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BRIEFING PAPER

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Off-patent Drugs Bill 2015

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Summary

The Off-patent Drugs Bill 2015 is a Private Members' Bill tabled by Nick Thomas-Symonds after he came eighth in the Private Members' Bill ballot this year. It had its first reading on the 24 June and is tabled for Second Reading on 6 November 2015. It is the second Bill on the list for consideration on this day.

The Bill intends to address the situation where a drug that has an expired patent is discovered to be effective for a new indication that is not within the scope of its licence. It would require the Secretary of State:

- to seek licences for off-patent drugs in new indications; and
- to request the National Institute for Health and Care Excellence to conduct technology appraisals for off-patent drugs in new indications.

Nick Thomas-Symonds described the Bill and its intentions in an article for the *Independent* in July 2015.[1] He said that it would improve access to low-cost treatments for a range of conditions, including Parkinson's disease, Breast Cancer and Multiple Sclerosis.

A very similar Private Member's Bill was tabled by Jonathan Evans MP in the 2014 Parliament. This did not pass Second Reading. In responding to the Bill, the Under-Secretary of State for Life Sciences said that the Government agreed with the intention of the Bill but did not believe it was necessary, as doctors can already prescribe 'off-label' where this in the patient's best interests and there is no licensed alternative.

The Bill has support from a number of medical charities, including Breast Cancer Now, Multiple sclerosis Society UK and the Cure Parkinson's Trust.

[1] The Independent, *Introducing the Off-patent Drugs Bill will save lives- and millions of pounds*, 23 July 2015

1. Background

The Bill intends to address the situation where a drug that has an expired patent is discovered to be effective for a new clinical indication.

In summary, pharmaceutical companies apply for patents for promising molecules often during the early stages of the drug development process. This patent will generally last for 20 years. In order to be sold and prescribed in the UK a drug must be given a marketing authorisation (licence), and this will be for the indication (clinical use) for which the drug has been proven to be effective.

However, it is sometimes the case that later, when the patent on a drug has expired, and a number of pharmaceutical companies may be producing versions of the same drug (generics), that a new indication for the drug may be found. In these cases, there is little financial incentive for the pharmaceutical company to apply for another marketing authorisation for the drug. Doctors can prescribe drugs for indications that are not within the licence, this is called "off-label" prescribing, but only where they believe it is necessary to meet the specific needs of the patient and there is not a licenced alternative. Supporters of the *Off-patent Drugs Bill* suggest that this situation prevents useful, and often cheap drugs being used consistently and effectively.

Box 1: Off-patent Drugs

The charity, Breast Cancer Now have been actively supporting and campaigning for the *Off-patent Drugs Bill 2015*. They have produced a briefing note for the Bill and provide examples of drugs that they believe the Bill would improve access to:

> **"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.
>
> **Preventing deaths from breast cancer** – Zoledronic acid (a type of bisphosphonate) for its new indication of preventing secondary breast cancer could save 1,000 lives every year at a cost of less than 5 pence per day per patient (around £80 per patient for the whole course of treatment). This alone would save the NHS millions of pounds every year.
>
> **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.[2]"

[2] Breast Cancer Now, Off-patent Drugs Bill: Briefing note,

This section will provide further information about marketing authorisations, prescribing off licence and the role of NICE.

1.1 Marketing authorisations

Pharmaceutical companies can patent any substance that they believe shows promise during drug trials. This allows them to have exclusive rights over selling that molecule for a set period of time, usually 20 years. Once a drug is out of its patent period, other companies can develop and sell versions of the same medicine; these are referred to as generics.

Marketing authorisations are the European licensing system for medicines. Applications for marketing authorisations mainly come from the pharmaceutical industry, but anyone with the necessary supporting data may apply. There are several routes that applicants can take to obtain a marketing authorisation, at the EU and national level (in the UK this is through the Medicines and Healthcare Products Regulatory Agency (MHRA)).

Marketing authorisations are valid for five years and then may be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the marketing authorisation will be valid for an unlimited period unless there are justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal. In addition, there is a three-yearly cycle of Periodic Safety Update Reports (PSURs).

