

HPRA MEDICINAL PRODUCTS

NEWSLETTER

ISSUE
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Brexit

(Human and Veterinary Medicines)

Potential withdrawals arising due to Brexit

For companies considering potential withdrawals arising solely from Brexit, the HPRA wishes to re-iterate its openness to discussing regulatory solutions that may avoid the need to withdraw a marketing authorisation or registration. The HPRA stands ready to discuss any regulatory issues with authorisation and registration holders that arise as a result of the UK's departure from the European Union.

Human Medicines

Where a withdrawal is unavoidable, the published guidance on the management of withdrawals for commercial reasons is outlined within [Guide to Withdrawal of Authorisations or Certificates for Medicinal Products for Human Use](#).

To that end and in the interests of maintaining continuous access to medicines we would ask that, irrespective of specific guidance, your company considers proactively discussing in confidence any potential plans to withdraw IE packs with the HPRA. Such information would not be binding or drive regulatory action, rather would allow the HPRA to proactively identify and manage generally any supply risks with other key stakeholders within the public sector. Initial contact can be made directly with your regular contact to coordinate discussions in confidence. Where stakeholder information points to a potential shortage the position will be managed within our 'Shortages Unit' with the direct involvement of your relevant member(s) on a case by case basis in line with current practice.

Veterinary Medicines

The HPRA is conscious of the possible negative impact of Brexit on availability of veterinary medicinal products in this country. In the interests of maintaining continuous access to medicines, we would ask that your company considers proactively discussing in confidence any potential plans to withdraw product authorisations in Ireland, in order to fully explore all available options.

Where a withdrawal is unavoidable the published guidance on the management of withdrawals for commercial reasons is outlined within [Guide to withdrawal of authorisations or certificates for veterinary medicines](#).

The HPRA must be notified of the withdrawal of a marketing authorisation. Notification of the withdrawal of an authorisation should be made using the form: [Notification of withdrawal of authorisations or certificates for veterinary medicines](#).

In the event of shortages, the issuing of exceptional authorisations (AR 16 licences) and operation of the Cascade fall under the remit of the Department of Agriculture, Food and the Marine (DAFM).



An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Packaging

The HPRA would like to remind Marketing Authorisation Holders (MAHs) that MAHs that dual labelling for human products and joint labelling for veterinary products, whereby a single approved label includes both the Irish and UK requirements will continue to be acceptable for the Irish Market.

Multilingual Packaging

Human Medicines

The HPRA [Guide to labels and leaflets of Human Medicines](#) has been updated to include specific guidance on the development of multilingual labelling.

Veterinary Medicines

Multilingual labelling continues to be acceptable for veterinary medicinal products. Guidance relating to labelling requirements is available in the [veterinary labelling section](#) of the HPRA website.

Request for PA/VPA numbers in advance of an application – Transfers

Please be advised that the HPRA processes all requests for PA/VPA numbers in accordance of date of receipt. Since 2017, the HPRA has encouraged MAHs to request these numbers well in advance of their application to allow the Receipt and Validation section manage the volume of applications being received. If an MAH plans to submit their transfer application shortly after the PA/VPA number(s) are issued, then it would be more valuable to submit the entire application leaving the proposed PA/VPA number(s) blank.

When requesting PA/VPA numbers in advance, please ensure you have provided the following information:

1. The correct current PA/VPA number and product name
2. PA/VPA numbers for authorised medicinal products only
3. If you plan to submit the PA/VPA transfer(s) in a specific way for e.g. in a date order, please indicate this as part of your request.

Before following up in relation to your request, please allow the Receipt and Validation section at least 5-10 working days to provide you with the new PA/VPA number. Please ensure that this timeline is incorporated into your planning times.

Brexit and Clinical Trials for Human Medicines:

- Sponsor or legal representative must be in EU/EEA

Clinical trials legislation requires that the sponsor or legal representative of the sponsor is established in the EU/EEA. Sponsors are requested to consider the impact of Brexit on this legal requirement. A change to the application form can be made prior to approval of a clinical trial. For approved clinical trials, a change to the sponsor or legal representative requires the submission of a substantial amendment.

For further information, please see the [Brexit Guidance for Stakeholders](#) on the HPRA website.

- Investigational medicinal products: In accordance with article 31(1) of Directive 2001/20/EC the site of EEA importation of investigational medicinal products (IMP) must hold a manufacturing authorisation which permits this activity. This authorisation is required if any aspect of the manufacture or packaging of the product is conducted outside the EEA.

