

A closer look at the MHRA

An interview with Prof Kent Woods, Chief Executive of the Medicines and Healthcare products Regulatory Agency (MHRA), focusing on the workings of the Agency, its role in the European and global regulatory arena, and its future directions. The interview was conducted by Sarah Roberts, Senior Director Regulatory Affairs, Celerion



Q How did your career lead to your current role at the MHRA?

A I came in by a slightly roundabout route. Before I came to work at the MHRA, I had spent 20 years working as a clinical academic. I was Professor of Therapeutics at Leicester University, where a lot of my time was spent in clinical practice in cardiology. Gradually, over several years, I began doing more work for the Department of Health. First, I was Regional Director of Research and Development on a part-time basis and then during my tenure as national Director for Health Technology Assessment (HTA), I was asked if the role at the MHRA would be of any interest to me. I am a trained clinical pharmacologist and so this area was indeed of interest to me, so much so that I gave up clinical practice to make the move across.

Q What does your day-to-day work involve?

A It's very varied, in fact, extremely varied. No day is typical. For example, this week I have just come back from two days of interesting discussions with the other EU Heads of Agencies and the European Commission. I have various meetings in my diary with industry associations and ministers at the Department of Health. There are the normal day-to-day administrative tasks associated with the Chief Executive role such as the formal or informal executive board meeting every week. The variety in the job reflects the external landscape. Our external stakeholders are very diverse, such as UK and EU government bodies, the healthcare community, the research community, industry, innovators, the patients and the wider public – they all have an interest in what we do. So we have a very broad range of external connections which drives the agenda.

Q Does the recent UK government election result change the role of the MHRA in any way?

A Of course, we have a new set of ministers and the essence of it is that everyone in this building is a civil servant with a responsibility to serve ministers. It is very important that we understand what the policy priorities are for the new government. We also need to develop good working relationships with the ministers as quickly as possible, so we can understand what their priorities are, and how we can help them deliver those priorities. Often, a great deal depends on personal relationships and mutual understanding. It is quite a challenge when the government changes – not in a formal sense, in

that our jobs do not change, the Agency continues doing its business, but in quite complicated ways. We have to orientate our thinking to make sure we understand and align with what this democratically elected government is trying to do, for instance in regulatory policy and the efficiency agenda.

Q Is it likely that recent cuts in funding to the public sector in the UK will have an impact on the MHRA?

A I think we are protected to a significant extent but it is very much under discussion at the current time. There are two points to consider here: firstly, it is only a small minority of our income that comes from the taxpayer, although there is the recognition that every part of the public sector has to be conscious of efficiency and good value for whatever it delivers. As an agency we have been focusing on this for several years now and we have our own programme of efficiencies which should align very well with what is happening in the rest of the civil service. It may be that we are outside direct across-the-board restrictions and reductions being put in place in some government departments, but that does not mean that we should not look hard at efficiencies. Secondly, the questions we need to ask ourselves are: what is it we must do as an agency? What are the priorities? How can we achieve our priorities in the best way? It is a good discipline for us as an organisation, as although we have a considerable degree of autonomy, we need to think in the public sector sense: 'Are we doing the right things?' and 'Could we do the same for less?'

Q What are the most important changes/results you have achieved so far at the MHRA?

A The Agency has gone through an evolution. When I first arrived, the MHRA was digesting the merger between the Medicines Control Agency and the Medical Devices Agency, and there were some challenging organisational issues we had to overcome. The biggest achievement has been the completion of the complex and ambitious IT development at the MHRA. I think we have IT which is as good as, or better than, any agency in the world. IT has transformed our business as we are now a paperless organisation. Even my desk is quite clear of paper. Since the IT deployment, we have managed to crank up the Agency's efficiencies in the way we operate. This year we effectively completed clearing out the backlogs which had been a source of dissatisfaction for some time. We are through that now

and I think the organisation is delivering on its obligations well, and I am very pleased with that. Another success is the establishment of a communications function which allows us to explain ourselves, what we do and how we do it, in ways we could not do before. It really was surprising to me when I joined the Agency that there was no dedicated structure for this within the MHRA. We did it, but we now have a dedicated communications team and with that a press office, and the opportunity to explain ourselves to the outside world both proactively and reactively. Now, if a problem crops up we can explain what the facts are and what we are going to do about it, and allow healthcare professionals and patients access to the best risk–benefit information we can get hold of. I see that as a major part of regulation. Most of our work is ensuring that the best risk–benefit information is available, which is why communication is so central. I could talk about our international role, but for me the three key successes are the operational (IT), structural (integration) and new communication accomplishments.

