



Department
of Health

Annual Accountability Review 2015-16

Parliamentary Under Secretary of State for Health
and the Medicines & Healthcare products
Regulatory Agency

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Executive summary

This paper contains the minutes of Annual Accountability Review, held between the Parliamentary Under Secretary of State for Health and the Medicines and Healthcare products Regulatory Agency on the 20th October 2016.

1. Medicines and Healthcare products Regulatory Agency (MHRA) Annual Accountability Review - 20th October 2016

Present:

Lord Prior PS(H)	Parliamentary Under Secretary of State for Health
Prof Sir Michael Rawlins	Chair of MHRA
Dr Ian Hudson	Chief Executive of MHRA
Patience Wilson	Deputy Director Head of Corporate Strategy, Accountability and Partnership (MHRA)
Elizabeth Woodeson	Director of Medicines and Pharmacy Division - DH
Libby Green	Deputy Director – MPD (NICE and MHRA sponsorship) – DH
Christopher Juliff	

Review of progress in 2015/16

Dr Ian Hudson provided an overview of the achievements of MHRA over the past year. MHRA had been an important supporter of the cross-Whitehall innovation and growth agenda, contributing to the Accelerated Access Review and improving innovation initiatives, for instance, through the Early Access to Medicines Scheme. They had built closer and strong collaboration with the Department of Health and partners in the health and care system. They had taken a lead in digital devices and technology – including promoting the safe use of medical apps, exploring enhancements to the Yellow Card reporting mobile App, and using digital technologies to deliver cost-effective and smart services across the Agency that put the user first. MHRA had continued to grow the Clinical Practice Research Datalink (CPRD) and increased uptake of its services. They had strengthened the capabilities of the National Institute for Biological Standards and Control (NIBSC) to ensure it remained a global leader in standardisation and control of biological medicines.

MHRA had also been active internationally, working with partners to promote collaboration between regulators through harmonisation, reciprocal agreements and mutual reliance. They had signed a Memorandum of Understanding with the Indian Central Drugs Standard Control Organisation, to increase collaboration with the aim of further improving public safety in the two countries. MHRA had completed the development of fifteen World Health Organization international standards to underpin consistent manufacture and accurate measurement of biological medicine and diagnostics, including standards for Ebola and several other 'first in

class' materials. They had involvement in a number of high profile regulatory product issues for example, Ebola, Flumist, St John's Wort, Valproate, and Zika. Dr Ian Hudson had been elected chairman of the International Coalition of Medicines Regulatory Agencies – an organisation to bring authorities together to address common challenges.

Lord Prior congratulated the MHRA on a very productive year both domestically and internationally and passed on the positive feedback he had received about the abilities and professionalism of the agency.

Working relations with the European Medicines Agency (EMA)

Dr Ian Hudson set out the MHRA's close working relationship with the EMA. Involvement included: being a permanent member of the EMA Management Board; developing the EU Medicines Agencies Network Strategy to 2020; collaborating on EU laws and initiatives; working with EMA and its scientific committees including chairing 3 of the 5 scientific committees and leading on marketing authorisations within EU Member States; acting as rapporteurs/co-rapporteurs for 20 centralised procedures granted marketing authorisation in Europe; and leading 96 European Scientific advice meetings, shaping regulation and approvals across Europe.

Major Strategic challenges 2016-17 and beyond

Attendees discussed the major strategic challenges facing the MHRA. The foremost of these would be the implications for MHRA of the UK's exit from the European Union. In addition, the MHRA had a programme in place to ensure that they were delivering services as efficiently as possible as well as a plan to ensure they were continuing to play their part in securing the global supply chain of medicines. The MHRA continued to focus strongly on the innovation agenda, including: the Accelerated Access Review; continued involvement in international discussions on Anti-Microbial Resistance; continuing to engage with the Department and industry on repurposing of medicines for new uses. MHRA continued to support companies via the Innovation Office scientific advice service. They continued to anticipate trends in technology and product development to ensure the Agency was well-prepared to support the safe and effective development of new medicines and medical devices.

Brexit

There was a discussion on the implications of the UK's exit from the EU on the work of the MHRA and the future of medicines and medical devices regulation. The MHRA made clear that the UK remained an active member of EU regulatory networks until we left the EU. MHRA work with the EMA was highly valued. The MHRA was working closely with stakeholders, including industry, to fully consider all the options for regulation of medicines, devices and blood products following Brexit. Lord Prior was clear on the importance of future regulatory arrangements to the Life Science sector and to patients accessing safe and effective medicines and devices.

Any other business

No other business was raised.

Lord Prior concluded the meeting by reiterating his thanks for the MHRA's impressive performance over 2015/16.