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

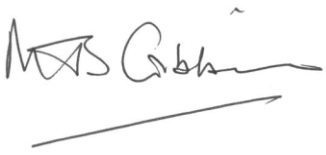
The MHRA has provided a clear and proportionate assessment of the costs, and has made appropriate use of its engagement with the BGMA to gain actual data on the savings associated with the measure. We were also pleased to see an appropriate and proportionate break-even calculation around familiarisation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