Off-patent Drugs Bill briefing

Context

Breakthroughs in research have meant that several existing drugs have been found to be effective in treating conditions other than the ones they were originally made and patented for. These drugs are known as “off-patent” drugs. Repurposing them could potentially have huge benefits for many people suffering from conditions like multiple sclerosis.

However they need to be licensed and approved for their new uses in order to be made available. There is little commercial incentive for pharmaceutical companies, who normally sponsor this process, to do so for off-patent treatments. This is largely because prices fall a great deal once a patent has expired.

Barriers to prescribing

More generally, there is no mechanism in place to enable licensing of drugs for uses other than their original purpose. Even if a GP strongly believed in prescribing an off-patent drug to a patient, they would likely be put off by the potential personal liability they may face in doing so.

These are the political, legal and commercial barriers in place against prescribing off-patent drugs. The Off-patent Drugs Bill seeks to overcome these barriers by obliging the Government to step in and ensure treatments are licensed and approved.

The Bill

In 2014, the former Conservative MP for Cardiff North, Jonathan Evans, introduced a similar Bill on off-patent drugs. The Bill gained widespread support from the public, clinicians and MPs across the House but unfortunately did not pass to Committee Stage because the Government did not choose to support it.

Now Nick Thomas-Symonds, the newly elected Labour MP for Torfaen has introduced this newer, refined version of the bill as a Private Member’s Bill. The crucial second reading will take place on Friday 6 November.

Part 1: Licensing off-patent drugs

The first part of the Bill requires the Secretary of State for Business, Innovation and Skills to work to secure licenses for using off-patent drugs in their new purposes. This only comes into effect after the drugs have been shown to be effective in their new purpose by a stage 3 clinical trial accepted for publication in a reputable journal. There is no requirement for the Secretary of State to fund these trials.
Part 2: NICE Technological appraisal and recommendation

Part two is triggered once an off-patent drug has been licensed and requires the Secretary of State to direct NICE to conduct technology appraisals for the drug and make recommendations for use. If NICE recommends using the drug it will become routinely available on the NHS.

Case Studies

These are just some of the many ways the Bill could really help save lives and money:

- **Preventing deaths from breast cancer** – Zoledronic acid (a type of bisphosphonate) shows new indications of preventing secondary breast cancer and could save 1,000 lives every year at a cost of less than 5 pence per day per patient. That’s around £80 per patient for the whole course of treatment. This alone would save the NHS millions of pounds every year.

- **Preventing breast cancer developing** – Tamoxifen costs 6p per day and raloxifene 61p per day. A 5 year course of either drug can reduce breast cancer risk by around a third in women who have an increased risk of the disease. Around 488,371 women could have their risk of breast cancer reduced if this treatment was made routinely available.

- **Slowing disease progression in multiple sclerosis** – If confirmed in phase 3 clinical trials, simvastatin – originally licensed for treating high cholesterol and the prevention of cardiovascular disease – would be the first drug that people with the secondary progressive form of MS could take to slow their disability progression. There are estimated to be around 65,000 people living with progressive forms of MS in the UK.

- **Potential benefit in Parkinson’s** – Simvastatin is also being considered as a potential treatment for Parkinson’s. Currently there is no cure for Parkinson’s, a degenerative neurological condition that affects nearly 130,000 people in the UK alone.

FAQs

1. **What is different about the Bill this time that could change the Government’s position?**

This new Bill is a refined version which speaks to the Government’s concerns that were raised last time:

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The Bill has been amended so that it simply mimics the process that a pharmaceutical company would normally use to license and approve a drug indication for use on the NHS.

The Bill has been amended so that there is no possibility it could create a conflict of interest for the Secretary of State for Health. Duties in the Bill have been shared with the Secretary of State for Business, Innovation and Skills in order to mitigate this.

The wording of the Bill has been altered to clarify that the MHRA is free to operate as they do at present and would not be mandated to award licences.

2. How is this different to the Access to Medical Treatments (Innovation) Bill 2015-16?

Chris Heaton-Harris (Conservative MP for Daventry) also won the Private Member’s Bill ballot and also put forward a bill dealing with accessing and using “innovative” treatments. Because it also tries to increase access to new and repurposes treatments some have suggested it negates the need for the Off-patent Bill.

However we, and other organisations supporting the Off-patent Bill, do not agree with this. There is no clear definition of “innovative” treatments in Heaton-Harris’s bill and it is not known whether this refers to off-patent treatments or not. This bill has also been criticised for undermining patient choice and data protection principles.

The Thomas-Symonds bill is, in our view, superior as it specifically addresses and details what treatments would be affected and how this process would work.

3. Can’t clinicians already prescribe drugs off-label?

Significant disincentives to prescribing off-label mean that an off-label treatment is unlikely to become routinely commissioned:

- General Medical Council guidance states that a licensed treatment should be considered before an off-label or unlicensed treatment. The effect of this guidance is that an off-patent, off-label treatment with the same level of evidence as a licensed treatment will only be considered as a secondary option.
- Guidance from the General Medical Council is clear that a doctor takes on an extra level of personal liability when prescribing off-label, which can be a significant disincentive to prescribing, especially where the doctor is not a specialist in that treatment area, and lacks confidence or knowledge on the new indication.
- If a treatment has a licence it is automatically included in the British National Formulary (BNF) which has a significant influence on prescribing behaviour amongst health professionals, in particular GPs.
An off-label indication does not make it into the BNF unless it has already become standard clinical practice. This creates a chicken and egg situation because it is unlikely to make it into standard practice if it is not in the BNF.

- In addition, the lack of NICE approval, in the form of a NICE technology appraisal, can be a significant barrier to getting an indication into routine NHS use (even if the treatment is cheap).

4. Who else supports this Bill?

The bill is supported by a number of charities including Alzheimer’s Society, Breast Cancer Now, Prostate Cancer UK, Leukaemia Care, The Cure Parkinson’s Trust, Breast Cancer Care and the Institute for Cancer Research.

Want to speak to someone or find out more?

Please get in touch with our campaigns team: campaigns@mssociety.org.uk