Medicines and Healthcare products Regulatory Agency
Board meeting

11 April 2016

Title: Review of the MHRA's Innovation office

Issue/purpose:
The purpose of this paper is to review the operation of the MHRA's Innovation Office since its introduction in March 2013, and recommend improvements.

Summary/Key points: The Innovation Office was introduced as one aspect of the MHRA's response to the government's life science agenda. It is a free service that has been operating successfully for the last 3 years. It has answered > 250 regulatory queries and held > 40 meetings, mainly with academics and SMEs. This has been achieved without any specific resource. It is recommended that the MHRA builds on this success by adopting a more proactive approach and strengthening the running of the Innovation Office, which would be aligned with and operated alongside the MHRA's scientific advice service and linking up early information exchange with the Horizon Scanning Group..

Timings: introduction of recommendations during Q2 2016

Action required: agree to the further development of the Innovation Office as set out in the recommendations

Links: This links to the many other procedures that the MHRA has to provide regulatory and scientific advice, e.g. Regulatory Information Service, Customer Helpline, Clinical Trials Helpline, Scientific Advice, Borderline queries portal, etc. This also links to the MHRA's Horizon Scanning activities with a 2 way flow information.

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FOI/publication issues: none

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MHRA's Innovation Office– 30 months review – December 2015

Summary
The MHRA's Innovation Office is a virtual office that was introduced in 2013 to engage with developers of innovative medicines and medical devices and to provide regulatory advice. While the MHRA has always provided advice to the developers of innovative products and services (with around 300 scientific advice meetings per year in the regulatory centre, as well as the regulatory information service, clinical trials helpline etc), the introduction of the Innovation Office was intended to provide a clear portal for such queries and to highlight the support available from the MHRA.

To date, the Innovation Office has received approximately 250 queries and held over 40 meeting with enquirers. As anticipated, the majority of the enquiries have come from academics and SMEs who were identified as the two groups most likely to need regulatory advice.

In 2014 the Innovation Office expanded its work to collaborate with three other UK regulatory bodies (the Human Tissue Authority, the Human Fertilisation and Embryology Authority and the Health Research Authority) to provide a 'one-stop shop' for regulatory advice on Regenerative Medicines. To date approx. 14 such combined regulatory advice queries have been received.

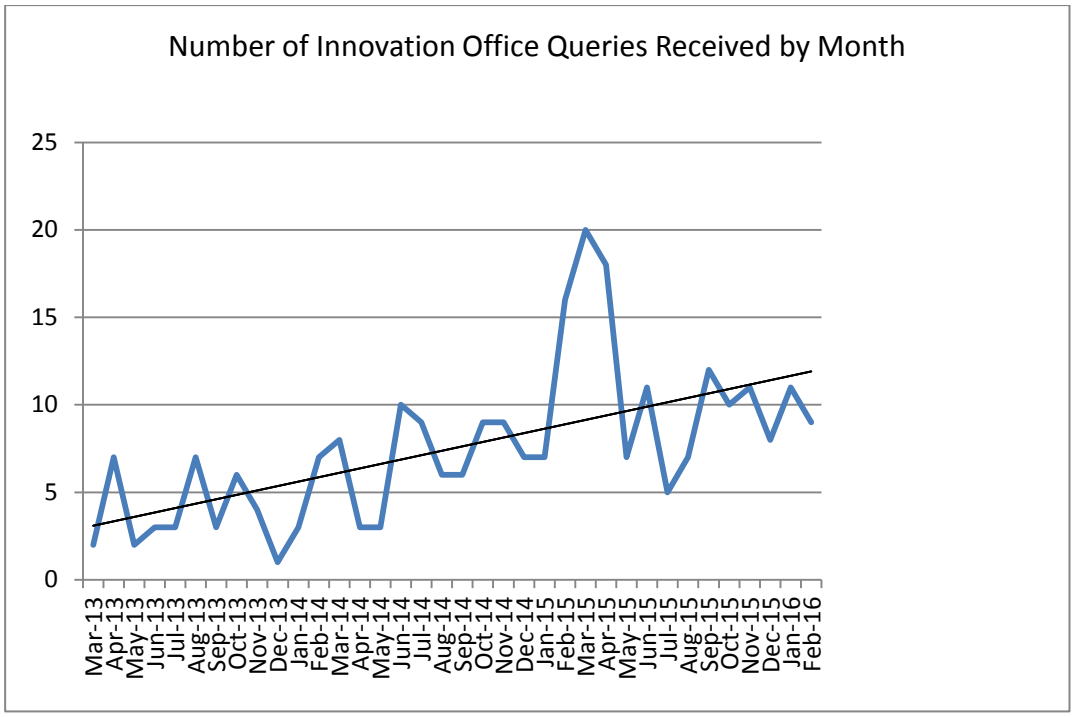
Eight case studies illustrating the varied work of the Agency in supporting innovation via the Innovation Office have been published and more are planned.

