisation holders should ensure that affected marketing authorisations are varied in advance of the end of the transition period to make provision for revised third country importation arrangements.

2. MIA Updates

In order to facilitate efficient processing of variations to MIAs for sites located in Ireland, MIA holders are requested to identify and submit any necessary variations in preparation for the end of the transition period (31 December 2020). Variations which may apply are summarised under the headings below.

2.1. Batch Certification Activity under Irish MIA

In Annex 1 to the MIA, there are separate entries for certification of products manufactured in the European Economic Area (EEA), i.e. in Part 1, and certification of imported products in Part 2) (or Annex 2 in the case of Investigational Medicinal Products (IMPs)). During the transition period, certification of products coming from the UK under batch certification activities listed in either Parts 1 or 2 (Annexes 1 or 2, as appropriate) can continue. However, from the beginning of 2021, products imported from the UK should be certified under the activities listed in Part 2 of the MIA. In preparation for this, the relevant MIA holders should make arrangements, ideally at an early stage, to submit variations to ensure that the appropriate batch certification activities for imported products are listed in Part 2 of the MIA.

Note that, where the product is physically imported to the site of batch certification, the activity ‘Site of Physical Importation’ should also be added in Part 2 by variation to the MIA, as appropriate.

2.2. Completion of Application Form F0211

UK sites of manufacture are no longer located within the EEA and the application form should be completed accordingly when submitting new variations to add contract manufacturers located in the UK.

2.3. Listing of Imported Products in Annex 8

There is no objection to continued certification of products imported from the UK which are not listed in Annex 8 to the MIA at this time. However, manufacturers should submit variations, at an early stage, to list imported products in Annex 8 in preparation for the end of the transition period. Quality Control (QC) testing in the EU will not be required for products, imported from the UK and listed in Annex 8, until the transition period has ended.

2.4. Sites of Physical Importation Located in the UK

During the transition period, batch certification may take place under an MIA in Ireland for products which are physically imported into the UK from outside of the EEA. However, before the end of the transition period, manufacturers should submit variations to replace these UK-based sites of physical importation with sites located in the EEA.

2.5. QC Testing in the UK

If a product intended for EU markets undergoes testing in the UK, there is no requirement for additional testing in the EU during the transition period. Prior to the end of the transition period, manufacturers should ensure that arrangements are in place for testing in the EU, including submission of any necessary variations.
Reminder for Distributors of Teeth Whitening Products Containing Hydrogen Peroxide

The HPRA wishes to remind all distributors, including retailers and pharmacies, supplying teeth whitening products about the requirements relating to hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide. The use of these ingredients is restricted in cosmetic products by Regulation (EC) No. 1223/2009, including in oral health and teeth whitening/bleaching type products. Cosmetic products that do not comply with the EU Cosmetics Regulation, and contain high concentrations of hydrogen peroxide above the level deemed safe, put consumers at risk.

The HPRA wishes to emphasise the importance of carrying out due diligence when sourcing teeth whitening products, including ensuring the level of hydrogen peroxide is compliant and confirming the product is intended for the EU market.

When sourcing products from online suppliers, particular care is required as a number of cosmetic products sourced online have been found to contain unacceptable levels of hydrogen peroxide.

If a company purchases cosmetic products from outside the EEA, this is classified as importation and the business is taking on the role of Responsible Person (RP), i.e. the legal responsibilities, namely, for ensuring the safety of the product.

Distributors should verify the following for all teeth whitening products supplied in Ireland:

For all cosmetic products, it is a legal obligation to check:
- That the text on the label is in English, in Irish or both.
- That the best before or expiry date, where this is relevant to the product, has not passed.
- The products must be labelled with:
  - An EU Name and Address (the Responsible Person for the product)*.
  - A list of ingredients
  - A batch number/reference identification number

In addition, there are extra controls for oral products, including mouth rinse, toothpaste and tooth whitening or bleaching products:

- If hydrogen peroxide or another peroxide is stated on the label, check if the content of hydrogen peroxide is declared:

<table>
<thead>
<tr>
<th>Concentration of Hydrogen Peroxide (present or released)</th>
<th>Restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1% or below</td>
<td>The product can be sold as a cosmetic without specific restrictions.</td>
</tr>
<tr>
<td>Higher than 0.1% up to 6%</td>
<td>The product can only be sold to dental practitioners. There are also other legal restrictions in relation to these products.</td>
</tr>
<tr>
<td>Higher than 6%</td>
<td>The product is not compliant with the EU Cosmetics Regulations; it is prohibited from use and considered an illegal cosmetic product. The product should be returned to the supplier or sent for destruction.</td>
</tr>
</tbody>
</table>

Further information is available on the HPRA website and access to the EU legislation on cosmetic products can be found on the European Commission website.

Any queries in relation to this topic can be sent to cosmetics@hpra.ie

* Retailers should note that purchasing cosmetic products from the UK after the end of the current transition period, 31 December 2020, will be an importation activity. Cosmetics products labelled with a UK name and address that were placed on the market before the end of the transition period can continue to be made available.

Please refer to the Brexit section of our website for more information: www.hpra.ie/homepage/about-us/stakeholders/brexit/cosmetic-products