OFF-PATENT DRUGS BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Off-patent Drugs Bill as introduced in the House of Commons on 24 June 2015 (Bill 14).

- These Explanatory Notes have been produced by Nick Thomas-Symonds MP in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill. So where a provision of the Bill does not seem to require any explanation or comment, the Notes simply say in relation to it that the provision is self-explanatory.

Overview of the Bill

1 This Bill aims to establish a process to enable off-patent drugs to be made routinely available when there is evidence of their effectiveness in new indications. An “off-patent" drug is one whose patent has expired and therefore is not subject to marketing protection. Other manufacturers can then make and sell the drug (but not under trademarked nomenclature).

2 An “indication” is a clinical use to which a drug is put; denoting the appropriate therapeutic treatment for a given condition, the route of administration, and the dose in relation to a specific patient population. An alternative way a drug can be used for a different defined purpose is a "new indication". An expired patent can reduce the incentives for a manufacturer to apply to license the drug for a new indication due to the cost/return ratio.

3 The result is that there may be new indications for which an existing drug is effective but for which it is not uniformly prescribed. This Bill seeks to remedy this situation by providing a route by which the new indication can be considered for a licence and a NICE technology appraisal. In doing so, it seeks to gain the national regulatory and financial 'stamps of approval' that, if achieved, usually result in a treatment being routinely prescribed and commissioned.

Policy background

4 There was debate of a similar Bill in the 2014-15 session during which the then Government was able to set out its policy approach. George Freeman MP, Parliamentary Under-Secretary, Department of Health, asserted that there was confusion between 'off-patent' (patent protection expired), and 'off-label' (used for indications outside of the terms of the licence). He argued that clinicians are perfectly able to use drugs for off-label purposes. Mr Freeman stated that the Government shared the aim of working to promote off-label use of medicines; the disagreement was on the mechanism to achieve that aim. He said that the lack of a licence for a new indication was not the restraining factor; the barrier was the lack of information for clinicians about off-label use.

5 The most recent references to Government policy in this area refer to work following a roundtable event for stakeholders on 11 February 2015 to discuss what action, could most expeditiously be taken to ensure that robust evidence about new uses for existing drugs is produced, disseminated and then used to inform clinical decision making about these medicines. In answer to parliamentary questions, the Government stated that a number of areas were identified where further work could help improve matters, including: supporting clinicians to identify the latest robust evidence on patient care and take it up in their own practice; and supporting and mapping clear pathways for innovators and those who want to "re-purpose" drugs. Since that event, "Officials have since been engaging with stakeholders to progress outputs associated with this event." (9 September 2015). Key stakeholders participating in this process include: charities, health professional networks, the General Medical Council, the National Institute for Health and Care Excellence and the Medicines & Healthcare products Regulatory Agency.

Territorial extent and application

6 The Bill would extend to England and Wales.

Commentary on provisions of the Bill

Part 1

7 Part 1 of the Bill requires the Secretary of State to take steps to seek licences for effective off-patent drugs in new indications by directly or indirectly (via a public body) taking on the role that drug manufacturers play when they are seeking to license new drugs. The Bill provides for delegated legislation to set out the detail of these requirements before the duty to seek a licence was triggered following consultation. It is envisaged that in practice this duty would be carried out by Business, Innovation and Skills' Ministers to prevent a conflict of interest arising between the Health Secretary's various responsibilities.

Part 2

8 Part 2 introduces a requirement for the Secretary of State for Health to direct the National Institute for Health and Care Excellence (NICE) to conduct technology appraisals for off-patent drugs in new indications and sets out a number of trigger criteria. There is an existing framework of regulations governing the clinical, administrative and financial implications of a NICE recommendation.

9 Part 2 is triggered, *inter alia*, where an off-patent drug in a new indication has been licensed under Part 1 of the Bill. The Secretary of State for Health may also direct NICE to conduct technology appraisals on unlicensed off-patent drugs in new indications in other circumstances. It is already possible within existing legislation for the Secretary of State for Health to direct NICE to conduct technology appraisals on unlicensed drugs. The Bill provides for delegated legislation to set out the detail of these requirements following consultation.

Part 3

10 Part 3 of the Bill contains self-explanatory technical provisions.

Commencement

11 The Bill would come into force 12 months after it having received Royal Assent in order to provide relevant bodies with adequate time to make preparatory arrangements.

Financial implications of the Bill

12 The Bill has no direct financial effects.

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