Although it has clearly had a successful first two and a half years, the Innovation Office could do more to enhance its support for developers of innovative products and services if further resources were available. Proactive engagement with developers could be considered, e.g. via university translational offices and science hubs, to explain the service that the Innovation Office provides. Integration of the various different MHRA advice procedures would also clarify what support is available and how to access them.

Review of 2.5 years of operation

The Innovation Office was launched at the MHRA's Annual Lecture in March 2013. The Office was set up to offer free regulatory advice on both medicines and medical devices to developers of innovative products (and to developers using innovative approaches, such as novel clinical trial designs, novel manufacturing operations, etc.). The Office does not have dedicated staff but calls upon experts from all areas of the agency to answer queries.

To date 250 queries have been received via a web-based portal and there has been a gradual increase in the number of queries received each month. This increase in the number of enquiries is considered a measure of short-term success.

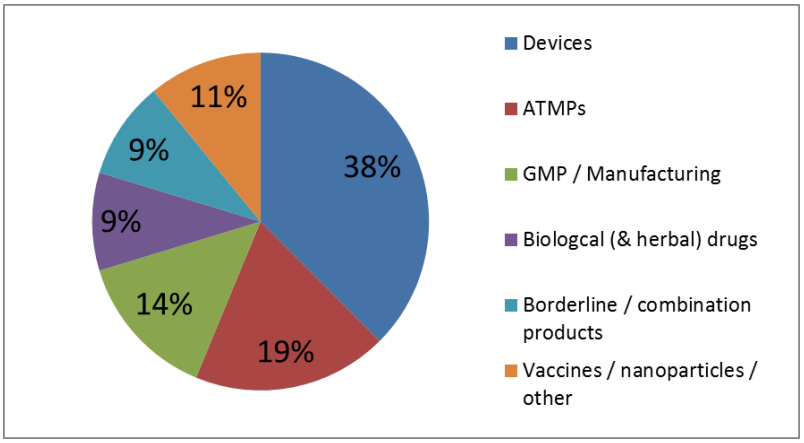


In round figures 50% of the queries have related to medicines and 40% to medical devices with another 10% relating to combination or borderline products. Most simple queries are answered by email; more complex queries are discussed at face-to-face meetings (to date there have been 40 such advice meetings). The Inspectorate, Enforcement and Standards Division in particular have had a number of meetings with enquirers on the design of manufacturing facilities and these have been greatly appreciated.
Only regulatory advice and high level scientific advice is provided which are appropriate for the majority of enquiries which are at early stages of development; enquirers are redirected to the (chargeable) scientific advice procedure where that is more relevant.

The Innovation Office queries have covered a very wide range of topics, from simple classification queries (e.g. when is software considered as a medical device?) to complex legal / regulatory questions (e.g. on re-purposing of established medical products by 3rd parties). Of the medical device queries, a common theme has been the use of smart phones for diagnosis, patient monitoring, etc., although the number of such queries has decreased since the publication of MHRA guidance on stand-alone software: http://www.mhra.gov.uk/Howweregulate/Devices/Software/index.htm).

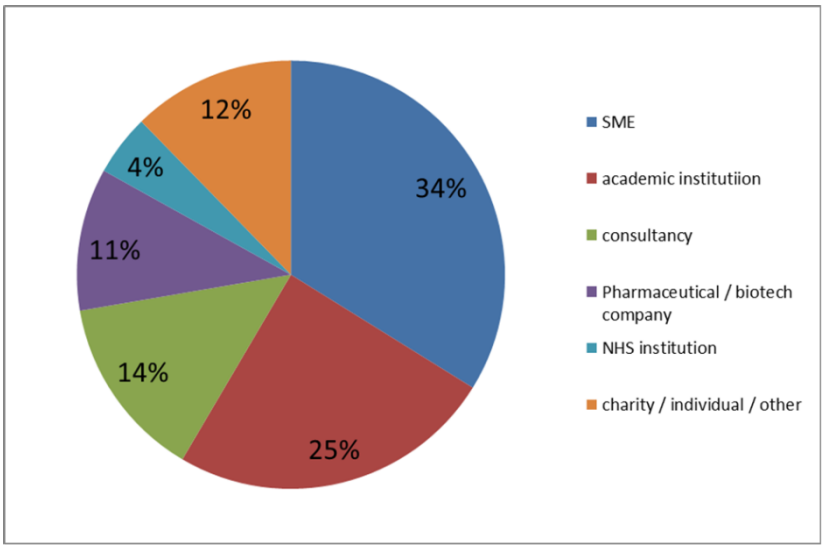
Of the medicines queries, no single topic stands out, although questions on several aspect of Advanced Therapies have been submitted (e.g. on the design of ATMP manufacturing facilities, scope of the 'Specials' and Hospital Exemption schemes, CE marking of scaffolds for regenerative medicines, etc.).

Innovation Office queries by type:



Although the Innovation Office is open to all, it was set up with the intention of providing assistance to companies and individuals who may not have access to regulatory expertise. It has been successful in this regard, with SMEs and academics being the two main categories of users.

