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.

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.

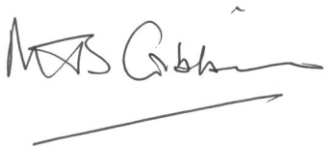
Departmental assessment

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

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.