1.2 Prescribing off-label

New medicines are required to demonstrate acceptable standards of safety, quality and efficacy for use in the treatment of a particular condition, and a marketing authorisation defines a medicine's specific terms of use.

However, a doctor can, in certain circumstances, prescribe an unlicensed medicine or prescribe a medicine outside the terms of its license (known as prescribing "off-label"). In a response to a written Parliamentary Question in September 2014, the Parliamentary Under-Secretary for Business, Innovation and Skills outlined the approach of prescribers when considering prescribing off licence:

> Prescribers should always consider using a licensed medicine within the terms of its licenses as the first option. Where this approach does not meet the clinical needs of a patient, clinicians can prescribe a licensed medicine outside the terms of its license. Information to support clinical decisions on the use of medicines outside their licensed indications is available from sources such as the National Institute for Health and Care Excellence and the British National Formulary.[3]

General Medical Council (GMC) guidance, Good Practice in Prescribing and Managing Medicines and Devices (2013), states that doctors should

[3] Written question 207483: Mr Roger Godsiff 29-08-2014

usually prescribe medicines in accordance with the terms of their license. However, it says they may prescribe unlicensed medicines or prescribe "off-label" where, on the basis of an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient:

> **68. You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.**
>
> 69. Prescribing unlicensed medicines may be necessary where:
>
> a. There is no suitably licensed medicine that will meet the patient's need, for example, where:
>
> - there is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
> - a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
> - the dosage specified for a licensed medicine would not meet the patient's need; or
> - the patient needs a medicine in a formulation that is not specified in an applicable licence.
>
> b. Or where a suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply; or
>
> c. The prescribing forms part of a properly approved research project.
>
> 70. When prescribing an unlicensed medicine you must:
>
> a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
>
> b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
>
> c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.[4]

The Medical Protection Society[5] provide guidance on the responsibilities of doctors in these situations.

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4 GMC, Good practice in prescribing and managing medicines and devices, 2013
5 MPS, Prescribing, September 2012

A recent example of where doctors have raised concerns about limitations regarding the prescribing of an off-label drug is with the use of Avastin (bevacizumab) for the treatment of wet age-related macular degeneration. Avastin was used widely off label in the NHS before NICE approval of another similar drug called Lucentis (ranibizumab). This April 2015 British Medical Journal article reports that Avastin, despite being effective, and much cheaper than Lucentis, is now rarely prescribed by doctors and provides more information on this issue.[6]

A Parliamentary Question response from the Parliamentary Under-Secretary of State for Life Sciences in March 2015 outlines that that European legislation, as well as guidance from the MHRA and GMC prohibits the supply of an unlicensed drug when a licensed one is available, unless there is a special need:

> The use of unlicensed medicines to treat wet age-related macular degeneration (AMD) has been the subject of discussions between the Department, the Medicines and Healthcare products Regulatory Agency (MHRA) and other stakeholders over several years. We can confirm that we have recently received several letters from National Health Service commissioners regarding the unlicensed use of Avastin for the treatment of wet AMD, and a copy of my response is attached. We have also been in contact with the company that manufactures Avastin. We have stressed that clinical commissioning groups' commissioning policies must respect the European legislation and guidance from the General Medical Council (GMC) and MHRA that prohibits the supply of an unlicensed medicine where a licensed one is available, unless there is a "special need" which means that the unlicensed treatment is better suited to the clinical need of an individual patient.
>
> Recent discussions and correspondence with the MHRA and NHS England relate to the ongoing development of Government policy in this area. In order to maintain the delivery of effective Government, it would not be appropriate to publish information about the contents of these discussions or to place any related correspondence in the Library. Departmental officials have had no recent discussions on the use of unlicensed treatments for the treatment of AMD with the GMC.[7]

A letter from the Minister for Life Sciences, published alongside the question response highlights a European Court decision on this issue.[8] It reports that this decision confirmed that, under the EU Directive for medicines for human use, the prescribing of an unlicensed medicine must be for a special need, and that need must be a clinical need of an individual patient. However, the letter also confirmed that new NICE guidance on macular degeneration will refer to both Lucentis and Avastin.