Innovation Office queries by organisation:



It may be difficult to measure the success or effectiveness of the Innovation Office with any given scale, since the advice given to “innovators or developers” at the early stage of product development means that a successful product may not be available until years later. Moreover, companies may not and often do not wish to share their confidential information publically for understandable reasons. However, we have been able to showcase some of our success stories. Eight case studies have recently been published to highlight the MHRA’s support for innovation https://www.gov.uk/government/groups/mhra-innovation-office#case-studies Together with colleagues from our Communication Division, we will continue to publicise the success of the Innovation Office via such case studies**.**

The Innovation Office was expanded in 2014 to introduce a “one-stop shop” for regulatory advice on Regenerative Medicine, now called the Regulatory Advice Service for Regenerative Medicine - RASRM (it was decided to use the term ‘Regenerative Medicine’

instead of the more precise term 'Advanced Therapies' as it is more widely used by the target audience). Four organisations (HTA, HFEA, HRA and MHRA) are co-operating to provide advice on Regenerative Medicines and the MHRA's Innovation Office web portal has been chosen to be the single entry point for any such query. Further links have been established with the Health and Safety Executive and DEFRA for enquiries on genetically modified organisms.

The RASRM has been extensively publicised at various ATMP conferences and meetings and has received 14 such combined queries, the majority of which have been for the MHRA and the HTA.

A satisfaction survey sent out after the Innovation had been in operation for one year, had a poor response rate (<20%), so although the responses were generally positive, the results were not particularly informative. Anecdotal evidence is that enquirers are appreciative of the response they get, e.g. (a) "*I would like to thank you again, we really enjoyed meeting you all, and thought the meeting was of great benefit to us*" and (b) *"The advice was very useful and really helped us gain confidence in our plans but also allowed us to address areas of concern before we progress to the full design".*

Symposium on support for Innovative Medicines
At the end of November 2015 the MHRA hosted a symposium for 90 delegates to highlight the advice and support available for innovative projects and also to outline specific topics such as genomics, drug/device combinations, and changes to clinical trials legislation. Feedback from delegates is that they symposium was very useful and it has signposted more specific areas for more focussed future symposia.

Interaction with EMA Innovation Task Force (ITF) and other innovation offices
MHRA is one of a network of member state innovation offices fostered by the EMA with objectives broadly similar to our own. We have actively participated in the network telecom meetings, contributed experts to advise on product-specific enquiries coming to the EMA ITF and presented on the achievements of our innovation office at the first face-to-face meeting of the network in Helsinki in November 2015. MHRA has also authored a reflection paper on regulatory gaps on the drug/device borderline; this has been discussed by the network and will be considered by HMA in due course.

Recommendations

1. The Innovation Office was established with a reactive remit, answering queries submitted to it via an internet portal. It is recommended that a more pro-active approach is adopted in the future, for example by visiting university technology transfer offices, academic hubs, medical charity organisations, etc. to inform them of the various ways that the MHRA supports innovation and can offer advice.
2. The MHRA is already an active contributor to the EU Innovation Network, the informal group of EU Innovation Offices co-ordinated by EMA. It is recommended that the MHRA continue to be a major contributor to this network and to participate in the EMA's innovation task force advice meetings which coordinate the availability of early regulatory support.

3. It is recommended that the MHRA internal procedures concerned with supporting innovation are refreshed, e.g.

    a. Whilst the administration of the Innovation Office sits within Licensing Division, the answers to queries are provided by staff from all different parts of the agency. It is recommended that a virtual team be set up with individuals identified from each of

the agency's Divisions or areas of operation (as appropriate). These people would be the designated points of contact for that area and would be responsible for directing queries and information to the relevant experts, and arranging participation in internal and external meetings as appropriate.

b. It is recognised that the Innovation Office is only one of the many ways in which the MHRA supports innovation. It is recommended that a system is introduced to track and to integrate the many different MHRA advice mechanisms that the Agency uses to support innovation, e.g. the scientific and regulatory advice meetings, the support provided to engineers designing manufacturing facilities, the CTU helpline, etc. This would allow the agency to coordinate the advice provided by different parts of the agency and also to track the overall resource being allocated to support innovation.

c. Once the post of Horizon Scanning lead is filled, it recommended that the existing links between the HS group and the Innovation Office be strengthened to enhance the flow of information in both directions. Innovation Office 'signals' are already fed into the horizon scanning group, and the HS reports can be used as an early signal for novel developments and identify challenges for the current development paradigm and the current regulatory frameworks.

To date the Innovation Office has operated without any dedicated resource. To allow the Innovation Office to continue to expand and to implement the recommendations in this report, there will be an administrative resource requirement that will be the subject of a future business case.

Finally it is recommended that a brief review of the 'refreshed' Innovation Office is carried one year after these changes are implemented to include the results of a more systematic review of feedback from users.