Article 13(2) of Directive 2001/20/EC requires the manufacturing authorisation holder to have, permanently at their disposal, the services of at least one qualified person located within the EEA.

As per article 11(2) of Directive 2003/94/EC mandatory retesting of IMPs, manufactured in third countries, upon importation into the EEA is not required.

Therefore, in the event of a 'disorderly' Brexit, post March 29 2019, all ongoing clinical trials with IMPs sourced from the UK will need to be imported into the EEA by an appropriately authorised site. Mandatory testing of the IMPD will not be required but QP certification (from a QP at the EEA site of importation) that the manufacturing standards comply with EU GMP standards will be needed.

If a UK site is currently approved for batch certification the CT application form will need to be amended to notify the HPRA of both the EEA site of importation and site of batch certification. One bulk substantial

amendment can be submitted which includes a line listing of all the CTs that are affected. Rather than submitting an updated application form for each product, the HPRA will accept the amended section (section D.9) of the application form and apply this change to all the CTs affected. A fee will apply for each CT substantial amendment required. The UK site of importation can remain listed on the Irish application form as long as it is clearly designated as the site for importation of IMP batches intended for the UK.

For further information, please see the [Brexit Guidance for Stakeholders](#) on the HPRA website.

European commission notice to stakeholders [Withdrawal of the United Kingdom and EU rules in the field of clinical trials](#)

Where these requirements may jeopardize supply to clinical trial sites in Ireland, we would ask that your company considers proactively discussing in confidence any potential implications with the HPRA, in order to fully explore all available options.

Type IA annual reporting of variations

The HPRA would like to remind Marketing Authorisation Holders (MAHs) that Type IA variations are considered minor variations that have no or minimal impact on the quality, safety or efficacy of the medicinal product. Type IA variations which do not require approval prior to implementation, should be submitted to the HPRA within 12 months following implementation ("do and tell"). The HPRA would like to encourage MAHs to use the "do and tell" approach where possible.

For further information, please see the [CMDh](#) and [CMDv](#) Best Practice Guides (BPGs) for the Submission and Processing of Variations in the Mutual Recognition Procedure for information.

MAH contact details

At this time, swift communication with all applicants and existing MAH Holders is particularly critical. To that end the HPRA would request that you ensure that the appropriate regulatory contacts are captured within your application forms. Alternatively, please complete the form provided on the HPRA website at the link below with your most up to date contact information: [Regulatory Affairs Contact Information form](#).

Brexit related changes to authorisations

MAHs are reminded that any changes to marketing authorisations required as a result of Brexit (changes to site of batch release, QPPV, transfers etc) should be submitted as soon as possible. The HPRA will endeavour to process all applications submitted in a timely manner, however, given that there are likely to be large numbers of such applications, it will not be possible to prioritise all of them and applications will be processed on a FIFO basis.

HPRA contact details

For human medicinal products, general queries in relation to Brexit should be sent to the following e-mail address article50changes@HPRA.ie

For veterinary medicinal products, general queries in relation to Brexit should be sent to the following e-mail address vetinfo@hpra.ie

Further details on how you can contact the HPRA can be found on our [website](#)

Queries to Receipt Validation section

Queries for the Receipt and Validation section are sent to submissions@hpra.ie. This mailbox is available to applicants who have any queries in relation to the receipt or validation of an application. This mailbox is closely monitored. However, a high volume of emails and requests are received daily. All emails are responded to on a first in first out (FIFO) basis.

The HPRA is committed to providing a high level of service and conscious of the impact that Brexit has on our stakeholders. In order to ensure we utilise our resources to best effect to serve your needs, before following up in relation to your query, please check the guidance provided in your acknowledgement email and allow the Receipt and Validation section at least five working days to respond. Also, please provide CESP, product and procedure numbers where possible.



Rialtas na hÉireann
Government of Ireland

Safety Features

Safety features: Batch-specific requests update

On the **9 February 2019**, the Commission Delegated Regulation (EU) 2016/161, that supplements Directive 2001/83/EC, with detailed rules for the safety features appearing on the packaging of medicinal products for human use will come into force in Ireland.

Batch-specific requests (BSRs) may be considered for medicines for the Irish market that come within the scope of the regulation but do not bear safety features (UI and ATD).