1.3 The role of NICE

The National Institute for Health and Care Excellence (NICE) provides evidence-based information for the NHS on the effectiveness and cost-

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6 Deborah Cohen, *Why have UK doctors been deterred from prescribing Avastin?*, BMJ, 1 April 2015

7 HC Written Question 227588 Macular degeneration: Drugs, 23 March 2015

8 Letter from Under-Secretary of state for Life Sciences, 23 March 2015

effectiveness of healthcare interventions. It publishes mandatory technology appraisal guidance (stipulating clinical interventions – mainly medicines – which must be funded by NHS commissioners (primarily clinical commissioning groups (CCGs) and NHS England), as well as advisory clinical guidelines and public health guidance (which commissioners are not obliged to implement). CCGs are legally required to make funding available for drugs and treatments recommended by NICE as part of a technology appraisal within three months of NICE's final guidance being published.[9]

The *Health and Social Care Act 2012* established the statutory independence of NICE as a non-departmental public body (it was previously a Special Health Authority), clarified its role and functions and extend its remit to social care.

Part 8 of the 2012 Act sets out that NICE must give advice and guidance and provide information, and make recommendations on areas including medicines and treatment. The Act also provides for NICE to develop a suite of quality standards to support the NHS commissioning bodies and those providing NHS care.

Section 233(1) of the 2012 Act sets out the general duties for NICE and section 237 sets out its specific duties to provide advice, guidance, information and recommendations. The Explanatory Notes to the 2012 Act provide the following on these duties and the scope for the Secretary of State or the NHS Commissioning Board (NHS England) to direct the work of NICE:

> [Section 237] describes how, as well as preparing quality standards, NICE may be able, under regulations, to give advice or guidance, or provide information or make recommendations on matters relating to the provision of NHS services, public health services or social care in England. The guidance provided for in regulations could include guidance on new and existing medicines, treatments and procedures and treating and caring for people with specific diseases and conditions or with particular social care needs. Regulations might also provide for NICE to be able to publish or disseminate advice, guidance, information or recommendations to the NHS, local authorities or other organisations in the public, private, voluntary or community sectors on how to improve people's health and prevent illness and disease.
>
> The section gives the Secretary of State a regulation-making power to enable him to confer additional functions on NICE. *Subsections (2)* and (*3*) enable provision to be made for functions conferred on NICE by regulations to be exercisable only on or subject to directions of the Secretary of State or the NHS Commissioning Board in relation to NHS services, or the Secretary of State in relation to public health services or social care. The direction-giving powers ensure that either the Secretary of State or the Board will have the flexibility to commission work from NICE. However, neither will be able to direct NICE as to the

[9] http://www.nice.org.uk/aboutnice/whatwedo/niceandthenhs/nice_and_the_nhs.jsp

substance of its advice, guidance or information or recommendations (*subsection (4)*).[10]

NICE technology appraisals

As noted above, NICE technology appraisals assess the clinical and cost effectiveness of new and existing health technologies, such as medicines and pharmaceutical products. This process is intended to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are available. The process normally covers new technologies (typically, new pharmaceutical products or licensed indications) and enables NICE to produce guidance soon after the technology is introduced in the UK.

As part of their assessment NICE uses quality-adjusted life years (QALY) to determine the cost effectiveness of new treatments; this is assessed by looking at how many extra months or years of life, of a reasonable quality, a person might gain as a result of treatment. When combined with information about the prices of different treatments, these techniques can be used to guide decisions on how to maximise health benefits from the available resources.

