**Regulator: Medicines and Healthcare Products Regulatory Agency (MHRA)**

**Business Impact Target Reporting Period Covered: 17 December 2020 – 16 December 2021**

Measures certified as being below de minimis (measures with an Equivalent Annual Net Direct Cost to Business below +/- £5 million)

MHRA has continued to work 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 helps 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 MHRA are taking during the COVID-19 outbreak can be found at <https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19>

The flexibility has allowed for the continued dissemination of Direct Healthcare Professional Communications (DHPCs) by email rather than post informing them of important new safety information about a medicine such as withdrawals and shortage problems and any actions they should take.  Email-only or email/post-hybrid models have been used for 7 pharmacovigilance or quality issues safety letters to healthcare professionals in the reporting period. We understand from stakeholder feedback that an electronic option for these letters is preferred by both industry and healthcare professionals as it saves both costs and time.

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 MAHs 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 reporting period, 3 BGMA projects were completed with between 7 and 20 companies involved in each.

Measures certified as concerning EU Withdrawal Bill operability measures

From 1 January 2021, the MHRA is 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 on <https://www.gov.uk/government/collections/mhra-post-transition-period-information>

In its July Command Paper, the Government set out proposals for a new balance in how the Protocol is operated, which are now being discussed with the European Union (EU).

In order to provide certainty and stability as discussions proceed between the UK and EU on these proposals, the Government has set out that it will continue to operate the Protocol on its current basis. This will mean that existing arrangements continue in force, including extending the specific arrangements/easements/grace period.

The Government will ensure that reasonable notice is provided in the event that any of these arrangements are to change, to enable businesses and citizens to make appropriate preparations. Further information will be provided soon.

MHRA are planning to deliver further webinars to companies on the post transition guidance in February of the next reporting period and recordings will be posted on gov.uk.