As part of any batch-specific request to certify batches without safety features, the MAH should provide the following details:

- Principal reason for non-adherence to the delegated regulation timeframe
- Information on whether one or both elements of the safety features are absent from the packs
- Batch number(s) included under the proposed BSR

- Time limit requested by the BSR for QP certification purposes
- Confirmation that BSR relates to absence of safety feature(s) only

In addition, the MAH must provide assurance on the following points:

- Safety features have been registered with the HPRA - this may be completed via a simultaneous Article 61(3) notification

- All efforts to ensure that serialisation of subsequent batches intended for the Irish market will be undertaken
- Registration by the MAH with the Irish Medicines Verification Organisation (IMVO) and registration by the MAH on-boarding partner (OBP) has been completed.

Please refer to [the HPR website](#) and HPR [Guide to Batch-Specific Requests for Human Medicines](#) for further information on BSRs.

Please refer to the [HPR website](#) and HPR [Safety Feature for Medicinal Products for Human Use Product Information FAQs](#) for further

information on the [Commission Delegated Regulation \(EU\) 2016/161](#) and safety feature registration and implementation.

Safety Features and Articles 23: Update for Wholesale Distributors

Safety features will become obligatory in Ireland and in the majority of EEA countries (with the exception of Italy and Greece) from 9 February 2019. In effect, this means that a Qualified Person (QP) certifying batches of medicinal products for human use that are within the scope of the Commission Delegated Regulation (EU) 2016/161, for these markets, on or after 9 February 2019, must ensure that the packs bear the 2D unique identifier and anti-tampering device and that the batch data have been uploaded to the EU central repository. The safety features requirements apply almost exclusively to prescription only medicines but there are a small number of exceptions. Further details on products impacted are included under Annexes 1 and 2 (the 'white' and 'black' lists) of the Delegated Regulation (EU) 2016/161.

Wholesalers must be able to verify the safety features present on such packs from 9 February 2019. From that date, wholesalers which physically handle medicinal products bearing safety features must be connected to the national repository managed by the Irish Medicines Verification Organisation (IMVO). In order to do this, wholesalers must have the necessary software, scanners and procedures in place to perform these tasks.

Article 23 Update

The Department of Health has confirmed that the totality of Article 23 of the Delegated Regulation will be transposed into national legislation in advance of 9 February 2019. This means that wholesalers will be obliged to verify and decommision the unique identifier on all packs bearing the safety features prior to supplying them to customers which fall under categories (a)-(k) of this Article

(see article 23 text below for ease of reference).

In relation to the customers that may fall under Article 23(a), the Delegated Regulation defines a healthcare institution in Article 3 as 'a hospital, in- or outpatient clinic or health centre'. The national legislation will further define 'in- or outpatient clinic' and 'health centre' as follows:

- 'In or out-patient clinic' means an in or out-patient/day patient clinic under the management or control of a hospital.
- 'health centre' means a health centre under the management or control of a hospital.

In summary, this means that wholesalers will be required to verify and decommision packs of medicinal products bearing safety features before these are supplied to:

- in respect of category (a), entities authorised or entitled to supply medicinal products to the public which are NOT, a 'hospital' or an 'in- or outpatient/day patient clinic' or 'health centre', under the management or control of a hospital. This includes, for example, general practitioner (GP) surgeries;
- all those entities listed in (b)-(k). 'Hospitals' and 'in- or outpatient/day patient clinics' and 'health centres' under the management or control of a hospital, will be required to verify and decommision packs of medicinal products onsite prior to dispensing/administration.

Each wholesaler involved is advised to review its customer database as soon as possible in order to identify each customer in relation to which it will be necessary to verify and decommision packs of a medicine bearing the safety features before supplying that medicine to the customer.

If you have any queries, please email compliance@hpra.ie.

Article 23 (of Commission Delegated Regulation 2016/161)

Provisions to accommodate specific characteristics of Member States' supply chains

Member States may require, where necessary to accommodate the particular characteristics of the supply chain on their territory, that a wholesaler verifies the safety features and decommisions the unique identifier of a medicinal product before he supplies that medicinal product to any of the following persons or institutions:

- persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
- veterinarians and retailers of veterinary medicinal products;
- dental practitioners;
- optometrists and opticians;
- paramedics and emergency medical practitioners;
- armed forces, police and other governmental institutions maintaining stocks of medicinal products for the purposes of civil protection and disaster control;
- universities and other higher education establishments using medicinal products for the purposes of research and education, with the exceptions of healthcare institutions;
- prisons;
- schools;
- hospices;
- nursing homes.