The *Guide to Methods of Technology Appraisal*, describes the concepts and principles that underpin the Appraisal Committees' assessment of evidence and how they reach their decisions. The Guide applies to appraisals in both the single technology appraisal (STA) and multiple technology appraisal (MTA) processes. The current version of the Guide was published in April 2013. [11]

NICE and the "off-label" use of medicines

NICE does not issue guidance on the use of a medicine until after it has been granted a Marketing Approval and will not carry out a technology appraisal for a medicine outside its licensed indication. However, in October 2011, NICE announced that it would provide advice on the use, in special circumstances, of unlicensed and off-label uses of medicines. The summaries are the first nationally-available source of information for healthcare professionals and patients. They allow evidence-based prioritisation, treatment and funding decisions to be made where there are no clinically-appropriate licensed alternatives. The strengths and weaknesses of the relevant evidence are critically reviewed, but the summaries do not constitute formal NICE guidance; it is intended to inform decision-making by healthcare professionals (NICE does not provide a 'yes' or 'no' recommendation on the use of unlicensed or off-label medicines).[12]

10 Health and Social care Act 2012 Explanatory Notes
11 NICE, Guide to the methods of technology appraisal 2013
12 NICE, Evidence summaries: unlicensed or off-label medicines

2. The Bill

This Section will provides an overview of the content of the *Off-patent Drugs Bill 2015*. Explanatory notes produced alongside the Bill provide further information.[13]

2.1 Part 1: New licences for off-patent drugs

Clause 1 of the Bill seeks to place a duty on the Secretary of State to seek licences for medicines that are:

- Out of their patent period;
- Where there is a new therapeutic indication for that drug that is outside of the original licence; and
- No other organisation has sought a new licence for the indication.

This application must be made within 6 months of the Secretary of State being aware of the existence of the circumstances outlined above.

Clause 2 of the Bill sets out that the Secretary of State may require the Technology Strategy Board (Innovate UK) or any other such body to seek a licence for a new indication for a drug.

Regulation making powers under Clause 3 of the Bill allow for further requirements to be made before a duty to seek a new licence will be triggered. The explanatory notes to the Bill state that it is envisioned that a phase 3 clinical trial or meta-analysis of phase 3 clinical trials and acceptance of publication of these in a reputable journal may be one of these requirements.

A notable difference between the 2014 Bill and the current Bill is that it is intended that the duty to seek licences for off-patent medicines is placed upon the Secretary of State for Business, innovation and Skills rather than the Secretary of State for Health. This is to avoid any potential conflict of interest which had been an issue raised at the previous Bill's Second Reading debate.

2.2 Part 2: Conducting NICE technology appraisals for off-patent drugs

Part 2 of the Bill seeks to place a duty on the Secretary of State to direct the National Institute for Health and Care Excellence (NICE) to conduct a technology appraisal on an off-patent drug in a new indication. There are two outlined circumstances in which this duty will be triggered.

Clause 4 of the Bill states that where the Secretary of State has a duty under Clause 1 of the Bill (to seek a new licence for an off-patent drug) there will also be a duty to direct NICE to conduct a technology appraisal for this drug.

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13 The Off-patent Drugs Bill Explanatory Notes, 5 November 2015

Clause 5 of the Bill state that where there is no duty under Clause 1, there will still be a duty to refer to NICE for consideration of a technology appraisal in certain circumstances:

- Where there is a new indication for an off-patent drug and that indication does not fall within the existing licence; and
- The drug meets NICE's existing prioritisation criteria; and
- The drug meets the minimum requirements under Clause 5 of the Bill

Clause 5 of the Bill seeks to create powers for the Secretary of State to make regulations setting out the circumstances under which they will require NICE to conduct a technology appraisal. Clause 5 states that the Secretary of State shall consult organisations and people who are likely to represent interests that would be substantially affected by the regulations before making regulations.

It is the intention that the duty to refer to NICE to conduct a technology appraisal remains the duty of the Secretary of State for Health.

2.3 Part 3: General provisions

Clause 6 of the Bill states that the Secretary of State shall produce an annual report on the steps taken in the exercise of the duties under the Act. This annual report should be laid before Parliament.

Clause 7 of the Bill provides that regulations under the Bill would be introduced by Statutory Instrument, and will be subject to approval by both House of Parliament. The first regulations under the Bill are to be laid no later than 4 months after the Bill comes into force.

The Bill would apply in England, Wales, Scotland and Northern Ireland, except Clauses 4-5 which would only apply in England and Wales. The Bill would come into force 12 months after it receives Royal Assent.

