Opinion: final stage IA
Origin: domestic
RPC reference number: RPC-DH-3098(1)
Date of implementation: not provided

Regulatory Policy Committee

# Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters

## Department of Health

## RPC rating: fit for purpose

## Description of proposal

The Department proposes to amend existing legislation to permit the General Pharmaceutical Council (GPhC) standards for registered pharmacy premises to take the form of a code of practice (outcomes-based standards) supported by guidance, as opposed to legislative rules (rules-based standards). Under current legislation, the GPhC are required to develop a set of rules that stipulate in detail the requirements for pharmacists in England, Scotland and Wales to ensure that they deliver their services safely and effectively. The IA explains that the proposal would provide pharmacy owners with flexibility in how they ensure safe and effective service delivery, while avoiding unnecessary costs to business.

## Impacts of proposal

The Department explains that under current legislation the GPhC is required to re-develop a set of rules-based registered pharmacy standards. Therefore, the costs and benefits associated with the GPhC formulating a new set of rules-based standards forms the baseline "do nothing" option against which the proposed legislative change is assessed.

The Department explain that ongoing costs, under the preferred option will be lower than under the "do nothing" option. This is because the outcomes-based standards will provide businesses with the flexibility to choose the most cost-effective means of achieving a specified standard as opposed to having the means prescribed by the GPhC. The Department states that evidence gathered at consultation supports this analysis.

The IA states that the cost to business of familiarisation with outcomes-based standards will be negligible. Since November 2013 the GPhC have been rolling out a prototype system of outcomes-based standards which would form the basis for the outcomes-based system under the proposal. The Department explain that most businesses are already familiar with these prototype standards. This view is

supported by consultation evidence. The proposal may therefore result in significantly lower familiarisation costs to business relative to the "do nothing" option.

## Quality of submission

The proposal provides pharmacists with greater flexibility in how they meet the premises standards. As a result, the Department have not monetised any of the direct costs or benefits of the policy. However, the IA makes reasonable use of qualitative arguments supported by consultation responses from pharmacists to suggest that the proposal will be beneficial to business. Therefore, based on current working assumptions, the RPC can validate this measure as a qualifying regulatory provision with an EANCB of zero.

The final stage IA sufficiently addresses the points raised in the RPC's consultation stage opinion of 9 January 2015. The IA now provides sufficient discussion, based on feedback from pharmacists, that the outcomes-based standards approach is not burdensome on small and micro businesses. The Department explains that the proposals do not disadvantage small and micro business and no mitigation or exemptions from the policy are necessary.

The IA would benefit from a more thorough discussion of the connection between the prototype standards system and the proposal. In particular, if the prototype system was introduced in anticipation of the proposed legislative change then familiarisation costs incurred upon the roll-out of the prototype should be discussed in the IA.

Additionally, the IA would benefit from explicitly discussing whether the proposal will affect the extent to which pharmacy businesses meet the required premises standards. This is because the stated objective of the proposal is to reduce costs to business while ensuring safety standards are upheld. Hence evidence to support the view that these standards can be upheld under the proposed change would be beneficial.

The IA states that under the proposal the GPhC will introduce a new inspection model to support the outcomes-based approach. The IA would benefit from a more thorough discussion of how this will differ from the inspection model under the "do nothing" option.

The IA explains that the proposal is expected to be beneficial to business. This is because an outcomes-based system will provide businesses with flexibility to choose the most cost-effective way of upholding safety standards. The IA would benefit from explaining whether pharmacy owners will consider refraining from taking advantage of this flexibility. This may occur, for example, because doing so could reduce the

evidence pharmacy owners are able to supply to insurance companies and courts to prove that safety standards are being upheld.

Finally, in paragraph 75 of the IA the Department discuss the estimated £200,000 saving to the GPhC under the proposal alongside the estimated EANCB. This is potentially confusing since savings to the GPhC do not directly benefit business and hence do not pertain to the EANCB. Therefore, the IA would benefit from separating the discussion of these points.

**Initial departmental assessment**

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| Classification | Qualifying regulatory provision |
| Equivalent annual net cost to business (EANCB) | £0 million |
| Business net present value | £0 million |
| Societal net present value | £0 million |

**RPC assessment**

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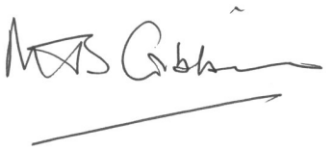
|---|---|
| Classification | Qualifying regulatory provision |
| EANCB – RPC validated | £0 million |
| Small and micro business assessment | Sufficient |



**Michael Gibbons CBE,** Chairman