Safety Features: Update for Manufacturers and Marketing Authorisation Holders

Manufacturers should work closely with Marketing Authorisation Holders to ensure that all relevant information on unique identifiers has been uploaded to the repositories system before they release medicines for sale or distribution (Article 33(2) of Commission Delegated Regulation (EU) 2016/161).

Manufacturers should also check that the 2D barcode is readable and contains the correct information as required by Article 14 of Commission Delegated Regulation (EU) 2016/161.

Medicinal products bearing safety features, and released for sale prior to the 9 February 2019, should have their unique identifiers uploaded to the repositories system before the entry into force of the new rules on 9 February 2019. This will prevent the generation of alerts in the repositories system for genuine products released before 9 February due to missing data in the system.

The Commission Delegated Regulation (EU) 2016/161 requires that medicinal products bearing EU safety features do not have any other visible 2D

barcode on their packaging that may be required by other jurisdictions for the purpose of identification and verification. Therefore, medicinal products imported into the EU should only bear one unique identifier that complies with the specifications of EU legislation. A written notification/letter has been provided by the European Commission and may be used by Manufacturers and Marketing Authorisation Holders to request an exemption from the Indian traceability system. A copy of this letter can be requested from the HPRA at the following email address:

compliance@hpra.ie

Human Medicines

Notification of marketing status for traditional herbal medicinal products (THMPs)

The HPRA would like to remind all traditional registration holders (TRHs) that a notification of the marketing status of each THMP must be provided to the HPRA. In line with S.I. No. 540 of 2007, the Medicinal Products (Control of Placing on the Market) Regulations 2007, the TRH must notify the HPRA of the date that the product was placed on the market.

In addition the TRH must notify the HPRA no less than two months in advance of a cessation of marketing, either temporary or permanent. Where marketing is temporarily interrupted, the TRH must notify the HPRA of the date that marketing resumes.

Notifications of marketing status should be made using the form [Notification of](#)

[Marketing Status of Human Medicines](#) and should be submitted electronically to medstatus@hpra.ie.

For more information please see the current version of the [Guide to Notification of Marketing Status of Human Medicines](#) available on the HPRA website.

Appropriate use of the Common Technical Document format for herbal medicinal products

The HPRA would like to draw companies' attention to the EMA's recent second revision of the [Guideline on the use of the Common Technical Document \(CTD\)](#) format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 2). The document aims to provide guidance on how to present the application for registration of traditional herbal medicinal products (THMPs) in the Common Technical Document (CTD) format. Although the guideline refers to traditional herbal medicinal

products the principles are applicable to all herbal medicinal products.

In the context of module 3, information on both the herbal substance and the herbal preparation should be presented in each of the sections: 3.2.S.1 (General information), 3.2.S.2 (Manufacturer), 3.2.S.3 (Characterisation), 3.2.S.4 (Control of drug substance), 3.2.S.5 (Reference standards or materials), 3.2.S.6 (Container closure system) and 3.2.S.7 (Stability). This format should also be used when drawing up submissions for variations of THMPs.

The guideline has been expanded with the addition of Appendix 2. This is a mock-up of a THMP application which should be read in conjunction with the main text and the best practice guide contained in Appendix 1. The mock-up is to be taken as an example illustrating an appropriate level of detail and the preferred location for information on the herbal substance / preparation / product. This example is for illustration and explanation, the details are not exhaustive and should be tailored to the specific application as appropriate.

HPRA decision to classify and regulate Faecal Microbiota Transplant products as medicinal products

The HPRA has taken the decision to classify and regulate Faecal Microbiota Transplant products (FMT) as medicinal products. Regarding the use of FMT, there are currently no licensed medicinal products or approved indications. The HPRA is aware of clinical guidance issued by the National Committee for Clinical Effectiveness and the joint British Society of Gastroenterology and Healthcare Infection Society guidelines.^{1,2}

In the absence of a licensed medicinal product, FMT can be supplied as an Exempt Medicinal Product when supplied to the order of a registered doctor for use by their individual patients under their direct

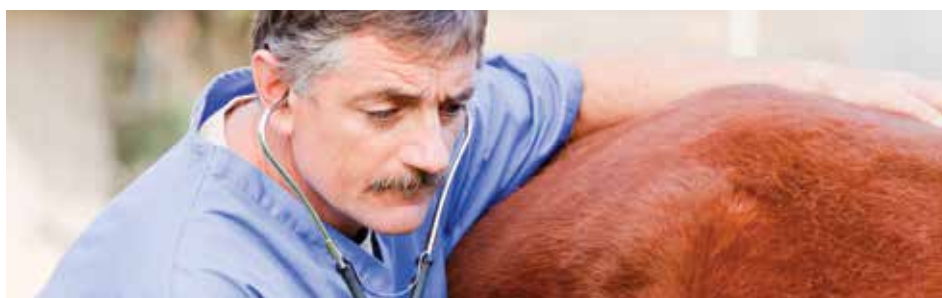
responsibility. Further information on regulatory requirements for manufacture, importation or supply of FMT can be found in the [Guide to the Notification System for Exempt Medicinal Products](#). Suspected adverse reactions can be reported to the HPRA or EudraVigilance.

