



Medicines & Healthcare products Regulatory Agency

Board Meeting

MHRA's support for Innovation: update on the work of the Innovation Office

15 April 2019

<p><u>Issue/ Purpose:</u> To update the Board on the work of the Innovation Office</p>
<p><u>Summary:</u> The Innovation Office is now established as a key source of regulatory advice on novel medicines, medical devices and methods. The focus over the past year has been to raise awareness of the Office with academics and SMEs.</p>
<p><u>Resource implications:</u> Existing resource</p>
<p><u>EU Referendum implications:</u> n/a</p>
<p><u>Implications for patients and the public:</u> The overall objective of the Innovation Office is to aid the introduction of innovative products and make them available to patients quickly and safely</p>
<p><u>Timings:</u> On-going</p>
<p><u>Action required by Board:</u> For information</p>
<p><u>Links:</u> Innovation Office: https://www.gov.uk/government/groups/mhra-innovation-office Innovation Office case studies: https://www.gov.uk/government/groups/mhra-innovation-office#read-our-case-studies</p>
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Which of the 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 was introduced in March 2013 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 700 queries and held over 100 meetings, and this service is run in tandem with the MHRA's more formal Scientific advice service.

IO History

Some notable milestones

- March 2013: The MHRA's Innovation Office was introduced at the Agency Annual Lecture
- October 2014: The MHRA, HTA, HFEA and HRA introduced the RASRM (Regulatory Advice Service for Regenerative Medicine) or 'one-stop shop'
- December 2014: The first Innovation Office case study was published. 7 more case studies were published in the following year
- November 2015: DEFRA and HSE joined the RASRM to provide advice on genetically modified organisms
- August 2016: NICE joined the RASRM to provide advice on Health Technology assessment issues
- March 2018: Meeting held between MHRA's Innovation Office and key funders of UK medical research.
- October 2018: A survey was issued to all enquirers to capture the experience and perceptions of the Innovation Office service in order to inform future campaigns

Some facts and Figures:

Number of Enquiries

Annual queries received by IO



192 enquiries were submitted to the innovation office in 2018. Efforts to promote the IO service have translated into more enquiries being received. The average number of enquiries received in 2017 was 12 per month. This rose to an average of 16 enquiries per month in 2018.

Innovation Office Responses

Responses are primarily issued in a written, email format. If deemed necessary to explore the question in detail, a meeting or teleconference is held. Since 2017 around 25% of all enquiries required a meeting or teleconference.

Responses utilise the expertise throughout the agency, as necessary. Input from Licensing Division experts is required for the majority of enquiries, however around 50% of all enquiries require input from either the Devices or Inspection, Enforcement & Standards Divisions.

We now request all enquirers 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.

Regulatory Advice Service for Regenerative Medicines (RASRM)

Annual RASRM queries



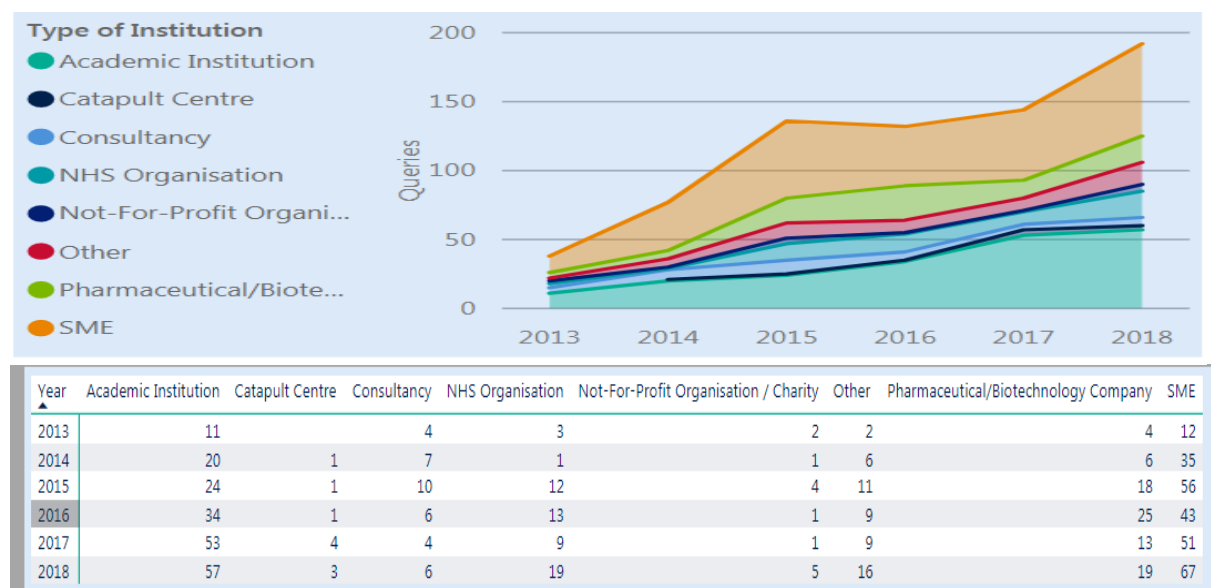
RASRM (joint advice with other regulators (HTA, HRA, HFEA, DEFRA, HSE and NICE) on Regenerative Medicines) remains an important service. The MHRA and HTA work closely together and the development of joint regulatory guidance is being