3. The Off-patent Drugs Bill 2014

The *Off-patent Drug Bill 2014* was introduced by Jonathan Evans MP in the 2014 Parliamentary session. It was introduced on 2 July 2014 and had its Second Reading on 7 November 2014. The Bill went to a division at this time and 20 Members were in favour, with two voting no. The deputy Speaker then declared that because fewer than 40 members had voted, the business under consideration would be stood over until the next sitting of the house. In this situation, a Bill can be tabled for a further Second Reading but in this case, a further Second Reading did not happen.

At the Second Reading of the Bill, Mr Evans described the circumstances where he believed cost-effective drugs with new indications were not being made available:

> A licence gives a clear indication to GPs that a drug is both safe and effective, so it is preferable that indications that could achieve such a licence are supported. We face an unacceptable situation where cost-effective drugs are not made routinely available for new and proven effective uses. Although a small number of people might be fortunate enough to get the drug, a far greater number with exactly the same condition, in exactly the same clinical circumstances but with a different GP, will not. That is the worst form of inequality.

He highlighted access to the breast cancer drug Tamoxifen as an example of this. He stated that even following 2013 NICE guidance on the use of the drug for a new indication, equal access to it had not been achieved. Mr Evans said that the Bill sought to "*address a clear market failure in the current system and to allow proven drugs to be considered for a licence after their patents have expired.*"[14]

The Parliamentary Under-Secretary of State for Life Sciences, George Freeman responded at the Bill's Second Reading. He said that the Government supported the intention of the Bill but did not think it was necessary, as doctors can already prescribe medicines off-label where it in the best interests of the patient. He said the lack of licence was not the problem here, it was a shortage of information for clinicians on off-label prescribing:

> So that there is no doubt, let me say that our position is basically that the Bill is not needed. Anyone can apply for a licence for a medicine, and doctors can already prescribe medicines for uses outside their licence, where that is in the best interests of their patients. Doctors do so every day: when they make such a judgment, it is safe, legal and right for them to do so if they feel that they have a basis for doing so.
>
> The truth is that licensing gets a medicine licensed; it does not get it into clinical practice. Whether clinicians use the medicine is driven by NICE guidance, and doctors ultimately decide what is best for their patients. That is why pharmaceutical companies invest so heavily in promoting their products. In turn, NICE exists, as an independent source of advice in the NHS, to provide our

14 HC Deb 7 November 2014 c1110

> clinicians with independent, world-leading advice on the cost-effectiveness and the clinical cost-benefits of new drugs.
>
> If we want to accelerate the uptake of innovative medicines, I suggest that we focus our efforts on NICE guidance and on supporting our medical profession to adopt innovation. Our concern is that the Bill may, completely inadvertently, impede progress on that by making doctors feel that they should not use medicines except for their licensed indications, which is the opposite of the message that we want to send. I understand that that is not the intention of the Bill, but we believe that it might be an inadvertent side effect.

He went on to say that the Government were working with NHS England and NICE to improve guidance to prescribers:

> What are we doing? The Government believe that the real issue involves better informing and enabling clinicians to embrace new indications, not dealing with a supposed problem of licensing. We are taking steps with NHS England and NICE to support local drugs and therapeutics networks, and improve how they pick up new evidence and translate it into clinical practice. Indeed, one role of the NIHR is to gather data—that word again—on which drugs are working and on outcomes across the system, and to feed such information back into guidance that is continually updated.
>
> We are also working with hospitals and GPs to support them to work together on delegated prescribing, and to consider how they can change clinical pathways to reflect the very latest evidence across the system. The truth is that we need more evidence about what is working, and we are now gathering that evidence through the NICE associates network and our contacts with local clinicians. [15]

Mr Freeman also reported that the Department of Health would set up a roundtable event, with NHS England and NICE to discuss the issues and agree a strategy and timetable for action. A Parliamentary Question response on 27 October 2015 confirmed that this roundtable event had taken place. The Minister stated that the Government's position on the current Off-patent Drugs Bill and how they relate to issues discussed at the roundtable event will be shared at the forthcoming Second Reading debate for the Bill.[16]

Mr Freeman also expressed concern at the Second Reading debate in 2014 that the duty on the Secretary of State for Health to apply for new licences for medicines could represent a conflict of interest with his role as overseer of the medicines licencing system.[17] There has been a move to address this potential conflict of interest in the 2015 Bill. This intends to place a duty on the Secretary of State for Business, Innovation and Skills to apply for new licences for medicines, whilst maintaining that the duty to refer off-patent drugs to NICE remain with the Secretary of State for Health.

