

A NEW VALUE-BASED APPROACH TO THE PRICING OF BRANDED MEDICINES

Stockholm Network Submission to the Department of Health Consultation

Prepared by Paul Healy, Dr Meir Pugatch and Helen Disney

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Stockholm Network

35 Britannia Row

London, N1 8QH

<http://www.stockholm-network.org>

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## 1. Summary

In December 2010, the Department of Health launched a consultation to assist and support the decision to move to a new system of drug pricing for branded pharmaceuticals in the National Health Service (NHS).<sup>1</sup> Such reforms had been planned long in advance by the Conservative Party shadow health team in opposition,<sup>2</sup> even though only a brief mention of “reforming the way drug companies are paid for NHS medicines” was made in the Conservative Manifesto in 2010.<sup>3</sup> The reforms would see branded pharmaceuticals which were launched after 2014 being priced using Value-Based Pricing (VBP) and not by the Pharmaceutical Price Regulation Scheme (PPRS), the current price control mechanism used in the NHS. This document is the Stockholm Network’s submission to The Department consultation and also serves as a briefing note on the proposed reforms.

In summary, whilst the Stockholm Network<sup>4</sup> supports the reform’s proposed aims and their emphasis on better patient access to effective and innovative medicines, it has concerns about whether a move to VBP is the best way to achieve this. In particular, it notes that the proposals have the potential to be counterproductive and could, in fact, hinder pharmaceutical innovation in the UK as well as restricting patient access to medicines in the future. There is also unease at the

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<sup>1</sup> Department of Health - A new value-based approach to the pricing of branded medicines - a consultation. See [http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH\\_122760](http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_122760) (Accessed on 19 Jan. 11).

<sup>2</sup> Conservative Party. *Improving Access to New Drugs*, 2009. See <http://www.conservatives.com/~media/Files/Policy%20Documents/NICE%20Policy%20Document.ashx> (Accessed on 11 Mar. 11).

<sup>3</sup> Conservative Party. *Conservative Manifesto*, 2010, p47. See <http://www.conservatives.com/Policy/Manifesto.aspx>, (Accessed on 19 Jan. 11).

<sup>4</sup> It is important to note that the views that are expressed in this document are those of its authors and do not necessarily represent the corporate view of the Stockholm Network or those of its member think tanks.

imposed nature of these reforms, which have been formulated in opposition without adequate consultation with relevant stakeholders, and the seemingly top-down nature with which they are likely to be implemented.

The Stockholm Network hopes that this consultation will allow a more open dialogue to emerge and that the government is willing to revise the reforms to allow changes to be made to make them more practical and implementable.

## 2. The Stockholm Network

The Stockholm Network is the leading pan-European think tank and market-oriented network. It is a one-stop shop for organisations seeking to work with Europe's brightest policymakers and thinkers. Today, the Stockholm Network brings together more than 120 market-oriented think tanks from across Europe, giving us the capacity to deliver local messages and locally-tailored global messages across the EU and beyond.<sup>5</sup> Combined, think tanks in our network publish thousands of op-eds in the high quality European press, produce many hundreds of publications, and hold a wide range of conferences, seminars and meetings.<sup>6</sup>

The Stockholm Network's health and welfare programme has been established since 2005 and aims to expand the intellectual borders within which health policy debates take place. The programme studies a spectrum of health issues, including health technology assessment (HTA), healthcare reform in Central and Eastern Europe (CEE) and patient safety and comfort. A series of ongoing events, publications and newsletters are produced within the programme, which aim to highlight existing problems and map out possible solutions for policy makers. A particular focus of all our work is on comparative research between countries to see what we can learn from reforms tried elsewhere.

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<sup>5</sup> 128 members as of 11 March 2011 - an up-to-date list of all the member think tanks of the Stockholm Network can be found at <http://www.stockholm-network.org/The-Network/Think-Tank-Details>.

<sup>6</sup> Based on research conducted in 2007 and available in *The Stockholm Network Annual Report 2006/07*. See [http://www.stockholm-network.org/downloads/publications/SN\\_annual\\_report.pdf](http://www.stockholm-network.org/downloads/publications/SN_annual_report.pdf) (Accessed on 19 Jan. 11).

