

**Amendments to the Human Medicines Regulations 2012 to widen access to naloxone for use in an emergency**

**Department of Health**

**RPC rating: validated**

**Description of proposal:**

The proposed amendments to the regulations will mean that organisations such as homeless hostels and individuals such as outreach workers will be able to hold naloxone for use in the emergency management of suspected overdose from opioids such as heroin.

**Impacts of proposal**

The Department anticipates that widening access to naloxone will result in more stocks of the drug being held and being used more often in suspected overdose cases. This will improve sales and profits of the producers of naloxone.

The Department has based its estimates on data from Scotland, where access to naloxone was widened in March 2011. The Department estimates that the stock of take-home naloxone (THN) kits will increase by 18,000 in each of the first four years of the proposal. By year five, the stock of THN kits in England and Wales is forecast to total 75,000 with annual replenishment sales of 30,000. The Department estimates the cost of a THN kit to be £18.30. As naloxone is out of patent (a 'generic' drug), the Department estimates the profit margin for producers to be 10%, which is representative of generic medicine producers. The RPC notes that this represents a net profit margin (net earnings/total revenue). The appropriate use of net profits is an on-going methodological issue and is yet to be decided upon by the Regulatory Framework Group. Until there is greater clarity on this issue, assessments will be undertaken on a case-by-case basis. Therefore, for future measures, the Department will need to clarify whether its estimates are based on net or gross profits and provide reasoning for their choice.

The Department confirms that only two of the nine producers of naloxone are based in the UK. As such, it assumes only 22% of the increased profit accrues to UK businesses. The Department thus estimates a net benefit to business of £8,600 each year and thus a net present value of £99,000 over the ten year period.

**Quality of submission**

The Department has produced a good assessment of the impact of the proposal. It includes a sensitivity analysis of the assumptions used in the analysis. For example, changing the replacement rates of the kits provides high and low estimates for the business NPV of £110,000 and £86,000 respectively. The Department also considered whether the wider availability of naloxone could displace stocks from existing facilities such as hospitals. This was considered unlikely as the effects of

naloxone are only temporary and further doses may need to be administered, for example, if an individual is later admitted to hospital.

The Department also addressed the RPC's concerns over whether the proposal could result in an increased risk to the public. It explained that naloxone does not produce pleasurable effects or act as a performance enhancer and therefore is unlikely to be diverted onto the black market. In terms of safety, the risks associated with administering a high dose of naloxone are thought to be negligible, compared to the potential number of lives saved. The Department confirmed that risks will be minimised via appropriate training and monitoring of individuals with access to naloxone. The costs of training and monitoring were not monetised. The Department could have done more to estimate costs associated with the storage and disposal of Naloxone as well as the associated training. The Department points to the pre-existence of online materials to suggest that training costs are likely to be small. Overall, it is likely that the EANCB, when measured with reasonable accuracy, would be largely unaffected by the inclusion of such costs. The Department's approach, therefore, appears proportionate.

#### Validated impacts

<b>EANCB – initial departmental submission</b>	<b>Not provided</b>
<b>EANCB – validated</b>	<b>-£0.0086 million</b>
<b>Classification</b>	<b>OUT</b>
<b>Small and micro business assessment</b>	<b>Not required</b>