discussed. Work with HRA is also increasing. RASRM enquiries are issued more formally with the final PDF response sent to all RASRM members for reference.

Innovation Office Enquiry Source

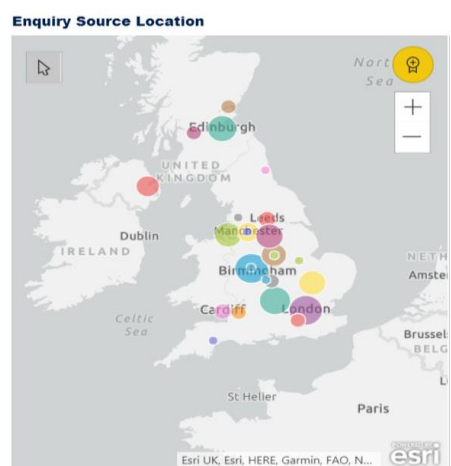
The Innovation Office receives enquiries from a wide range of organisations, suggesting that knowledge of the existence of the Office is spreading through the research community. Even though the focus of the Office was to provide informal advice to academics and SMEs, there is no restriction placed on who can submit queries, with enquiries being also received from NHS organisations, not-for-profit organisations, catapult centres and larger pharmaceutical/ biotechnology companies. Balance is maintained with all organisations in order to engage sufficiently closely to understand issues and provide timely advice but with the avoidance of any conflicts.

Innovation Office Enquiry Source



This data shows the trends of enquiry source. In general, there is an upward trend from all enquiry sources. However, notably more enquiries were received from academic institutions, SMEs and NHS organisations (affiliated with academic institutions) in 2018.

Geographical distribution of IO enquiries from academic institutions



There is a small increase in enquiries from academic institutions in 2018. Analysis on the source of enquiries from academic institutions show that certain universities are repeat users. For example, University College London was the top enquirer with 32 enquiries in 2018.

International activities

There is a wider forum of international regulators under the ICMRA umbrella (International Coalition of Medicines Regulatory Authorities) that the MHRA is a member of and chairs. 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 National Medical Products Administration (formerly China Food and Drug Administration), the FDA, Japan's Pharmaceuticals and Medical Devices Agency, Swissmedic, the Indian Ministry of Health and Family Welfare, and many other European and non-European regulators. The Innovation Office is participating in an ICMRA workstream that aims to identify critical product and technology innovation which will benefit from or require regulatory science-based approaches in terms of future regulation. The UK Innovation Office contributed to case studies on genome editing, included in the innovation strategic priority project report finalised in January 2019. These activities are co-ordinated with the MHRA's input to the ICMRA workstream on Horizon Scanning.

The MHRA's Innovation Office has also been active in the EU-Innovation Network which arranges participation in the Horizon 2020 'Coordination and Support Action on Training Academy in Regulatory Science' (CSA-TARS).

