Regulatory Policy Committee

Medicines and Healthcare products Regulatory Agency (MHRA)

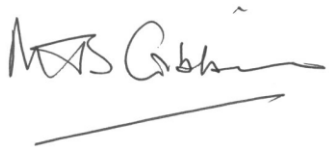
Department of Health

Non-qualifying regulatory provision assurance statement: confirmed

The Regulatory Policy Committee (RPC) is content that, on the basis of the summary information provided, none of the measures or activities covered in the summary document should be considered as a qualifying regulatory provision for the purposes of the business impact target. This statement does not provide a detailed view of any specific activity in the regulator's summary document. Nor does it comment on any activities not included in the summary. Some activities might, however, have been the subject of separate assessments of qualifying regulatory provisions.

Comments on the non-qualifying regulatory provision summary

The NQRP summary would benefit from clarifying in the EU and International section that the simplified template and guidance for Pharmacovigilance does not represent a change in the regulatory requirement placed on business by the MHRA.



Michael Gibbons CBE, Chairman

Date of issue: 14 August 2017
www.gov.uk/rpc

Medicines and Healthcare products Regulatory Agency (MHRA)

Non-qualifying Regulatory Provisions that came (or are expected to come) into force during the second and final Business Impact Target reporting period (i.e. 27 May 2016–8 June 2017) - NOT YET VALIDATED BY RPC	
Excluded Category	**Summary of measure(s), including any impact data where available**
A – EU and International	An European Medicines Agency consultation on simplified template for Good Pharmacovigilance Practice completed and guidance template was published in January 2017. This addresses the request from industry for a simplified risk management plan format for standard generic medicines. Whilst no EU regulation and directives were implemented in 2016/17, a lot of work took place preparing for the implementation of directives including Clinical Trials Directive, Falsified Medicines Directive and Medical Devices Directive.
B – Economic Regulation	The MHRA has not introduced or changed any regulatory provisions relating to economic regulation in this reporting period.
C – Price Control	The MHRA has not introduced or changed any regulatory provisions relating to price control in this reporting period.
D - Civil Emergencies	The MHHRA has not introduced or changed any regulatory provisions relating to civil emergencies in this reporting period.
E – Fines and Penalties	The MHRA has not introduced or changed any regulatory provisions relating to fines and penalties in this reporting period.
F – Pro-Competition	The MHRA has not introduced or changed any regulatory provisions relating to pro-competition in this reporting period.
G – Large Infrastructure projects	The MHRA has not introduced or changed any regulatory provisions relating to large infrastructure projects in this reporting period.
H – Misuse of Drugs/National Minimum wage	The MHRA has not introduced or changed any regulatory provisions relating to misuse of drugs/national minimum wage in this reporting period.
I – Systemic Financial Risk	The MHRA has not introduced or changed any regulatory provisions relating to systematic financial risk in this reporting period.
K – Industry Codes	The MHRA has not introduced or changed any regulatory provisions relating to industry codes in this reporting period.
L1 – Casework	A list of marketing authorisations, traditional herbal registrations, manufacturing and wholesale dealer's licences, parallel import

	licences granted, and early access to medicines scheme scientific opinions are published on gov.uk website. The MHRA received and dealt with over 900 enquiries and complaints in 2016/17; equating to over 3500 products. Where voluntary compliance was not achieved we issued 4 final determination notices and 174 urgent notices to remove unlicensed medicines from sale. In the build up to the 2016 Olympics, the Medicines Borderline Section carried out a review of the sale of unlicensed medicines marketed as sports supplements. The Section reviewed 33 websites and found 16 companies selling 69 unlicensed medicines and took action to remove these products from the market. This work, and other work carried out by the Section in 2016, highlighted the continued availability of unlicensed medicinal products containing DMAA (also known as 1,3-dimethylamylamine, methylhexanamine or geranium extract) and the MHRA held a 'Week of Action' in January 2017; working with a range of stakeholders to highlight the safety concerns that are associated with the consumption of this substance. In addition to routine criminal investigations conducted in relation to illegal activity involving medicines and medical devices, a specific issue concerning the diversion of certain Controlled Drugs / Prescription medicines from the UK authorised supply chain has been identified. A distinct investigation team has been set up and a number of separate investigations are underway. In 2016/17 there were 15 cases sent to CPS resulting in 7 completed prosecutions. There was 1 appeal against sentence (unsuccessful). There were several investigations into the advertising of medicines. Information is published on the gov.uk website. There were 342 devices incidents raised in 2016/17, of these 79 cases were received via the European Compliance and Enforcement (COEN) Group. - 84 resulted in compliance and enforcement notices being issues - Approximately 75 incidents resulted in no action - Approximately 183 compliance investigations opened There have been no prosecutions as of yet. The Committee of Human medicines considered 2 oral hearings and 4 written representations in relation to regulatory decisions

	in 2016/17
L2 – Education, communications and promotion	In January 2017 we introduced the MedRegs blog, which helps subscribers to stay up to date with developments and information relating to medicines regulations. To date the blog has received x unique views and has x subscribers. The regulatory blog will include information on licence variations. The website has also been updated reminding industry that combined strength SPCs are already permitted in Europe. To assist industry with the understanding of the Falsified Medicines Directive: Safety Features, we set up an e-newsletter to inform over 3,000 stakeholders from across the medicines supply change of any updates around the forthcoming legislation. MHRA have carried out significant proactive engagement with industry in the wake of the EU Referendum result in the form of stakeholder meetings to capture the views and information industry have to offer in exploring the potential for a new regulatory landscape for medicines in the UK. We have held several conferences and smaller events to inform and share best practice about regulatory affairs across the year, on a range of topics from Advertising of Medicines to Good Manufacturing Practice, which have all been well-attended or sold out. We work across the year to sell-in content to medical publications such as The Regulatory Rapporteur and Medicine Maker that showcases the work that MHRA are doing and how to be innovative in the context of regulatory affairs. Typically at least one article in each publication per month is authored by MHRA or features our content and quotes. The Medicines Industry Liaison Group and Medical Devices Liaison Group met quarterly. There are various helplines offering regulatory advice. These are listed on the gov.uk website https://www.gov.uk/guidance/contact-mhra
L3 – Activity related to policy development	The MHRA issued 7 consultations in the current reporting period. These are published on the gov.uk website. Work has started on the post implementation review of the Human Medicines Regulations 2012. This will be completed in the

	next reporting year.
L4 – Changes to management of regulator	The MHRA appointed a new Chief Operating Officer in this reporting period. The outcome of the EU referendum may impact upon the regulatory burden on business and will form part of the 2017/18 QRP and NQRP process where necessary. The MHRA are scheduled to move to a new building in 2017/18.