Recent publications<sup>7</sup> by the Stockholm Network that are relevant to the topics discussed in this consultation are:

- **Sharing the Burden: Could risk-sharing change the way we pay for healthcare?** (2010)

This paper examined and compared risk-sharing schemes in five key countries (Australia, Germany, Italy, the United Kingdom, and the United States);

- **Patient Safety and Comfort: The challenges of switching medicines** (2010)

This paper explored the practice of switching patients between different medicines or medical therapies and/or using different therapies interchangeably. It surveyed five countries (Canada, Spain, Sweden the United Kingdom and the United States) where switching and substitution policies are being actively used;

- **Weathering the Storm: Central and Eastern European healthcare in financial crisis** (2010)

This paper assessed the future for CEE healthcare reform in light of a financial crisis that has exposed the fragility of public budgets;

- **From Test Tube to Patient: National innovation strategies for the biomedical field** (2010)

This explored the issue of promoting biomedical innovation, particularly via national policy tools, analysing five categories of key components of biomedical innovation and discussing policy measures taken by a range of countries;

- **Europe's "Postcode Lottery": The challenge of central authorisation versus national access to medicines** (2009)

This paper examined in detail the state of the European pharmaceutical market as a whole and asks what impact European regulatory structures are having on patients' ability to access medicines promptly; and

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<sup>7</sup> All of these publications can be accessed online at: <http://www.stockholm-network.org/Publications>

- **Theory Versus Practice: Discussing the governance of HTA systems** (2009)

This paper explored the issue of governance of HTA systems, comparing the different systems in place in Australia, Canada, Germany and the United Kingdom.

### 3. Pharmaceuticals in the NHS

Pharmaceuticals are an important part of the treatment of patients in the NHS and pharmaceutical consumption has increased steadily in line with life expectancy over the last 40 years. By 2000, the UK pharmaceutical market had increased in value to almost £7 billion from just over £600 million in 1976<sup>8</sup>. Since then, it has continued to grow exponentially and by 2014 it is estimated to be worth £19.28 billion.<sup>9</sup> Meanwhile, over the same period, life expectancy has leapt from 72.8 to 79.9, for both sexes combined.<sup>10</sup>

Yet, although it is the case that the UK continues over time to consume a greater number of medicines it is not necessarily the case that spending on pharmaceuticals is growing as a proportion of the total NHS budget. In fact, pharmaceutical spending as a percentage of total health spending in the UK has decreased on average by 2.19% each year between 1999 and 2008.<sup>11</sup> Specifically, the “burden” of pharmaceutical spending on the NHS budget has dropped from 12.5% in 1999 to 9.8% in 2008.<sup>12</sup> Pharmaceutical spending overall works out at around 55p per person per day, which is less than the average person spends on alcohol.<sup>13</sup> In comparison to other major healthcare systems, this annual pharmaceutical spending level of £192 per person is significantly lower than Belgium (£263), France (£322) and the United States (£467).<sup>14</sup> As a percentage of GDP, UK pharmaceutical spending of 0.91% is also lower than levels in both France (1.53%) and Germany (1.22%).<sup>15</sup>

<sup>8</sup> World Health Organisation. *The World Medicines Situation*, 2004, Table 4.3. See <http://apps.who.int/medicinedocs/en/d/Js6160e/6.html> (Accessed on 11 Mar. 11)

<sup>9</sup> “UK’s coalition government has identified drug prices as an area of cost containment” in *The Pharma Letter* (17/02/11). See <http://www.thepharmaletter.com/file/102165/uk-coalition-government-has-identified-drug-prices-as-an-area-of-cost-containment.html> (Accessed on 14 Mar. 11).

