Regulator: Medicines and Healthcare products Regulatory Agency

Business Impact Target Reporting Period Covered: 9 June 2017 to 20 June 2018

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 introduced a **new system for registering class I devices and in vitro diagnostic (IVDs) devices and for registering certificates of free sale**. Although there is a one-off impact to industry with respect to migrating existing registrations, the longer-term burden reduction related benefits are: • companies that want certificates of free sale for products that they have registered will be able to refer to those products in the system rather than having to enter them again (as required in the old system); and • companies will be able to include both IVD and Medical Devices Directive (MDD) products in the same registration. Previously they had to be registered separately incurring separate registration fees (£100 per registration). **MHRA developed guidance to enable desk top assessment of GMP compliance of overseas**. The guidance provides a tool and framework which aims to help competent authorities (CA) prioritise resources for GMP inspections for human and veterinary medicines. The main feature of the new guidance is that it outlines a process for desk top assessment of GMP compliance of overseas facilities to identify instances where an acceptable level of GMP compliance can be confirmed and assured from the activities of another CA without the need for an on-site inspection, saving valuable time and resources. A **Validation Correct Request** (VCR) has been introduced by the MHRA's Information Processing Unit (IPU) for variation applications[1]. The new functionality allows MHRA to issue a VCR which will provide customers with the chance to resolve minor issues during the validation process, which is more efficient. So far, there have been 157 VCRs. As well as avoiding wasted time (i.e. the c.2 weeks it would take for an initial application assessment and corrected resubmission), it also saves customers the 10% fee[2] charged for an invalid application.

[1] This new functionality is initially available on Type 1B and Type II variations with plans in place to roll this out to more work types in the near future.

[2] For Type 1B variations the fee is £277 and for Type 2 variations it is £734.

Excluded Category*	Summary of measure(s), including any impact data where available**
	MHRA provides a new **Pay on Invoice** option[3] for medicines licences, clinical trial authorisations, and devices investigations. Applicants no longer have to attach proof of payment to applications, reducing the regulatory burden and making the end-to-end process simpler, easier and quicker. There are now 10,000 active customers, encompassing more than 12,000 invoices / validated applications per year. Feedback from customers, going into the initial trial was that the change would save approx. 2hrs per application including pre submission and post reconciliation work. Using a more conservative 30 minutes time savings estimate (based on 2016/17 data), this saves industry approximately £83,000 annually[4]. In addition, MHRA high level estimates (using 2016/17 data) is that, removing the 10% fee charged for an invalid application saves industry approx. £200,000 annually[5]. As reported in the last BIT, the MHRA worked with the British Generic Manufacturers Association (BGMA) to agree a new process and associated protocol for the c**o-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 three initiatives (each involving 13 participating companies) which BGMA estimates has saved industry £815,000.
EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement	Whilst no **EU regulation and directives** were implemented in 2018/19, a lot of work took place preparing for the implementation of directives including Clinical Trials Regulation, Falsified Medicines Directive safety feature and Medical Devices Regulations.
Measures certified as concerning EU Withdrawal Bill operability measures	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.
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.

[3] This is being offered as an option for customers prior to updating the wording in the fees regulations.
[4] This is based on 4000 invoices per month, 27% of which were paid in advance on previous system (i.e. c.1080 invoices / applications per month).
[5] This is based on current invoicing and fees income (using 10% administration fee against a 5% rejection rate).

Excluded Category*	**Summary of measure(s), including any impact data where available****
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	To assist industry with the understanding of the Falsified Medicines Directive: Safety Features, our regular e-newsletter informs 3,000 stakeholders from across the medicines supply change of any updates around the forthcoming legislation. We published interactive guidance documents on both Apps and Software as Medical Devices and the new EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR). These were promoted with press releases and social media and ongoing interaction with Industry which indicates they were well received. In April the MHRA announced a pregnancy prevention programme to accompany the prescribing of sodium valproate.
Activity related to policy development	The MHRA issued 9 consultations in the current reporting period. These are published on the gov.uk website.
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 full, legal definitions of these exclusion categories, please see https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-06-20/HCWS776/

** 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.