HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA INNOVATION OFFICE

Supporting innovation through regulation and science

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The HPRA's Innovation Office provides regulatory support and advice to individuals, academics, small and medium enterprises, pharmaceutical and medical device companies, and other groups who are developing innovative health products or technologies.

What types of innovation are supported?

Innovation will typically involve the development of a novel concept, idea or approach into a prototype, product or technology that offers real and practical benefits for patients, health providers or the life sciences sector.

Innovation could include:

- new treatments for use in conditions where there are currently no or limited treatment options;
- innovative types of products such as vaccines, advanced therapy medicinal products (which can be based on genes, cells or tissues) or novel medical devices;
- targeted-drug delivery systems aimed at maximising efficacy or minimising adverse effects such as antibody-drug conjugates;

- new technologies or approaches for the manufacture or testing of medicines or devices such as nanotechnology and continuous manufacturing;
- new diagnostics using novel or established technologies;
- novel formulations for cosmetic products.

What kind of support and advice is available?

- The Innovation Office can advise individuals or companies directly on regulatory requirements and provide general guidance on technical or scientific issues that they need to consider during the development of their product or technology.
- Queries can relate to any area regulated by the HPRA including medicines, medical devices, drug-device combination products and cosmetics.
- Where more detailed scientific advice would be appropriate, the Innovation Office will provide information on how such advice can be obtained.
- The Innovation Office will also publish general updates and information about regulatory and scientific issues related to innovation.

Anyone developing an innovative product or process can submit a query to the HPRA's Innovation Office.

At what stage of development is support available?

The Innovation Office can provide regulatory support from an early stage in the development of an innovative product or technology including:

- initial research and design;
- formulation;
- pre-clinical testing;
- clinical studies;
- manufacture;
- post-approval research and monitoring.

How do I submit a query to the HPRA?

- Anyone developing an innovative product or process can submit a query to the HPRA.
- Our Innovation Office will act as an initial point of contact for such queries and requests for advice in relation to innovative health products or technologies.
- Queries should be submitted using our online enquiry form. This is available via the Innovation Office webpage which can be accessed through our website **www.hpra.ie**
- Alternatively you can e-mail us at **innovationoffice@hpra.ie**
- We aim to respond to all queries as soon as possible and within 20 working days. If a longer review period is necessary, we will contact you to inform you of the expected timeline for responding.
- All queries will be treated as confidential.

Supporting innovation – A strategic priority for the HPRA

Supporting innovation is a key strategic goal of the HPRA. This reflects both the high density of innovative companies across the life sciences sector in Ireland and the presence of an extensive research, development and innovation sector within academia and other areas.

Strong links between academia, industry and regulators will help to encourage and support innovation. Such interaction will support the research and development of innovative health products and technologies in the life sciences sector and ultimately will provide benefits to patients.

The HPRA is committed to providing regulatory advice and support to facilitate innovation within the following areas that we regulate:

- Human medicines
- Veterinary medicines
- Clinical trials
- Medical devices
- Blood and blood components
- Tissues and cells
- Cosmetic products

The HPRA has scientific and clinical expertise in all of the above areas and we also have access to other experts within the European regulatory network.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

We use our scientific and clinical expertise to review and monitor health products available in Ireland or exported abroad. Our aim is to make sure that the health products we regulate are as safe as possible and do what they are intended to do.

Further information

If you have any questions about the innovation supports available from the HPRA, please e-mail: **innovationoffice@hpra.ie**

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