Medicines and Healthcare products Regulatory Agency (MHRA)

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)			
Title of measure	**Description of measure**	**BIT score (£ millions)**	**RPC reference number**
Over £50k			
Co-ordination of safety and risk management materials for generic medicines (November 2015)	In response to a request from industry, the MHRA reduced regulatory burden on business by introducing a scheme with the British Generic Manufacturers Association (BGMA) that enabled the co-ordination of mandatory direct healthcare professional communications by marketing authorisation holders. This reduced duplication of effort for up to 30 separate companies. It also means multiple copies of the same information are no longer sent to busy healthcare professionals.	-£2.5 million	RPC17-DH-MHRA-4043(1)
E-correspondence via CESP (October 2016)	In response to customer feedback, the MHRA reduced administrative burden on business by moving to paperless communications for submissions made via the Common European Submissions Portal (CESP). This reduced costs to industry through providing faster access to information, removing need to manage paper communications, and reducing risk of data loss.	-£2.0 million	RPC17-DH-MHRA-4044(1)
Under £50k			
Improved processes on reclassification of medicines (February 2017)	Following requests from industry, the MHRA set up a new streamlined process, reducing the burden on businesses with the reclassification of medicines. Under the previous system, there had been delays in the application process, difficulties in contacting assessors, and a lack of clarity about the reclassification procedures.	Zero	RPC-4038-DH-MHRA
Dedicated contact for backlog submissions (June 2016)	The MHRA has provided a dedicated contact for industry to speak to regarding product licence applications and any associated regulatory activity. This may be used if businesses are experiencing delays in hearing from the Regulatory Information Service (RIS), to which enquiries of this kind are referred in the first instance.	Zero	RPC-4039-DH-MHRA
Remove need to communicate with named individual over clinical trials (June 2016)	The measure allows business employees, other than the applicant named on a clinical trial application form, to access clinical trial data from the MHRA. Previously this had resulted in delays if the named contact was not available. Under the new system, the MHRA can liaise with anyone from an applicant business that is aware of the trial number and the relevant security information.	Zero	RPC-4040-DH-MHRA

Regulatory Policy Committee

Co-ordination of safety and risk management materials for generic medicines

Medicines and Healthcare products Regulatory Agency (MHRA)

RPC rating: validated

Description of the measure

The assessment explains that when important new safety information about a medicine becomes known (normally via updates to product information agreed by national and/or European regulatory procedures, including drug safety reviews), all individual drug manufacturers are required by law to communicate this to healthcare professionals.

The MHRA has worked with the British Generic Manufacturers Association (BGMA) to agree a new process and associated protocol whereby BGMA issues a single set of materials on behalf of all affected Marketing Authorisation holders. Previously, up to 30 separate companies would have had to work individually with the agency in response to such updates.

Impacts of the measure

The assessment explains that the revised process and new protocol reduces duplication of effort by drug manufacturers in the production and dissemination of mandatory materials. This benefits both drug manufacturers, who will no longer waste resources duplicating effort, and healthcare professionals, who will now –only have to read a single communication for generic products. The BGMA provided a breakdown of businesses affected as:

- Generic medicines manufacturers (30)
- Pharmacies (14,000)
- GPs and other healthcare professionals (50,000)

The total saving to business is estimated at £567,000 per annum, based on actual savings data for the first 20 months the policy has been in force.

The BGMA has assured the MHRA that any familiarisation costs will be negligible relative to the savings (which the MHRA has confirmed by carrying out a simple break-even calculation), and there are no other costs associated with the measure.

The MHRA also expects that there will be improvements to patient safety as a result of the measure, as information on safety will be clearer and more consistent. It has not monetised these benefits.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of -£0.5 million. This is a qualifying regulatory provision that will score under the Business Impact Target.

Quality of submission

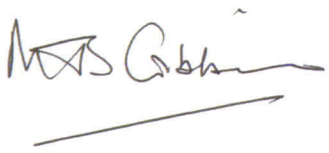
The MHRA has provided a clear and proportionate assessment of the costs, and has made appropriate use of its engagement with the BGMA to gain actual data on the savings associated with the measure. We were also pleased to see an appropriate and proportionate break-even calculation around familiarisation costs.

Departmental assessment

Classification	Qualifying regulatory provision (OUT)
Equivalent annual net direct cost to business (EANDCB)	-£0.5 million
Business net present value	£4.88 million

RPC assessment

Classification	Qualifying regulatory provision (OUT)
EANDCB – RPC validated[1]	-£0.5 million
Business Impact Target (BIT) Score[1]	-£2.5 million



Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.

Regulatory Policy Committee

E-correspondence via CESP

Medicines and Healthcare products Regulatory Agency (MHRA)

RPC rating: validated

Description of the measure

The assessment explains that MHRA operates its own national portal for exchanges of information. However, the Common European Submission Portal (CESP) provides an easier electronic based system for secure information exchange between applicants and regulatory agencies.

Following customer demand and feedback, requesting an electronic solution to reduce costs for industry, the MHRA has moved to paperless communications via CESP for submissions relating to Marketing Authorisations. The project went live in October 2016.

Impacts of the measure

The assessment explains that, by using CESP, companies save time and money and gain faster access to information, at the same time reducing the administrative burden and data loss. The MHRA estimates that the change affects notifications from a range of applicants, including pharmaceutical companies. The MHRA acknowledges that businesses will need to set up an appropriate electronic mailbox, but argues that the cost of doing so is negligible.

