Regulator: Medicines and Healthcare products Regulatory Agency

Business Impact Target Reporting Period Covered: 21st June 2018 – 20th June 2019

Excluded Category*	**Summary of measure(s), including any impact data where available****
Measures certified as being below *de minimis* (measures with an EANDCB below +/- £5 million)	MHRA worked with the British Generic Manufacturers Association (BGMA) to agree new and improved process and associated protocol for the co-ordination of safety and risk management materials for generic medicines. This year, BGMA issued a single set of safety materials on behalf of affected Marketing Authorisation holders for four initiatives (each involving between 11 and 25 participating companies) which BGMA estimates has saved industry £1,962,000. Under Combined Ways of Working (CWoW) pilot, UK organisations involved in the review and authorisation of clinical trials of investigational medicinal products (CTIMPs) are harmonising our assessment, producing a single UK decision on a clinical trial. The pilot process requires only a single CTIMP application dossier to be submitted for both the Clinical Trial Authorisation (CTA) and the Research Ethics Committee (REC) opinion. The application is assessed by both organisations and any requests for further information are co-ordinated and combined. A single communication to confirm the final UK decision is sent to the applicant. To date, 62 initial applications, 50 amendments and 6 end-of-trial notifications have been received. Of the 62 initial applications, 50 have been completed and 12 are still under assessment or awaiting a response to questions raised. Following a two-part review looking at the scheduling of cannabis-based products, the Government subsequently introduced the Misuse of drugs (Amendment) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018, which came into force on 1 November 2018. These amendments introduced a definition of “cannabis-based product for medicinal use in humans”. MHRA worked with Home Office and DHSC on this change which has enabled the prescribing and supply of cannabis-based medicines, primarily for administration to children for treatment of refractory epilepsy. MHRA published guidance to assist importers and manufacturers of cannabis-based medicines. Imports have proceeded in an orderly and prompt manner so as to ensure a smooth supply to meet patient demand.
EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement	MHRA consulted on the steps proposed to make sure the UK meets its obligations to transpose the provisions of FMD safety features. FMD safety features came into force on 9 February 2019. The MHRA has published a wide range of guidance relating to FMD and the safety features. https://www.gov.uk/government/consultations/implementing-safety-features-under-the-falsified-medicines-directive

Excluded Category*	Summary of measure(s), including any impact data where available**
Measures certified as concerning EU Withdrawal Bill operability measures	MHRA consulted on legislation and regulatory processes that would need to be modified in the event of the UK not securing a deal with the EU after the UK's exit with no Implementation Period. The MHRA has published updated guidance on the regulation of medicines, medical devices and clinical trials if there's a no deal Brexit. https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal
Pro-competition	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Systemic Financial Risk	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Civil Emergencies	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Fines and Penalties	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Misuse of Drugs	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Measures certified as relating to the safety of tenants, residents and occupants in response to the Grenfell tragedy	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Casework	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
Education, communications and promotion	In preparation for and post-implementation of the Falsified Medicines Directive: Safety Features, we coordinated a group of external stakeholders representing the different points of the medicines supply chain to produce sector-specific guidance, which we published online and through our regular e-newsletter. This ensured that all those impacted by the new Regulations were clear on their role and the changes to be made to their business. We carried out significant work to inform and engage with industry on preparations for a potential no-deal Brexit scenario, involving external representatives in our plans and developments of new systems to replace those the UK would lose access to through leaving the European Union, and staging large scale training opportunities for industry to

Excluded Category*	Summary of measure(s), including any impact data where available**
	test the new systems and make ready for a potential day 1 scenario. Feedback on our proactive engagement in this area from industry has been very positive. We also sent regular updates to industry trade associations (for onward cascade to their members) highlighting recently published guidance on GOV.UK and details of the progress of legislation to allow the continued sale of/access to medicines, medical devices and clinical trials. For those companies on our Marketing Authorisation Holder database that may not have been a member of a trade association, we sent a one-off summary of all no-deal guidance published to date.
Activity related to policy development	MHRA consulted on the steps proposed to make sure the UK meets its obligations to transpose the provisions of FMD safety features. FMD safety features came into force on 9 February 2019. The MHRA has published a wide range of guidance relating to FMD and the safety features. https://www.gov.uk/government/consultations/implementing-safety-features-under-the-falsified-medicines-directive There were 4 public consultations held by the MHRA (two in conjunction with DHSC) during the period. These are available at https://www.gov.uk/search/policy-papers-and-consultations?organisations%5B%5D=medicines-and-healthcare-products-regulatory-agency&parent=medicines-and-healthcare-products-regulatory-agency
Changes to management of regulator	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.

* For detailed guidance on the exclusion categories, please see https://www.gov.uk/government/publications/better-regulation-framework

** Complete the summary box as 'Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.' where this is appropriate.