Medicines & Healthcare products Regulatory Agency

Board Meeting

The MHRA's Innovation Office – update of MHRA's support for academics and SMEs developing innovative medicines and medical devices

16 December 2019

Issue/ Purpose: To provide an update on the work of the MHRA's Innovation Office
Summary: During 2019 the MHRA's Innovation Office has been targeting researchers developing innovative products and approaches to explain the various regulatory and scientific advice procedures that the MHRA can offer.
Resource implications: this work uses existing MHRA resource
Timings: on-going work
EU Referendum implications: n/a
Implications for patients and the public: The overall objective of the Innovation Office is to aid the introduction of innovative products and make them available to patients quickly and safely. The intention is to encourage early dialogue with researchers and companies to help clarify regulatory requirements
Action required by the Board: for information only
Links: n/a
Author(s): Julian Bonnerjea & Nathalie Gilmore
FOI/publication issues:
Which of the five themes in the Corporate Plan 2018/2023 does the paper support? 2a: We will support innovation and growth in Life Sciences
CET Sponsor: Dr Siu Ping Lam

Summary

The MHRA's Innovation Office is now established as a key source of regulatory advice to developers of novel medicines, medical devices and methods. The Office receives approx. 10 – 20 queries each month which are answered by telephone, email or at face-to-face meetings, depending on the complexity of the questions asked.

While the reactive response to queries remains the day-to-day work of the Office, the focus over the past year has been to engage with the research & development community to raise awareness of the Office, especially with academics and SMEs.

Background information

The MHRA's Innovation Office was introduced in March 2013 as a free service and it has been the centrepiece of the MHRA's support for developers of innovative products and services relating to both medicinal products and medical devices.

The Innovation Office provides regulatory advice to developers of these products and approaches who are often academics and SMEs and who are less likely to be familiar with regulatory affairs than large companies.

To date the Office has answered over 900 queries and held over 150 meetings, and this service is run in tandem with the MHRA's more formal Scientific Advice service.

The Office has no dedicated staff but utilises the expertise that exists throughout the Agency. One staff member organises both the Agency's Innovation Office and the Scientific Advice service, and answers the less complex regulatory queries and liaises with experts to provide answers to complex queries.

All enquirers are now requested to quote the Innovation Office reference number for any future communications with the MHRA for that product, be it scientific advice, clinical trial advice or applications for clinical trials, medicinal products or medical devices. This will allow us to monitor and track the translation of the product into new authorised products, processes and facilities and give us a better understanding of the success of the Innovation Office.

The Innovation Office also works with the MHRA's Horizon Scanning Working Group to identify emerging trends. This enables the Agency to prepare itself to regulate emerging technologies where necessary and to identify areas where new guidance is required.

