**Regulator: Medicines and Healthcare Products Regulatory Agency**

**Business Impact Target Reporting Period Covered: 13 December 2019 – 16 December 2020**

Measures certified as being below de minimis (measures with an EANDCB below +/- £5 million)

MHRA has worked closely with the Department of Health and Social Care (DHSC) and other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medicines and medical devices may be possible. This is with a view to supporting the healthcare products supply chain and wider response to the coronavirus (COVID-19) outbreak in the UK.

Guidance for industry on flexible approaches to regulation we are taking during the COVID-19 outbreak.https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19

On 16 April 2020, flexibility was allowed for dissemination of Direct Healthcare Professional Communications (DHPCs) via email rather than sending hard copies by post. Before this time, a Marketing Authorisation Holder or representative of a group of MAHs traditionally disseminated these letters by post.  Since April, we understand email-only or email/post-hybrid models have been used for 7 safety letters to healthcare professionals (up to 1 October). While the time and monetary resource gained would be a question for industry, we understand from feedback that an electronic option for these letters is preferred by both industry and healthcare professionals. Industry estimates that savings from 7 safety letters is in the region of £300,000.

For a number of years the British Generic Manufacturers Association (BGMA) has been working with MHRA to co-ordinate the implementation and dissemination in the UK of a single Direct Healthcare Professionals Communication (DHPC) or other educational materials on behalf of marketing authorisation holders for a medicine or group of medicines. This has the advantage of ensuring consistency of messaging and materials, less burden for recipients of what could otherwise be many sets of similar materials, and reduced costs for individual companies. During the period 13 December 2019 to 16th December 2020, five BGMA projects were completed with between four and twenty companies taking part in each one. The total savings to industry are about £2,210,000.

Measures certified as concerning EU Withdrawal Bill operability measures

From 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) will be the UK’s standalone medicines and medical devices regulator.

As such, the MHRA has published detailed guidance on how medicines and medical devices will be regulated at the end of the Transition Period, in both a negotiated and non-negotiated outcome with the EU. <https://www.gov.uk/government/collections/mhra-post-transition-period-information>

MHRA successfully delivered nine webinars to companies on the post transition guidance in October 2020. 11,500 joined the live event with full representation across pharmaceutical and devices industry. Recordings of the webinars will be posted on gov.uk and emailed to delegates and those o wait lists. Full evaluation of the events will be available in November.

Changes to management of regulator

Stephen Lightfoot was appointed Chair of the MHRA from 1 September 2020.