<sup>10</sup> UN data - Life expectancy at birth, both sexes combined (years). See <http://data.un.org/Data.aspx?q=life+expectancy&d=PopDiv&f=variableID%3a68> (Accessed on 11 Mar. 11)

<sup>11</sup> Stockholm Network. *Sharing the Burden*, 2010, p12. See [http://www.stockholm-network.org/downloads/publications/Sharing\\_the\\_Burden.pdf](http://www.stockholm-network.org/downloads/publications/Sharing_the_Burden.pdf) (Accessed on 11 Mar. 11).

<sup>12</sup> OECD. *Health Data 2010*. See [http://www.oecd.org/document/16/0,3746,en\\_2649\\_37407\\_2085200\\_1\\_1\\_37407\\_00.html](http://www.oecd.org/document/16/0,3746,en_2649_37407_2085200_1_1_37407_00.html) (Accessed on 11 Mar. 11).

<sup>13</sup> ABPI. *Did you Know?* 2011, p6. See [http://www.abpi.org.uk/publications/pdfs/Did%20you%20know\\_Jan11.pdf](http://www.abpi.org.uk/publications/pdfs/Did%20you%20know_Jan11.pdf) (Accessed on 11 Mar. 11). See also, Office for National Statistics. *Family Spending*, 2010, p48. See [http://www.statistics.gov.uk/downloads/theme\\_social/family-spending-2009/familyspending2010.pdf](http://www.statistics.gov.uk/downloads/theme_social/family-spending-2009/familyspending2010.pdf) (Accessed on 11 Mar. 11).

<sup>14</sup> ABPI 2011, p8. Op Cit.

<sup>15</sup> Ibid.

One reason why UK pharmaceutical spending is relatively low is the high percentage of generic medicines prescribed in the NHS. Overall, 83% of NHS prescriptions are made for generic medicines and the competition that this creates is calculated as saving the NHS almost £7 billion every year.<sup>16</sup> As a result, the UK generic market is one of the biggest in Europe, in both volume and value. On top of this, further savings of £3.4 billion are expected for the NHS between 2008 and 2012 owing to a sharp “patent cliff”, which will see manufacturers of a number of successful “blockbuster” drugs lose their patent protection.<sup>17</sup> Conversely, whilst the NHS uptake of generic medicines may be high, its distribution of new innovative medicines is comparatively low.<sup>18</sup> A major reason for this is the role of the National Institute for Health and Clinical Excellence (NICE), which currently decides if medicines are eligible to be reimbursed in the NHS. Through NICE “guidances”, access to innovative medicines can be restricted whilst those that are approved for reimbursement are not often available until after a lengthy appraisal, many of which can take up to two years to complete.<sup>19</sup>

In truth, future healthcare needs will demand a greater uptake of innovative pharmaceuticals in the UK. They will also demand greater innovation from the pharmaceutical industry. An ageing society will place an immense burden upon the healthcare system, as older patients develop more diseases such as advanced stage cancer, which currently rely on more expensive medicines. In addition, the development of pharmaceuticals has also now allowed for the possibility of innovative personalised medicines, such as tailored therapeutics, which can make treatments more effective and comfortable for patients. Such innovation, however, will depend on significant levels of investment in research and development (R&D). It is encouraging that the pharmaceutical industry in the UK already invests more in R&D than any other industry, with this figure steadily rising each year. Some £12.1 million is invested in R&D every day by pharmaceutical companies in the UK, with the industry as a whole spending 36.3% of its sales on R&D - compared to only 8%

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<sup>16</sup> British Generic Manufacturers Association website - Key facts: Contribution of generic medicines in the UK. See <http://www.britishgenerics.co.uk/about-generics/key-facts> (Accessed on 11 Mar. 11).

<sup>17</sup> ABPI. *Annual Report 2009/10* p3. See <http://www.abpi.org.uk/publications/pdfs/AnnualReport0910.pdf> (Accessed on 11 Mar. 11).

<sup>18</sup> ABPI 2011, p5.