FMT can also be supplied as an Investigational Medicinal Product, subject to assessment and approval of a clinical trial application. The HPRA recommends a pre-submission inquiry before submission of a clinical trial application. Further information can be found at [Clinical Trials Applications](#) on www.hpra.ie.

This decision was taken in context of the current information available in the relevant scientific fields, regulatory environments and without prejudice to evolving developments and future adaptations of the HPRA position on FMT medicinal products.

1. <https://health.gov.ie/wp-content/uploads/2015/01/National-Clinical-Guideline-No.-3-Clostridium-difficile.pdf>
2. <https://gut.bmj.com/content/67/11/1920>

Veterinary Medicines



New veterinary regulation

The new veterinary regulation (NVR) has been adopted by the EU Parliament and EU Council and was published on 7 January 2019. It will come into effect on 28 January 2019 and will be applied on 28 January 2022. The NVR will lead to a number of important changes in how applications for marketing authorisation are authorised and monitored, e.g. the requirement for periodic safety update reports will be abolished and replaced by monitoring of adverse event signals; there will be a change to the list of variations that require assessment and the scope of the centralised authorisation procedure will be expanded considerably. There are many other changes too, and readers are encouraged to consult

the document to understand its impact. Furthermore, a number of delegated and implementing acts are to be elaborated to augment specific areas, such as further new controls on antibiotics. Work on these acts is expected to begin shortly.

There is significant work needed to prepare for the implementation of the NVR and the HPRA will begin its preparations during 2019. We expect that complementary national legislation will also be needed to amend certain provisions of the existing national legislation, and this will be undertaken by the Department of Agriculture, Food and the Marine.

Booking slots as Reference Member State

Currently, the HPRA has a busy order book regarding requests to act as Reference Member State (RMS) for new decentralised procedures and mutual recognition procedures. Our availability to act as RMS is published on our [website](#). We are grateful for the support of marketing authorisation holders in choosing the HPRA as RMS. However, we would urge that if a choice is made not to go forward with a proposed application slot the MAH notifies us as soon as possible, so that we may use the available resource capacity effectively and offer the slot to another applicant. Please notify us if you have changed your plans in respect of any application in the order book (contact vetinfo@hpra.ie).

Periodic Safety Update Reports for veterinary medicines

From the beginning of 2019, Marketing Authorisation Holders (MAHs) are kindly requested to submit Periodic Safety Update Reports (PSURs) for non-centrally authorised veterinary medicinal products directly to the Receipts and Validation department of the HPRA. The preferred method of submission is via CESP, or alternatively via electronic submission (i.e. Eudralink) to submissions@hpra.ie.

In order to minimise administrative burden for both the HPRA and MAHs, please note that for PSURs for products authorised purely nationally, the HPRA will no longer be issuing communications regarding the outcome of assessment of these PSURs, unless there are specific issues or follow-up action(s) that need to be brought to the attention of the MAH.

Any questions relating to the processing of PSURs for veterinary medicinal products may be sent to vetsafety@hpra.ie

Personnel changes

Please note the following recent changes in personnel. The Veterinary Sciences department welcomes Ms. Laura McCarthy, an additional administrative officer to support the planning and authorisation team, Ms. Orla Ní Dhubhda who has joined the HPRA as a scientific officer in pharmacovigilance and Ms. Aoife Lordan who has joined the pharmaceutical assessment team as a scientific officer. We wish Ms. Lisa Woods and Ms. Estefania Perez, who have both left the department all the best in their future careers. The up-to-date organogram of personnel in the Veterinary Sciences Department is available on the [HPRA website](#).

