

Rebalancing medicines legislation and pharmacy regulation programme: dispensing errors

Department of Health

RPC rating: fit for purpose

Description of proposal

The Department explains that the criminalisation of dispensing errors was intended to address a problem where those involved in the supply of medicines act against the best interests of the patient. Evidence exists that the fear of prosecution deters the reporting of errors by pharmacy professionals which may reduce learning from errors and put patient safety at risk. The Department proposes to introduce a new legislative provision whereby, if a registered pharmacy professional makes a dispensing error, they would be exempt from criminal sanctions unless they had used their professional skills for an improper purpose or shown a deliberate disregard for patient safety.

Impacts of proposal

The Department explains that pharmacy businesses will incur one-off familiarisation costs. The Department assumes that familiarisation will take 32,850 privately employed pharmacists and 11,660 privately employed pharmacy technicians 20 minutes each. This was confirmed as reasonable by pharmacy owner representatives. Using earnings data from the ONS 2013 Annual Survey of Hours and Earnings, the Department estimates a total cost to business from familiarisation of £340,000.

The Department explains that the proposal will reduce the probability of a pharmacy professional undergoing criminal investigation. The Department has monetised the direct benefit associated with the reduction in prosecution risk by using professional indemnity insurance market costs as a proxy for the value that pharmacy professionals attach to risk. The Department estimates that the professional indemnity insurance premium is, on average, £145 per year per professional and assumes that the probability of prosecution will fall by 1% under the proposal. This results in an estimated benefit to business of £508,000 in present value terms over the ten-year appraisal period.

The Department explains that the proposal may increase the willingness of pharmacy professionals to report dispensing errors and hence increase the number

of error reports. The Department estimates this will result in an indirect cost to business of £3.9 million over the ten-year appraisal period as a result of the time taken per additional error report and the relevant employment costs.

Additionally, the Department explains that the proposal will result in an indirect benefit to business due to cost reductions from reduced numbers of dispensing errors (beyond the impacts on costs of error reporting). This is as a result of preventing potential errors and error reports by learning from reported errors. The Department estimates this benefit to be £4.5 million in present value terms over the ten-year appraisal period.

Overall, the Department estimates a benefit to business of £0.02 million per year over the course of the ten-year appraisal period.

Quality of submission

As initially submitted, the RPC did not consider the IA to be fit for purpose. Following the RPC's initial review, the Department submitted a revised IA which responded adequately to the following issues:

- The revised IA explains that a variety of resources are available to pharmacy professionals for protecting themselves from the risk of criminal prosecution from their professional activities. The Department now justifies its choice of using professional indemnity insurance as a proxy on the basis that this type of insurance explicitly covers legal advice, representation and expenses (page 25). This appears reasonable.
- The Department assumes that a decrease in the probability of prosecution is equivalent to a conservative scenario of a 1% decrease in individual's valuation of risk, using the proxy of insurance premiums paid by pharmacy professionals. The Department now explains that 94% of consultation respondents supported the assumptions made. This also appears reasonable.
- The Department expects that professional and regulatory bodies will provide guidance to support pharmacy professionals in familiarising themselves with the proposal. The Department has provided evidence that Pharmacy Voice (Industry Representative), General Pharmaceutical Council (Pharmacy Regulator) and the Pharmacy Services Negotiating Committee have all confirmed that such guidance and information are part of their statutory duties. They have also confirmed that the figures used by the Department, in the calculation of familiarisation costs, are realistic (page 19).

Additionally, the re-submitted IA now clearly states the direct and indirect costs and benefits to business of the proposal.

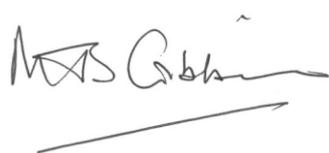
Based on current working assumptions, the RPC can validate this measure as a qualifying regulatory provision with an EANCB of -£0.02 million.

Initial departmental assessment

Classification	Qualifying regulatory provision
Equivalent annual net cost to business (EANCB)	-£0.02 million
Business net present value	£0.17 million
Societal net present value	£0.75 million

RPC assessment

Classification	Qualifying regulatory provision
EANCB – RPC validated	-£0.02 million
Small and micro business assessment	Not required (deregulatory)
RPC rating (of initial submission)	Not fit for purpose



Michael Gibbons CBE, Chairman