

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.

Quality of submission

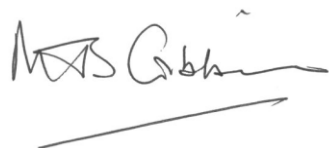
The assessment is clear and proportionate, and makes appropriate use of the MHRA's existing contacts with industry in support of its estimates. The absence of any assessment of wider costs and benefits is appropriate.

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.