Regulatory Policy Committee	Regulatory Triage Confirmation	
Title of regulatory proposal	Amendments to the Human Medicines regulations 2012 to widen access to naloxone for use in an emergency	
Lead Department/Agency	Department of Health	
Origin	Domestic	
Expected date of implementation (and SNR number)	SNR 10	
Date submitted to RPC	20 November 2014	
Confirmation date and reference	3 December 2014	RPC14-FT-DH-2285
Departmental triage assessment	Deregulation	

Departmental rationale for triage rating

The Department is proposing to remove certain regulatory barriers to make the prescription drug naloxone more readily accessible to certain service providers e.g. homeless shelters. Removing these regulatory barriers is likely to increase the sale of naxolone and increase profits to business.

RPC confirmation

The RPC confirms this for the fast-track as a deregulatory proposal. It provides for a less burdensome regulatory environment in respect of the availability of naloxone.

CONFIRMED

RPC comments

The Department explains that naloxone is an antidote used in cases of overdose from heroin and other opioids. At present, it is only available on prescription. The Advisory Council on the Misuse of Drugs (ACMD) recommends that naloxone should be made more widely available. The Department is proposing to change legislation to make naloxone more readily available to reverse opioid overdose and prevent death.

The Medicines and Healthcare Products Regulatory Agency (MHRA) consulted on the proposal. 122 responses were received – 118 were in favour of wider distribution of naloxone. The remainder did not express an opinion.

The Department estimates that the incremental benefits of the proposal (increased profits) to business lies between £18,000 and £162,000.

- This assessment is based on consultation responses on the likely profits generated on between 10,000 and 90,000 packs of naxolone being made available each year. The Department explains in its RTA, however, that approximately 90,000 packs of naloxone a year on average would need to be distributed to ensure that each heroin user had access to the antidote.
- The estimate of the unit cost is £18 per pack. The Department's assessment is based on retail cost of the most expensive product currently available on the market.
- The estimate that the margin on sales is 10% which the Department explains is consistent with margins for generic medicines manufacturers.
 The Department also explains that this margin may be too large for distributors and pharmacies.
- Therefore, the Department's assumption is that 90,000 packs would equate to additional profits of £162,000 each year (which will be shared between manufacturers, distributors and pharmacies).

The Department estimates that the incremental costs (lost profit due to the effect of displacement) will be 'very substantially lower' than the benefits.

The Department explains in its RTA that "These amendments will open up the market for producers of naloxone kits, thereby increasing the profits of the fourteen companies that currently manufacture naloxone and of the companies that distribute the kits". The RPC can accept that the proposal is likely to be beneficial to business (producers and distributors of naloxone), and that removing regulatory barriers that increase the availability of naloxone kits can be classified as deregulatory.

When the Department submits an impact assessment to the RPC for validation of the EANCB at final stage, it should improve the robustness of the assessment of the likely net benefits of the proposal.

'One-in, Two-out' (OITO) assessment

In scope

The Department explains in its RTA that the proposal will have a direct net benefit to business. As a consequence, the RPC considers the proposal to be in scope of OITO. Based on the evidence presented, the Department's assessment appears reasonable and is consistent with the current Better Regulation Framework Manual (paragraph 1.9.11). The evidence supporting the estimated equivalent annual net cost to business will have to be strengthened so that it can be validated at final stage.

MAS Goh

Signed

Michael Gibbons, Chairman