Q The MHRA is moving offices soon. Could you tell us a bit more about the move and any transition plans that will be put in place?

A Yes, we are moving to offices adjacent to Victoria Station in London. The move is planned for October and the current plan is to phase the move over the course of a month. There is a lot of ongoing preparatory work. The most important enabler is IT, as we are all converting to laptops which will allow staff, in principle, to leave this building and set up immediately in the new building. This is not something we could have even considered if we were not a paperless organisation. We think we have done everything we can to ensure a smooth transition and we do not expect any functional disruption to doing business.

Regulators have been working in our current building since 1980, firstly as the Medicines Division of the Department of Health, then the Medicines Control Agency and now the MHRA. The lease finally runs out next year. In office terms, it is quite an old building. The choice was between refurbishing our current office, which would be very disruptive, assuming we could renegotiate the lease, or bite the bullet and move to more modern accommodation. The layout of the new building is much more suited for our operations. At the moment, the departments of the MHRA are scattered across the 21 floors of Market Towers and this does not lend itself to good internal communication.

The move itself should not cause us to lose staff since the new office is only one-and-a-half miles away. The new building is slightly smaller, but we are going to be able to use space a lot more efficiently. We conducted some formal analyses which showed that a lot of the workspace in Market Towers is not used at any one time. The new building allows for more flexible, imaginative use of space – to accommodate the variety of meeting types and spaces for staff to be able to work effectively. It will be a totally different way of working.

Q Is the approach also utilised for work to support and audit local notified bodies?

A There has been a lot of discussion surrounding the recognition and auditing of notified bodies across Europe as we need to be consistent. A CE mark given at any European notified body can provide access to the UK market. Therefore, it is important that all notified bodies conform to a consistently high standard. We have been in discussion as how to best ensure that we can increase this

consistency. Each member state is responsible for auditing notified bodies in their country but there is active discussion on how we can harmonise better the standards of notified bodies.

Q What in the MHRA's view would be the best arrangement at a European level to deliver a robust and responsive regulatory framework for medical devices?

A Coordination is the key here. The way the medical device regulations are written gives direct responsibility to member states, as I mentioned in relation to auditing the notified bodies, but also with respect to the vigilance function and market surveillance. We do need to work on how we can best achieve consistency of standards in both of these areas. It does not require that we have a single European authority in order to achieve consistent European standards, providing that the member states cooperate effectively to achieve a greater degree of harmony. My own preference is towards the latter route through closer links between the competent authorities.

Q The FDA issues pod-casts with updates of regulations/news items – would the MHRA consider this mode of delivery and other social media platforms for updates to UK/EU legislation/guidance?

A We have taken a close interest in communication via social media and we are watching it carefully. Internally we use podcasts – we don't yet use them externally. We recently had a paper at an Agency Board Meeting where we systemically reviewed the different types of new media. We also carried out some internal pilot studies as to what we might do. We have yet to roll them out as it is unclear what the precise place for them will be. Our main thrust is developing and refining the website – automatic email links etc. We cannot ignore the fact that the communications world is changing quickly.

Q What is the status/outcome of the joint MHRA/NICE scientific advice meetings and when will the pilot conclude?

A It is early days and we have not had enough experience to say where the collaboration will go. We have had a number of expressions of interest but it is still unclear if this will become a major activity or for only a small number of applicants who may wish to take advantage of such parallel advice meetings.

Q Does the MHRA find it frustrating as regulators when a product is approved by the Agency but is then 'not approved' by NICE?

A I used to be the Director of the Health Technology Programme for the NHS, so I have seen this problem from both sides over many years. Regulatory decisions are based primarily on the medical risk–benefit profile for a definable patient group. If you are running a healthcare system, there is a quite separate question which is 'is that product going to deliver sufficient clinical benefit in relation to its cost?'. That will always be a decision that needs to be addressed by the healthcare provider. In the UK, 93 per cent of healthcare is delivered by the NHS, and NICE is an NHS organisation that advises the NHS in England about what it should be purchasing.

There is a logical separation of tasks which need to exist in any healthcare environment. While there may be some areas of

convergence where the HTA and the regulatory requirements can be more closely brought together, fundamentally at the end of the process the driving rationale for decisions made by each body are different.

Q Do you think the UK is an attractive place to conduct clinical research? There is a perception that the UK regulatory environment is much tougher than other countries and this is driving research away, are there any plans to help stop this?