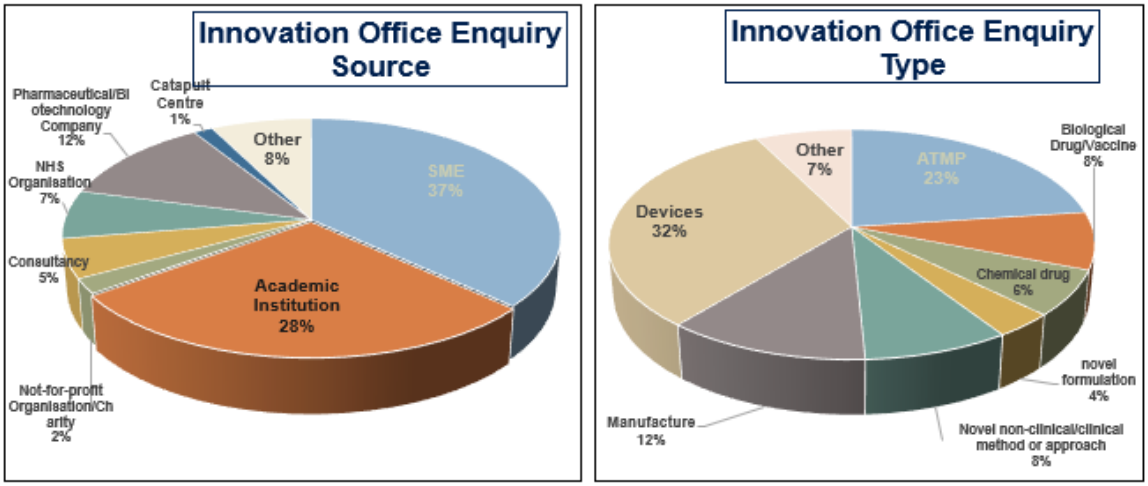
Brief History of the Innovation Office

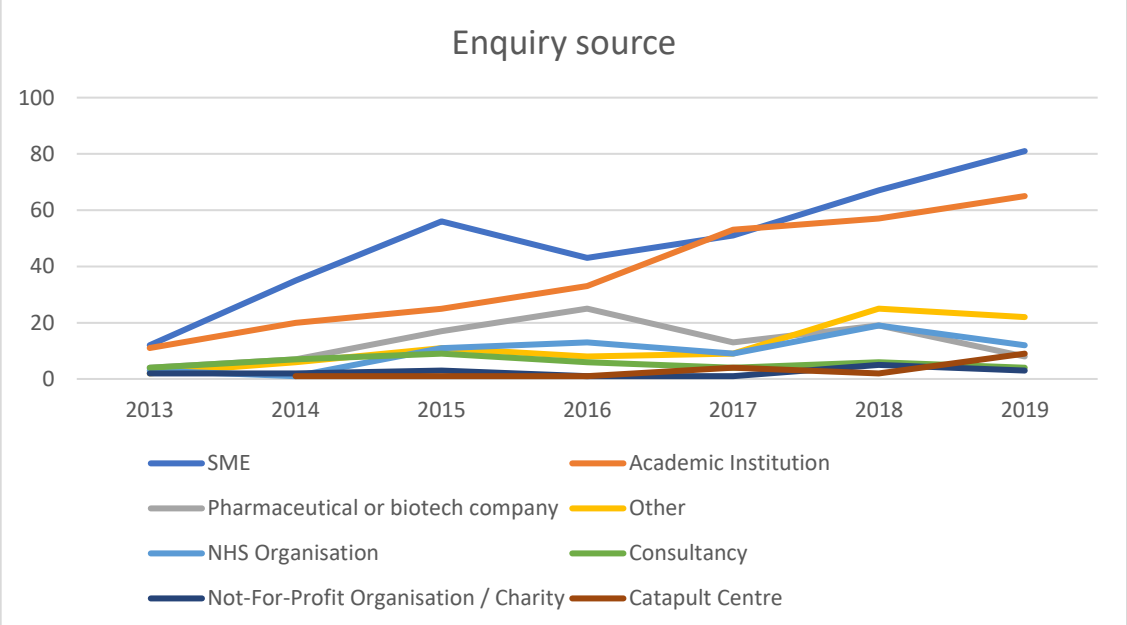
2013:	The MHRA introduced the Innovation Office
2014:	The MHRA, HTA, HFEA and HRA introduce the RASRM (Regulatory Advice Service for Regenerative Medicine) or 'one-stop shop' to answer queries concerning the regulation of Advanced Therapies
2015:	DEFRA & HSE join the IO / RASRM
2016:	NICE joins the IO / RASRM
2018:	IO built links with medical research funders (e.g. Wellcome Trust, Research Councils, Innovate UK, Cancer Research UK, British Heart

	Foundation, Duchenne UK, NIHR, medical research charities, etc)
2018:	IO built links with NHS Academic Health Science Networks (AHSN).
2019	IO built links with academic researchers e.g. Oxford Bioescalator event (April 2019), and Manchester University event (December 2019)
2019:	MHRA selected to lead on ICMRA Innovation Network document on regulatory issues associated with genome editing products and to contribute to the network's document on regulatory issues associated with the microbiome

Brief Facts and Figures:

Innovation Office - enquiry types and users





Examples of topics covered by the Innovation Office

Discussions between the MHRA and companies / academics are confidential, although approx. 10 case studies have been published (with the companies' consent) to illustrate the wide variety of topics covered:
https://www.gov.uk/government/collections/mhra-innovation-case-studies

Typical queries may involve: Use of smartphones & software for medical purposes, e.g. diagnosis / patient monitoring / etc; Use of synthetic biomaterials in medical devices; Use of live micro-organisms as therapeutic products; Development of scaffolds for regenerative medicine; Cloud-based software for clinical research, Use of Real World Evidence in the licensing of medicines, etc.

Further examples include:

Vaccines

- novel delivery devices, including needle-free delivery
- design of vaccine manufacturing facilities, e.g. VMIC (Vaccines Manufacturing Innovation Centre at Harwell)
- platform technologies for vaccine manufacture
- synthetic vaccines
- formulations/stabilisers to eliminate cold-chain requirements
- toxicology programmes for vaccine Marketing Authorisation

Novel Clinical Trial Protocols:

- platform trial designs (e.g. to test multiple interventions, with interventions changing throughout the trial, e.g. to add or delete treatment arms early)
- umbrella trials (e.g. single disease, multiple targeted interventions)
- basket trials (e.g. testing an investigational drug in different populations

Areas of active discussion:

- Discussions on the use of 'Real World Evidence' in the licensing of medicines
- In-vitro safety testing methods

International activities

There is a forum of international regulators under the ICMRA umbrella (International Coalition of Medicines Regulatory Authorities) that the MHRA is a member of. ICMRA is a voluntary association of worldwide medicines regulatory authorities set up to provide strategic coordination, advocacy and leadership in regulatory science. Its members include the Chinese, Indian, Japanese, Swiss, US and many other European and non-European regulators.

During 2019 the MHRA led an ICMRA group that produced an agreed statement on Biosimilar products.

The Innovation Office is currently leading on a project initiated by the ICMRA Informal Innovation Network to produce a document on the key regulatory challenges associated with gene editing products. It is also participating in a parallel project to produce a document on the regulatory challenges associated with microbiome treatment. Experts from Licensing Division's Biologicals and Clinical Trials Units and IE&S are contributing to these projects. It is expected that both documents will be published in conjunction with the ICMRA conference in October 2020.

Communications Plan

A digital marketing campaign has been planned for early 2020 with the specific aim of promoting the Innovation Office to academic audiences using social media. Customer insight conducted by the Communications Division revealed that 55% of respondents reported finding out about the Innovation Office from the website, with 50% reporting that they found out by 'Word of Mouth'.

From December 2019 until the end of March 2020), the campaign aims to reach over 40,000 members of our target audience with refined messages about the MHRA Innovation Office, and drive approx. 5,000 unique visitors to the site, delivering c.40 additional, relevant queries.

We will do this by:

- Conducting 10-15 short, focused interviews with the target audience to develop our core messages and to inform our creative approach.
- Developing digital assets to effectively communicate these messages.
- Delivering a targeted digital marketing campaign that will utilise LinkedIn, Twitter, pay-per-click and direct email to reach our target audience.
- Evaluating success by running a short survey to assess changes in prompted awareness of the MHRA Innovation Office.

In addition, we will explore the opportunities available to us in developing a partnership marketing agreement with the Medicines Discovery Catapult (MDC), with a view to re-using our campaign assets in partner activities that extend the reach of our message through MDC communications channels.