

## **Annual Accountability Review 2016-17**

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

#### **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 27<sup>th</sup> September 2017.

### **Medicines and Healthcare products Regulatory Agency (MHRA) Annual Accountability Review – 27 September 2017**

#### **Present:**

Lord O'Shaughnessy	Parliamentary Under Secretary of State for Health
Prof Sir Michael Rawlins	Chair of MHRA
Dr Ian Hudson	Chief Executive of MHRA
Jonathan Mogford	Director of Policy, MHRA
Carly McGurry	Deputy Director, Medicines Regulation and Prescribing, DH
Rebecca Diment	Head of MHRA sponsorship, DH
Alex McLaughlin	Senior Private Secretary to Lord O'Shaughnessy

#### **Review of progress in 2016/17**

Dr Ian Hudson provided an overview of the achievements of MHRA over the past year. MHRA had developed their links with wider aspects of the health and social care system. Their organisational transformation programme was progressing well, including the creation of an apprentice scheme.

MHRA had a successful year at the EU level, highlighting work on the implementation of Falsified Medicines Directive and Tobacco Products Directive, including 50,000 notifications on e-cigarettes and tobacco products.

MHRA had continued to take an active role within the international community, encouraging and promoting collaboration with other global regulators and sharing training and skills with other countries; MHRA signed further Memorandums of Understanding with the Swiss Regulator, Swissmedic.

MHRA had contributed to the Life Sciences Strategy, which has been positively received, and the Accelerated Access Review. Enquiries to the MHRA Innovation Office continue to increase and the

MHRA had provided scientific opinions on a number of medicines through the UK Early Access to Medicines Scheme.

Patient Safety and Vigilance is a critical pillar of the MHRA's work and the organisation had undertaken a major campaign on risks of fake medicines and medical devices. This included a story line on slimming pills in Coronation Street to increase public awareness. The organisation had also invited journalists on enforcement actions to further increase public awareness. During the year over £13m of potentially dangerous medical products had been seized.

The MHRA continued to grow its data and services operation through the Clinical Practice Research Datalink, with a significant increase in the numbers of GP practices agreeing to contribute anonymised patient data for use in public health research studies. The MHRA continued to be mindful of the recommendations from the Caldicott Review whilst building this database.

Lord O'Shaughnessy congratulated the MHRA for an impressive list of achievements and commented that he looked forward to working with the organisation and building further on their strengths.

## **MHRA and EU Exit**

There was a discussion on MHRA's on-going work to prepare for the UK's exit from the EU. The UK and the EU have a shared objective in the negotiations to protect the health of patients; and ensure safe and timely access to medicines and medical devices. Lord O'Shaughnessy recognised the progress MHRA had made in preparing for April 2019 and supported further collaboration with industry to consider all options for regulation of medicines and medical devices post EU Exit.

## **Cyber Security**

Dr Ian Hudson recognised the importance of MHRA remaining active on cyber security particularly in the wake of recent cyber-attacks. The MHRA had worked closely with NHS Digital and will continue to engage with specialists as needed.

## **Organisation Transformation**

There was a brief update on MHRA's change programme, Operational Transformation Programme. This will see the organisation move to Canary Wharf as well as an organisation wide IT upgrade.

## **International**

MHRA is working with the WHO and others to put in place a programme to help develop pharmacovigilance programmes in low and middle income countries

## **Any other business**

No other business was raised.

Lord O'Shaughnessy concluded the meeting by reiterating his thanks for the MHRA's hard work over 2016/17 and his enthusiasm to continue to work closely with them.