MHRA estimates, based on administrative data, that the change will affect 5,000 notifications per month. Consultation with industry has validated their estimate that the new system saves 30 minutes of time per notification compared to the old system.

Industry also provided detail that the average member of staff conducting such a task would be paid around £16 per hour. Given the number of notifications affected per year (5000 x 12 = 60,000) and a saving per notification (£16 x 0.5= £8), this provides an annual saving of £480,000.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of -£0.4 million. This is a qualifying regulatory provision that will score under the Business Impact Target.

Regulatory Policy Committee

Quality of submission

The assessment is clear and proportionate, and makes appropriate use of the MHRA's existing contacts with industry in support of its estimates. The absence of any assessment of wider costs and benefits is appropriate.

Departmental assessment

Classification	Qualifying regulatory provision (OUT)
Equivalent annual net direct cost to business (EANDCB)	-£0.4 million
Business net present value	£4.13 million

RPC assessment

Classification	Qualifying regulatory provision (OUT)
EANDCB – RPC validated[1]	-£0.4 million
Business Impact Target (BIT) Score[1]	-£2.0 million

Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.

Regulatory Policy Committee

Improved process on reclassification of medicines; dedicated contact for backlog submissions; removing need to communicate with a named individual over clinical trials

Medicines and Healthcare products Regulatory Agency (MHRA)

RPC rating: validated

This opinion covers three small measures; for each, a brief description of the change, its impacts and the quality of the submission is given in the table below. The equivalent annual net direct cost to business (EANDCB) of each measure is listed underneath.

Measure	Description	Impact	Quality of submission
Improved processes on reclassification of medicines (February 2017) RPC-4038	Following requests from industry, the MHRA set up a new streamlined process, reducing the burden on businesses with the reclassification of medicines. Under the previous system, there had been delays in the application process,	The assessment explains that pharmaceutical companies aiming to reclassify medicines would be affected by the proposal. Industry horizon scanning indicates that a total of 19 applications from 7 companies are expected over the next year. The streamlined system would create time savings for these businesses through more transparency at each stage of the procedure, clearer communication between applicants and the MHRA, improved business planning for the	The regulator has provided a proportionate level of evidence for the RPC to be able to validate an EANDCB of zero, including a very clear and carefully reasoned break-even calculation. The assessment would benefit from setting out in more detail how businesses would benefit under the new

	difficulties in contacting assessors, and a lack of clarity about the reclassification procedures.	reclassification process, and the provision of a named contact for businesses. Based on the expected number of reclassifications each year, the regulator estimates that there would need to be a benefit of over £2,600 per reclassification to have a material effect on the EANDCB. This would equate to a saving of 72 hours of business time in each case. On the basis of this information, the regulator has assumed that the measure has an EANDCB of zero.	system, and considering whether streamlining would lead to a rise in reclassifications in future.
Dedicated contact for backlog submissions (June 2016) RPC- 4039	The MHRA has provided a dedicated contact for industry to speak to regarding product licence applications and any associated regulatory activity. This may be used if businesses are experiencing delays in hearing from the Regulatory Information Service (RIS), to which enquiries of this kind are referred in the first instance.	The assessment explains that the main impact of the measure is a benefit to pharmaceutical companies. These businesses will save time through quicker advice and more flexibility in the licence application process. A response from industry suggests that this would amount to £35-£50 per delay prevented. As this is a new provision, the regulator has not been able to estimate the number of times this saving will be made, however the assessment explains that there would need to be over 1,000 delays prevented annually to generate a benefit of £50,000 a year. As the regulator expects a number significantly lower than this, it has assumed that the EANDCB will round to zero.	The regulator has provided sufficient evidence for the RPC to be able to validate an EANDCB of zero. The assessment would benefit from a clearer statement of the regulator's reasons for believing that the number of delays prevented would be considerably lower than 1000, both now and in the future. It would also have been improved by including a wider range of businesses in its estimate of the unit costs of delay.

Regulatory Policy Committee

Remove need to communicate with named individual over clinical trials (June 2016) RPC-4040	The measure allows business employees, other than the applicant named on a clinical trial application form, to access clinical trial data from the MHRA. Previously this had resulted in delays if the named contact was not available. Under the new system, the MHRA can liaise with anyone from an applicant business that is aware of the trial number and the relevant security information.	The assessment explains that, while the initiative is open to all sponsors (including civil society organisations), only commercial businesses have utilised it since its implementation. A total of 127 separate requests have been received since the measure was introduced in June 2016. The increased flexibility is expected to create a benefit to businesses because they will experience fewer delays during the application process. Based on an estimated annual saving of £120 per firm, and the number of businesses currently benefitting from the measure, a total saving of £14,000 a year is estimated. This translates into an EANDCB of zero, when rounded to the nearest £0.1 million.	The regulator has provided sufficient evidence to support its assessment of the measure. However, the assessment would benefit from further explanation to support the assumptions around annual savings per business. The assessment could also be improved by expressing the aggregate savings calculation more clearly. However, the RPC is satisfied that these issues would not affect the rounded EANDCB.

Departmental assessment

Classification	All qualifying regulatory provisions
Equivalent annual net direct cost to business (EANDCB)	All zero

Regulatory Policy Committee

Business net present value	£0.0 million (RPC-4038) £0.02 million (RPC-4039) £0.12 million (RPC-4040)

RPC assessment

Classification	All qualifying regulatory provisions
EANCB – RPC validated[1]	All zero
Business Impact Target (BIT) Score[1]	All zero

Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANCB and BIT score figures to the nearest £100,000.