Strengthening collaborations with academia

- 1) In March 2018, a meeting was held between MHRA's Innovation Office and key funders of UK medical research (Wellcome Trust, Medical Research Council, Innovate UK, Cancer Research UK, British Heart Foundation, Duchenne UK, UK Stem Cell Foundation, National Institute for Health Research, Association of medical research charities). The goal was to highlight the work of the Innovation Office and explore ongoing working relationships.
- 2) Wellcome Trust (April 2018) - Following on from the meeting with academic funders we have followed up with the Wellcome Trust to expand on the work of the Innovation Office.
- 3) Health Systems Partnerships at the Medical Research Council which is part of UK Research and Innovation (May 2018) – a meeting was held to discuss the work of the Innovation Office.
- 4) The increase in enquiries from NHS organisations (affiliated with academic institutions) may be explained by our efforts to promote the Innovation Office at Academic Health Science Networks (AHSN). AHSN's were set up by NHS England to operate as the key innovation arm of the NHS. They work in partnership to identify, develop, adopt and spread new products and services and focus of needs of patients and local populations. These are the only

bodies that connect NHS and academic organisations, local authorities and industry to identify and spread health innovation. Each regional AHSN works within its own area to develop projects, programmes and initiatives that reflect the diversity of the local population and healthcare challenges. The previous report alluded to initial to strengthen collaborations with academia. We have built on that and focussed much attention to building on these contacts in AHSNs, by engaging with and presenting at:

- 5)
 - a) Academic Health Science Networks, Chief Executives meeting (July 2018). We presented at their Chief Executives meeting that included all regional AHSNs to promote the MHRA Innovation Office and Scientific Advice Services.
 - b) UCL Partners Academic Health Science Partnership - UCL Partners initiated contact at the AHSN meeting to discuss the work of the Innovation Office. We plan to meet with them shortly.
 - c) MedCity (presentation, December 2018). Medcity was launched in April 2014 to promote and grow the life sciences cluster of England's Greater South East. It facilitates and supports collaboration across all parts of the sector to turn innovations into commercial products and services and works with the region as academic, research and NHS institutions as well as local enterprise partnerships. MedCity was founded by King's Health Partners, Imperial College Academic Health Science Centre and UCL Partners, thus strengthening our collaboration with these academic institutions.
- 6) Developed engagement with London Advanced Therapies at Kings' College London, promoting the services of both the Innovation Office and Scientific Advice Service (February 2018).
- 7) BioEscalator - is a hub for new and developing life science innovations at the University of Oxford – We will be presenting at an outreach event in April 2019 to highlight the services of the Innovation Office.

Over the next year we will continue to focus on promoting our services to the health science networks and academic institutions to increase awareness of the Innovation Office within the research community who in turn can pass on information on the services offered by the Innovation Office to their researchers.

Analysis of enquiries from academic institutions show that the majority of enquiries (32) have come from University College London. Eight enquiries were received from Oxford University and 7 from Cambridge University and 4 each from Imperial College London and Kings College London. These are well known/large research centres excelling in innovative research and focus in the next year will be on promoting the Innovation Office and Scientific Advice Service to these institutions as well as other academic institutions and innovation centres around the UK.

Communications Plan

A survey was issued to all enquirers in October 2018 to capture the experience and perceptions of the Innovation Office service in order to inform future campaign planning. Customer feedback on survey suggests that the majority of respondents

state that 'access to free and expert advice' was the principal advantage of the service. Second only to the MHRA website, a large proportion of the respondents cite 'word of mouth' as a main source when it came to finding out about the Innovation Office (including being told by named current and former staff).

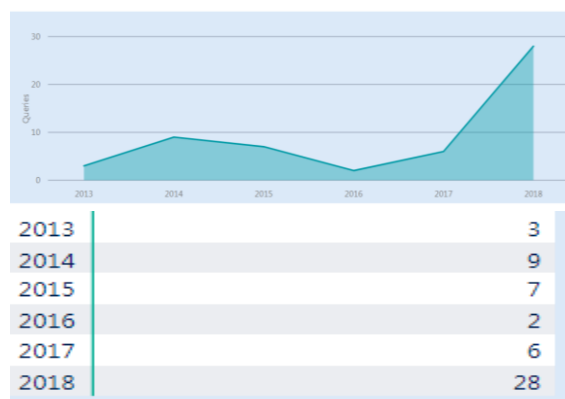
- Insight from survey:
 - 92% found the service 'very' or 'extremely' useful
 - 79% found the main advantage being 'free and expert advice'
 - 71% said it saved project time; 36% said it saved project money

A digital marketing campaign is planned for the next financial year with the specific aim to promote the Innovation Office to academic audiences.

