Off-patent drugs bill
BMA briefing
House of Commons second reading stage – 6 November 2015

About the BMA
The British Medical Association (BMA) is a voluntary professional association and an independent trade union which represents doctors and medical students from all branches of medicine all over the UK. With a membership of over 160,000, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare.

Background
The Bill would provide a route to market for off-patent drugs when used for a new indication, or treatment for a different condition. It costs money to get a licence to market a drug for a specific indication, but where a drug has gone off patent there is no incentive for a pharmaceutical company to pay for that licence. Once a drug has gone off patent it can be manufactured generically, limiting the ability of a particular company to control the market share and sell it at a profit. Where this happens there is no incentive for any pharmaceutical company to market the drug for the new indication and no proper governance mechanism for the use of that drug. Some doctors may use the drug if they know of the indication but some may not.

A licence for a drug is effectively market authorisation and is granted once the proper checks have been carried out to ensure that the drug meets high standards of safety and quality required. In the UK a licence can be granted by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA). The granting of a licence effectively provides a route to informing clinicians about that drug, and inform them of how it can be used.

The Bill is designed to overcome the current lack of commercial incentive to licence a drug when it is shown to be useful for a new purpose after its original patent has expired. It will also ensure a proper governance mechanism for off-patent drugs (including NICE appraisal and inclusion in the British National Formulary). The Bill could help in terms of consistency of prescribing and giving wider access to these drugs and avoiding the issue where some GPs are more prepared than others to prescribe off-licence drugs and take on the extra responsibility that entails.

The adoption of the Bill would be the government intervening and acting in the public interest to make the most out of available medicines.
The BMA notes two barriers to the use of off-patent drugs in a new indication:

1) **Clinicians confidence in prescribing:** clinicians take on a personal and professional liability if they prescribe an off-patent drug in a new indication therefore requires adequate reassurance.

2) **Awareness:** As drugs without a second-use patent are not marketed the prescribing of off-patent drugs for a new indication varies.

*We support the Bill as it would provide a route to market for off-patent drugs and a proper governance mechanism which would improve consistency of use for patients.*

**Second-use patents**

It’s not clear what impact this Bill will have in relation to second-use patents. Second-use patents exist to provide financial incentives to pharmaceutical manufacturers to seek alternative uses for medicines, while still allowing generics to be used for the original indication. In practice this means that a doctor can prescribe a generic version of a particular drug for the condition it was originally developed for. However, where a second-use patent has been granted for the treatment of a different condition, the branded version with the patent must be prescribed. This can create confusion for clinicians who may be aware of the dual use of the drug but unaware of the patent restrictions. In a recent case where a drug has been granted a second-use patent, the drug company wrote to pharmacists to tell them that generic prescribing of that drug for the second-use condition in question would be ‘unlawful’, and NHS England wrote to GPs to tell them to prescribe the branded version for the condition related to the second use patent.

Whilst we recognise the incentive for drug companies to undertake research regarding second-use indications, the current situation creates practical challenges and uncertainty for clinicians when prescribing. It also raises questions about cost-effective prescribing.

The BMA would like to see the practice of granting second-use patents ended.

**Encouraging greater off-label use**

Clinicians are currently able to prescribe drugs off-label but there are significant disincentives to do so. Guidance from the General Medical Council (GMC) states that a licensed treatment should be considered before an off-label or unlicensed treatment. The guidance also indicates a greater level of responsibility for the doctor prescribing off-label and therefore potential greater risk of liability which would be a disincentive for a doctor prescribing off-label drugs.

We support this Bill and believe that this legislation will increase appropriate off-label prescribing which could not be achieved under the current applicable guidance.

**For further information, please contact:**

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**References**

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