HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Provision of Clinical Advice to the HPRA

Call for Expressions of Interest

An opportunity for clinical experts to participate in the regulatory evaluation and assessment of medicines and medical devices

Expressions of interest requested by
30 September 2022

Provision of Clinical Advice to the HPRA
Call for Expressions of Interest

The Health Products Regulatory Authority (HPRA) is inviting applications from clinical experts who would be willing to provide clinical expertise to assist the HPRA when making decisions in relation to the efficacy and safety of medicines and medical devices. Collaborating with external clinical experts, including doctors, pharmacists and other healthcare professionals, is an important part of how the HPRA ensures public health is protected.

As well as being responsible for the regulation of medicines and medical devices at a national level, the HPRA plays a prominent role in the European network. We have a very close and strong working relationship with European authorities such as the European Medicines Agency (EMA), as well as our national counterparts in other EU member states.

We contribute to and regularly take a lead role in the assessment of applications to market innovative medicines that offer new treatment options for patients, contribute to safety reviews of products authorised for use in Europe, as well as providing scientific advice in relation to novel medicines currently under development, and assessing applications for clinical trials.

We also carefully monitor the use of medicines and medical devices on the market to quickly identify, evaluate and appropriately respond to any emerging quality or safety concerns.

To support this work and ensure that our decision-making takes into account current clinical practice, we are seeking to recruit experts in a number of clinical areas to join our panel of external experts and provide advice to the HPRA as required.

Why join the HPRA's panel of external clinical experts?

- Contribute to ensuring that health products are safe and effective for patients.
- Gain an insight into the development of innovative health products.
- Develop a greater understanding of how health products are regulated nationally and in Europe.
- Contribute clinical expertise to benefit-risk determination for medicines and clinical trials.
- Potential to participate in European authorisation processes.
- Enhance your professional and personal development.

In which areas is the HPRA seeking clinical expertise?

- Oncology and Haematology
- Cardiovascular, Endocrinology, Renal, Respiratory
- Gastroenterology, Rheumatology, Immunology, Dermatology
- Neurology, Pain and Psychiatry
- Infectious Diseases
- Ophthalmology
- Paediatrics and Geriatrics
- Clinical Pharmacology
- Diagnostic & Therapeutic Radiopharmaceuticals

What role does a clinical expert have in the work of the HPRA?

We value the expertise of clinical specialists in Ireland and recognise the beneficial role their contribution adds to regulatory evaluation and assessment of health products.

External clinical input is beneficial in the following circumstances:

- When the HPRA is lead European member state reviewing an application submitted to the EMA to market a new medicine for the first time in Europe;
- European Scientific Advice providing advice on the development of novel medicines, where the HPRA has taken a lead role;
- National applications to market medicines in Ireland;
- Clinical trials for medicines or clinical investigations for medical devices;
- Review of safety concerns regarding medicines or medical devices on the Irish market;

The type of input sought from external clinical experts could include:

- Contextualisation of the current treatment landscape, including where unmet need exists;
- Clinical importance and relevance of clinical trial endpoints used to support marketing authorisations;
- Information on how safety and tolerability compare to current standard of care;
- Opinion as to whether the overall benefit-risk is acceptable from a clinical perspective;

We recognise the nature of clinical work and any clinical expert involvement would be contingent on an expert's availability, with no expectation or defined minimum commitment.

We are involved in assessment of diverse medicines and medical devices across the spectrum of clinical specialities, thus individual expert involvement is expected to be infrequent and will depend on the particular product type being assessed, expertise being sought or clinical issues that emerge in a national/EU context. However, proactively becoming an external clinical expert will ensure that the HPRA can contact the relevant professional expert if advice specific to their clinical expertise is required. We will keep experts informed on relevant national and EU regulatory news and any training or research collaborations that may be available.

What qualifications and experience are needed to apply?

Experts expressing their interest in joining the HPRA's panel of external clinical experts should have the following qualifications and experience:

Essential

- Be a healthcare professional registered in Ireland or another EU/EEA country with their professional and regulatory body.
- Be a recognised expert as demonstrated by clinical experience, research and publication in their chosen field.
- Have clinical expertise in one of the clinical areas listed (see page 3) above or a related area.

Desirable

- Previous advisory experience including membership of advisory boards, expert societies, consensus guideline groups or Drug and Therapeutic boards.

How do I apply?

Clinical experts who meet the eligibility criteria are invited to submit an expression of interest to join the HPRA's panel of external experts by email to scientificaffairs@hpra.ie

Each application must include:

- A cover email stating the expert's area(s) of clinical expertise from the list above, highlighting relevant qualifications and experience and outlining their interest in providing clinical expertise to the HPRA;
- A curriculum vitae (CV) clearly listing all relevant educational qualifications and professional experience.

Expressions of interest should be submitted by 30 September 2022. The evaluation of expressions of interests will be based on the cover email, the expert's CV and the criteria listed in the Qualifications and Experience section above. Selected experts will be notified and their appointment to the panel of experts will be confirmed following completion and review of a declaration of interests and confidentiality undertaking.

Any queries in relation to the eligibility criteria or application process can be sent to scientificaffairs@hpra.ie

Although the HPRA is not in a position to offer payment to external clinical experts for providing advice, in the event that expenses are incurred (e.g. related to attendance at meetings), reasonable and receipted expenses directly associated with the HPRA's work will be reimbursed. In addition, experts will be recognised and acknowledged for their contribution and may be invited to attend HPRA meetings or training events, which may be eligible for recognition for Continuing Professional Development (CPD) points. The HPRA can provide confirmation of attendance and other evidence to support CPD applications.

Potential Conflicts of Interest and Confidentiality

Given the nature of the HPRA's regulatory functions, particular care is necessary in relation to potential conflicts of interest in relation to entities regulated by the HPRA. All experts will be required to complete a declaration of interests prior to providing any advice to the HPRA. Any interests declared will be evaluated and any potential conflicts will be addressed in advance of requesting any advice to ensure that the impartiality of the HPRA's decision making is maintained. Further information in relation to the types of interests to be declared and how such interests will be addressed is available in the HPRA's Conflicts of Interest Policy.

The HPRA deals with highly confidential matters including identifiable details pertaining to healthcare professionals, patients and commercially sensitive information. Experts will be required to sign a confidentiality undertaking prior to joining the HPRA's panel of external experts, and renew the undertaking annually.

Data Privacy Statement

All personal data provided by applicants will be processed in compliance with data protection legislation. Personal data will be processed in order to select candidates with appropriate experience and knowledge for appointment as clinical experts.

The legal basis for processing personal data for public interest/official authority is Article 6(1)(e) of the General Data Protection Regulation (GDPR), which states: Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

Your information will not be shared outside of the HPRA. In the event that your application is successful and you are added to the HPRA's panel of external experts, your application details will be retained. Details from any unsuccessful applications will be deleted within 3 months.

Please see the HPRA data protection notice for experts for additional information on how to contact the HPRA if you have queries regarding data protection and how your data will be used if your application is successful. Further information on data protection can also be found on the HPRA website.

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Health Products Regulatory Authority

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