



Department
of Health

Annual Accountability Review 2014-15

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

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Annual Accountability Review 2014-15

Medicines & Healthcare products Regulatory
Agency

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1. Executive Summary

This paper contains the minutes of the Annual Accountability Review, held between the Parliamentary Under Secretary of State for Life Sciences and the Medicines and Healthcare products Regulatory Agency on 9th September 2015.

2. Medicines & Healthcare products Regulatory Agency (MHRA) Annual Accountability Review – 9th September 2015

Present:

George Freeman PS(LS))	Parliamentary Under Secretary of State for Life Sciences
Dr Ian Hudson (IH)	Chief Executive of MHRA
Prof Sir Michael Rawlins (MR)	Chair of MHRA
Peter Commins (PC)	Finance Director of MHRA
Jonathan Mogford (JM)	Policy Director of MHRA
Will Cavendish (WC)	Director General – Innovation, Growth and Technology (IGT) – MHRA sponsor – DH
Liz Woodeson (LW)	Director - Medicines, Pharmacy and Industry (MPI) - DH
Nicole Mather (NM)	Director - Office of Life Sciences – DH/BIS
Claire Armstrong (CA)	Deputy Director – MPI (NICE and MHRA sponsorship) - DH

Review of Progress in 2014/15

Dr Ian Hudson gave an overview of the successes of MHRA over 2014/15 including the launch of the Early Access to Medicines Scheme, their rapid and flexible response to the Ebola crisis, their positive engagement with the Accelerated Access Review and Cabinet Office Triennial Reviews of MHRA, BPC (British Pharmacopeia Commission) and CHM (Commission on Human Medicines), their on-going work in support of the safety agenda such as extending the Yellow Card scheme and deploying safety officers in trusts, and significant strides in engagement both nationally and internationally. They have also celebrated two significant anniversaries, 150th of the British Pharmacopeia (BP) and 50th of the Yellow Card Scheme. PS(LS) acknowledged the critical role played by the MHRA both nationally and internationally such as in responding to the Ebola crisis, thanked Dr Ian Hudson and Prof Sir Michael Rawlins for the work the MHRA have done over the past year and their continued support of Government's ambitious Innovation and Growth agenda

Major Strategic Issues – 2015/16 and Beyond

Accelerated Access Review

PS (LS) thanked MHRA for their constructive engagement with the work of the Accelerated Access Review (AAR). NM thanked MHRA for seconding a member of their staff into the AAR team and for the expert input they are providing. The Minister asked the MHRA to bring radical proposals forward to help differentiate the UK in Europe.

NM also thanked MHRA for pushing forward data for research and flagged the importance to move fast and be ambitious in this domain.

Attendees discussed the need for the development of clearer guidance and case studies to illustrate the existing licensing flexibilities and support a strong UK offer in the domain of new technologies development; the response to Ebola was given as a good example that could be used. Attendees also spoke of the work going on in conjunction with NICE to provide joint scientific advice and the need to encourage take up of this.

Safety: improvements, innovations and digitisation

The opportunity for harnessing the power of digital eg real time data feed and links in support of the safety agenda was discussed. PS(LS) noted that the Yellow Card app launched in July had made a good start in terms of making real-time safety information available digitally, and welcome plans to extend the scheme to include devices and counterfeits. MHRA described how they are taking a more proactive approach to vigilance, for example through the Yellow Card app and deploying safety officers in trusts. Medical device safety was discussed and PS (LS) welcome and encourage MHRA's engagement with the Unique Device Identifiers developments (development of product safety recalls systems, possible link to patient records).

Europe and bio-economy

Attendees discussed making the UK more competitive in Europe, and the opportunities and challenges of convergence between foods/medicines (neutraceuticals), drugs/devices etc. and associated regulatory environment.

Vaccines

MHRA spoke of the work they had been doing on vaccines and how they maintain a close working relationship with DH, PHE and NHS England on those issues.

Any other business

No other business was raised

PS (LS) closed the meeting by reiterating his thanks to Dr Ian Hudson and Prof Sir Michael Rawlins for MHRA's on-going work in support of the Innovation and Growth agenda.