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[15] HC Deb 7 November 2014 c1114
[16] HC Written Question 13077: Breast cancer, 27 October 2015
[17] HC Deb 7 November 2014 c1120

4. Responses to the Bill

This section will provide an overview of some responses to the Bill, also included are some responses to the similar 2014 Bill.

The charity, Breast Cancer Now, is actively supporting the *Off-patent Drugs Bill*.[18] It has an ongoing campaign 'Unlock our drugs' that provides parliamentary briefing on the Bill and allows supporters to contact their MP to encourage them to support the Bill. The charity says that the Bill would saves lives and benefit people with a wide range of conditions, whilst also reducing the financial burden on the NHS.[19]

A number of other charities have expressed support for the *Off-patent Drugs Bill 2015*. These include the Cure Parkinson's Trust, the Multiple Sclerosis Society UK[20], and the Alzheimer's Society.[21]

Medical organisations have also expressed support for the Bill. The British Medical Association has said that it believes the Bill will "*increase appropriate off-label prescribing which could not be achieved under the current applicable guidance.*"[22]

On 30 October 2015, a group of clinicians, including the President of the Royal College of Radiologists, and the President of the Royal College of Surgeons of Edinburgh wrote a letter supporting the Bill to the *Telegraph* newspaper.[23] This letter said that the Bill had the potential to save lives and that it could benefit hundreds of thousands of people:

> The Government must act in order to address the widespread variation in access to low-cost, clinically effective treatments.
>
> On November 6, Nick Thomas-Symonds's Off-Patent Drugs Bill will be debated in the House of Commons. By reducing the barriers to the availability of repurposed drugs on the NHS, this Bill has the potential to save lives.
>
> We fully endorse the principles of this Bill and hope the Government will support it so that it becomes law. It could benefit hundreds of thousands of people – some of whom currently face limited treatment options – with a range of diseases, including cancers of breast, prostate, brain and blood, as well as multiple sclerosis, Parkinson's disease and Alzheimer's disease.
>
> It is vital to have a mechanism in place to ensure that drugs that have been shown to be clinically effective in a new way can be made routinely available to patients who need them.[24]

The Association of the British Pharmaceutical Industry produced a briefing on Off-label prescribing and the *Off-patent Drugs Bill 2014* in November 2014. In response to the 2014 Bill this said that the ABPI

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18 Breast Cancer Now, Unlocking Off-patent drugs
19 Breast Cancer Now, A parliamentary briefing on the Off-patent Drugs Bill 2015
20 MS Society UK, The Off-patent Drugs Bill update, 28 October 2015
21 Breast Cancer Now, Unlock Drugs
22 BMA Parliamentary Briefing, The Off-patent Drugs Bill 2015,
23 The Telegraph, Drugs 'costing pennies' could help those with breast cancer, Parkinson's disease and MS, experts say, 29 October 2015
24 The Telegraph, Letters: Barrier to treatment, 30 October 2015

supports improved patient access to medicines but that patients should receive the right medicines in a way that safeguards patient safety:

> The ABPI supports improved patient access to treatments whilst maintaining the integrity of the medicines licensing system, which supports the use of safe and effective medicines. We wish to see the right patients receiving the right medicine at the right time, in a way that safeguards patients' safety. This Bill highlights how, even after the expiry of a patent, new uses of a medicine may come to light that will need further evaluation. ABPI will engage with all stakeholders to explore further how best to advance the development of a medicine in this situation.[25]

25 ABPI, ABPI Brief on UK Medical Innovation Bill and Off-Patent Drugs Bill, 11 November 2014

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