Trends in Technology Area

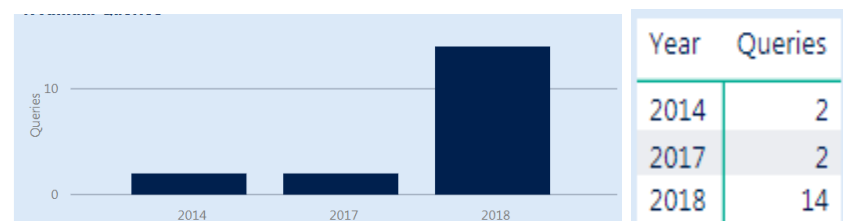
The Innovation Office analyses the data that is captured about historical (and future) queries and searches for trends in all technology areas. The idea is that this can formalise routine queries in guidance that can then be used as promotional 'hooks' for engaging and informing audiences. The benefits are that audiences can quickly access guidance that could answer their query or help them focus their query, so that they get the best out of the Office.

Software/apps



Guidance on software/apps was first published on the MHRA website in 2014. This correlates with a decline in enquiries about software/apps. In the past year enquiries on this technology type has increased significantly. This guidance has now been updated in June 2018.

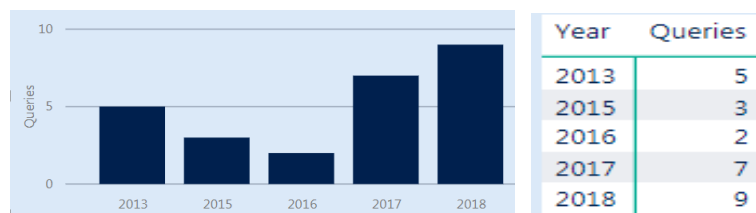
Artificial Intelligence



Queries on the use of artificial intelligence has increased greatly in 2018. This includes novel software solutions for use in clinical trials as well as use in healthcare

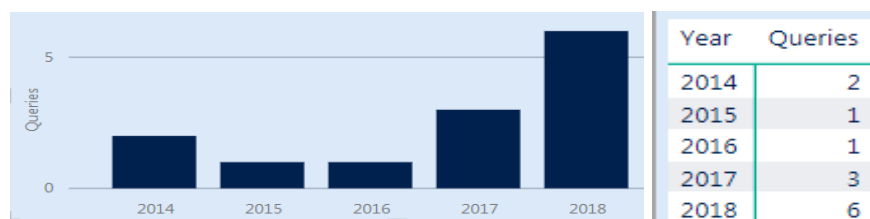
applications to monitor the progression and identify treatment options for a range of medical conditions.

Vaccines



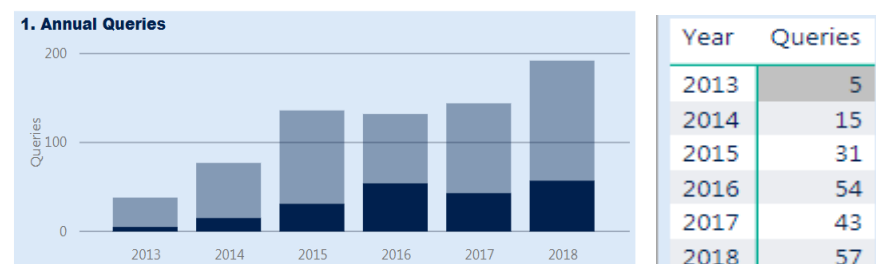
Enquiries regarding vaccines seem to be on the increase. Already in 2019, we have received about 20% of total enquiries received in 2018.

3D Printing



Since 2017 there has been an increase in enquiries about 3D printing (or 'additive manufacturing') in medicine manufacturing. There is a growing demand for customised pharmaceuticals and medical devices especially in areas of niche and personalised medicines.

Advanced Therapy Medicinal Products (ATMP)



ATMP queries have been stable for the last 3 years at about 20-30% of all enquiries. Advanced Therapies require different methods of manufacturing and delivery to patients. This, coupled with advancements in technologies such as 3D printing, mean that an effective framework to ensure the safety of these products will be essential. As set out in the UK Life Sciences Industrial Strategy Sector Deal 2, the MHRA has been awarded a grant to develop a framework for point-of-care manufacture.

The MHRA Innovation Office is also looking to develop global recognition and recently met with Massachusetts Institute of Technology (MIT) to discuss novel approaches to regulation.

The Innovation Office also works with the Horizon Scanning Working Group to identify any emerging trends. This approach helps to consolidate the view that the Innovation Office acts proactively to support innovation in medicines and medical devices.