Compliance

Certificate of a Pharmaceutical Product (CPP) - Notice regarding discontinuation of the Product Specific Details (PSD) for a marketing authorisation

In July 2018, the [HPRA announced](#) that it would be transitioning to a new electronic workflow system for human medicines which was subsequently implemented as of 26 July 2018. One of the changes resulting from this is that the Product Specific Details (PSD) section of the marketing authorisation, which details composition and manufacturing sites, is no longer included. Therefore, section 2A.4

of the Certificate of Pharmaceutical Product (CPP) will no longer be applicable.

Applicants for CPPs are reminded that they can continue to include a Composition document, which can be appended to the CPP for the medicinal product listed. However, as before, this must be strictly in accordance with the approved composition for the product

as detailed in the HPRA database. This will apply to both Human Medicines as well as Veterinary Medicines authorised by the HPRA.

An amended draft CPP template will be published shortly on the HPRA website noting this change and should be used for all future CPP applications.

Introduction of new variation process for investigational medicinal product manufacturer's / importer's authorisation (IMP MIA) manufacturer's / importer's authorisation (IMP MIA)

The HPRA is currently implementing a new variation process applicable to IMP MIAs in order to reduce the regulatory burden. A new 'immediate notification' variation process for IMP MIA holders can be utilised for variations related to EU/EEA based contract manufacturing

sites (listed in Annex 3 to the MIA) and contract laboratories (listed in Annex 4 to the MIA). This new process means that no prior approval is necessary and enables IMP MIA holders to commence proposed activities after submission of the variation application. Additionally,

all variations of this type will be subject to a reduced fee. IMP MIA holders will receive a notification relating to the go live date for this new variation process, which is anticipated to be in January 2019.

Upcoming revision of guide to new applications and variations to manufacturer's / importer's authorisation (MIA)

The HPRA is in the process of revising the guide to new applications for and variations to manufacturer's / importer's authorisation (MIA) (AUT-G0140). The guidance is being revised to streamline the application processes for MIA applicants/holders by providing additional clarification regarding the requirements for naming of contract manufacturers (listed in Annex 3), contract laboratories (listed in Annex 4) and listing of imported products (Annex 8) in MIAs. Details of the new immediate notification variation process for investigational medicinal product (IMP) MIAs will also be included in the updated guidance document. The revised guidance will be published within the coming weeks on our website www.hpra.ie and a notification will be received by subscribers.

Sampling and Analysis Programme: Dealing with out-of-specification test results – A message for marketing authorisation holders

The Market Compliance section of the HPRA runs a risk-based national surveillance programme for human and veterinary medicines which focusses on patient and animal health protection. The programme monitors the quality of medicines on the Irish market as well as those manufactured in Ireland for export. This programme gives effect to national and EU legislation for the independent surveillance of medicines and their active substances. The analytical testing is performed at an Official Medicines Control Laboratory located within Ireland or within the European Economic Area (EEA).

Products selected for surveillance work are prioritised using a risk ranking tool. Testing includes physico-chemical, microbiological and biological analyses. The programme also includes product usability and packaging and labelling checks. Samples are taken from manufacturers, wholesalers and pharmacies, without payment, and an official HPRA receipt is provided.

Products selected for laboratory analysis are normally tested using company methods. Should the HPRA contact you to request the test methods and other items needed for analysis of your product, please ensure the following are provided:

- The release and shelf-life specifications for the product;
- The current analytical test methods used by the QC laboratory – these are needed as they often contain additional information on the analysis that will not be detailed in the marketing authorisation dossier for the product.

Note that other documents, such as, certificates of analysis or product stability data, may also be requested by the HPRA.

Following completion of the laboratory testing, if an out-of-specification (OOS) test result is confirmed, our Sampling and Analysis team will inform you, the MAH, via email of the result. This email will ask you to do certain things, for example:

- To provide a comment on the OOS result.
- To initiate a manufacturing investigation into the issue – this will need to include a review of the batch manufacturing record, relevant deviations, change controls, the test data for the batch, and any similar OOS (or out of trend) results for the batch.
- To test a retained reference sample of the batch.
- To test a marketplace sample.

In other instances, our Sampling and Analysis team may contact you to follow-up on issues that may have arisen during the analytical testing, such as test method deficiencies, problems with the reference standard, etc.

On receipt of such emails from the HPRA, please provide the requested information within the timeframe specified. If delays are expected, or further investigation is required, please keep our Sampling and Analysis team updated and provide interim investigation reports as required.

For further information please refer to <https://www.hpra.ie/homepage/medicines/quality-information/sampling-and-analysis> or contact samplingandanalysis@hpra.ie

For further information visit www.hpra.ie

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