A I have heard this for a while. It is complex, but an important question. My background is in clinical research in both multinational and single centre trials so I have seen the problems myself. We have to be careful to examine the evidence behind these assertions. There have been some problems with the changing set of regulatory requirements over the past ten years for both industry and academic researchers but we need to look more closely at the underlying issues. I co-chair with Prof. Janet Derbyshire a taskforce of the MHRA, Medical Research Council (MRC) and the Department of Health (DH), which has spent the past year looking at the real remaining obstacles to clinical trials research in the UK. We have gone a long way to disentangling the various factors. Since the implementation of the Clinical Trials Directive, the ethics approval process has been simplified to a single national ethical opinion given by a single ethics committee. The requirements of the regulator have changed and certainly academic researchers have found GCP and the Clinical Trial Authorisation processes unfamiliar and more burdensome. We have tried to simplify this as far as we possibly can within EU law. I think there is another set of factors in the way the NHS hosts trials. The complaints I hear from industry are about the long periods which elapse while they get approval of the protocol from the NHS trust(s) to host a study. This is outside our control, it is not a regulatory or ethics matter. The time it takes to recruit patients is another factor. To a large extent that is about having detailed knowledge of the clinical population of patients, which is sometimes missing from the NHS. The cost to recruit is high compared to some emerging markets. However, there is no one country that provides an ideal clinical trial environment.

The taskforce is looking to progressively identify the bottlenecks one by one and propose how they can be fixed. When the last bottleneck is fully resolved, I would expect a clear increase in the volume of clinical research in the UK. Our records show that the CTA approvals are flat; we are authorising the same number of studies as we were five years ago. Given the amount of investment in clinical research networks we should have had the increase by now and I am determined that we should do everything we can to make the UK an attractive place for clinical researchers.

Q Do you think it would it ever be possible to have bio-equivalence studies from a reputable company run in UK with EC approval only – we are losing our competitive edge compared to other countries based on the regulatory environment (especially if these studies can be run in the US without an IND or in Canada where for single dose bioequivalence studies only the Certificate of Analysis [not the full CMC] is required)?

A This is not a problem which is specific to the UK, we are working within the framework of European legislation. Where the risks of a trial are perceived to be low, there are arrangements to simplify

the amount of data needing to be brought forward to the Agency for CTA. A lot more could be done in Europe to risk-assess types of study to simplify the low risk end of the spectrum. As the Clinical Trials Directive is being reviewed, we should look towards risk-basing it so that it is not one size fits all, ie, a known compound in a straightforward study should require the minimum amount of data for the CTA.

Q What new initiatives/schemes/investments are the MHRA planning for in the future?

A The move is a big project for us. It is not just about a move to a different address but a substantial organisational development project – it's about the way we work, use space, use IT, use our time. Rolling out continual development of IT is important. We have made big investments in the past and will continue to invest in it (ie, online CTA submissions).

Those are the major capital programmes. As regards other initiatives, we are coming to the end of consolidating and reviewing all of the medicines legislation going back to the Medicines Act 1968 – to which approximately 80 pieces of secondary legislation have been added over the years. What we are doing is simplifying all that to a single, comprehensive, integrated legislative package to make it easier for people who need to comply with the regulations and therefore to know what they are.

Q Is the MHRA flexible enough to respond to new European level initiatives quickly?

A Yes. I think the MHRA has the required flexibility. I have recently been chairing a group of the Heads of Agencies in Europe developing the five-year strategy for the network. We did a thorough environmental analysis of the changes that will have an impact on us over the next five years including scientific and technical, trade, legislative, and social developments. I think the MHRA is very well placed to adapt and adopt as appropriate. We are looking at two, three and five year views of what the Agency should be doing.

The MHRA is simultaneously both a national (UK) agency and a European agency. There will always be a need for national agencies to perform certain tasks and for the Member State agencies to work together to perform tasks in other areas. For instance, communication to a local population about an issue comes best from the national agency concerned. Some other functions are more efficiently delivered at the European level. We are continually working to determine which model (national or European) is best placed to deliver specific tasks. This is a networked system unique to Europe; I am not aware of anything that is quite like the regulatory network that now exists in Europe.

Q Could you tell the readers something which they would not know about you?

A I am a thwarted sailor. I would love to do more sailing but I live in the part of England which is furthest from the sea and the times I get to go away and sail are vanishingly rare. It is something I would like to find more time for in the future.

Note: This article has been abridged due to space restrictions. To read the full interview please go to: <http://www.topra.org/useful-articles>