<sup>19</sup> Stockholm Network. *Theory versus Practice*, 2009, p55. See [http://www.stockholm-network.org/downloads/publications/Theory\\_versus\\_Practice.pdf](http://www.stockholm-network.org/downloads/publications/Theory_versus_Practice.pdf) (Accessed on 11 Mar. 11).

in the aerospace industry and 4.2% in motor vehicles industry (the nearest comparable investors).<sup>20</sup>

Taking all the above into account, it would be empirically unrealistic to expect that an entrenched rationale that aims to further decrease UK expenditure on pharmaceuticals as a whole, and specifically on innovative pharmaceuticals, can lead to improved and more effective access to medicines. Rather, it would seem that, given the comparative starting point of the UK, such a pursuit would inevitably result in a more pronounced shift towards rationing-based models. In particular, future demands on the NHS should encourage UK policymakers to concentrate efforts on ensuring a higher level of innovation and a greater, and more rapid, uptake of new innovative medicines, with the ultimate aim of improving patient outcomes.

#### 4. PPRS versus VBP

The UK's coalition government currently proposes to reform the pricing of pharmaceuticals in the NHS in order to achieve the goals identified above, i.e. a higher level of innovation and a greater, and more rapid, uptake of new innovative medicines, with the ultimate aim of improving patient outcomes. Specifically, the reforms will entail a shift from pricing through the Pharmaceutical Price Regulation Scheme (PPRS) to a new system of Value-Based Pricing (VBP). Both systems will now be briefly outlined, before they are compared to assess if the proposed reforms are likely to achieve their stated outcomes, looking in particular at innovation and patient access.

##### The Pharmaceutical Price Regulation Scheme (PPRS)

The Pharmaceutical Price Regulation Scheme (PPRS), first introduced in 1957, is an indirect price control mechanism that fixes maximum profits for drug companies which manufacture branded pharmaceuticals with annual sales to the NHS of more than £1 million.<sup>21</sup> The scheme is voluntary,

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<sup>20</sup> ABPI 2011, p11. See also, Office for National Statistics. UK Business Enterprise Research and Development, 2010. See <http://www.statistics.gov.uk/pdfdir/berd1210.pdf> (Accessed on 11 Mar. 11).

<sup>21</sup> Department of Health website - Introduction to pharmaceutical price regulation. See [http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH\\_4071841](http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH_4071841) (Accessed on 14 Mar. 11).

but the Secretary of State for Health has the statutory power to act against companies that fail to sign up. Individual profit frameworks are negotiated regularly by The Department and the Association of the British Pharmaceutical Industry (ABPI), with the current PPRS running from 2009 until 2014. The scheme takes into account sales made through pharmacies and self-dispensing doctors, as well as sales to NHS hospitals.

As part of the PPRS, the profit of each pharmaceutical company is restricted to a target annual return on capital (ROC) after allowances provided for research, marketing and administrative expenses. If its profit is higher than the approved amount, the company must either pay back the excess to the NHS or reduce the prices of their products. However, no company within the PPRS is guaranteed the target earnings set and there are tight restrictions on the increase of medicine prices. The current PPRS sets a common ROC target of 21%, with marketing expenses and information expenses restricted to 4% of turnover and R&D allowances of up to 28%.<sup>22</sup> The scheme allows for an “upper margin of tolerance”, where companies are able to retain additional profits that are strictly based on innovation, efficiency and competitiveness, and this is currently established at 140% of the target set. Conversely, there is a “lower margin of tolerance” that allows price rises to be considered if a company’s profit levels have fallen below a set percentage - currently 60% - with price rises considered when profits fall below 50%. In addition, agreements will often carry across-the-board price cuts agreed by the ABPI. The current PPRS deal, for example, saw two separate price cuts – 3.9% in 2009 and 1.9% in 2010.<sup>23</sup> The last agreement also incorporated the further use of patient access schemes, also known as risk-sharing schemes, which provide patients with provisional access to medicines that have been deemed too expensive for reimbursement by NICE.<sup>24</sup>

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<sup>22</sup> European Communities. *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, 2006, p756. See [http://ec.europa.eu/competition/mergers/studies\\_reports/oebig.pdf](http://ec.europa.eu/competition/mergers/studies_reports/oebig.pdf) (Accessed on 14 Mar. 11).

<sup>23</sup> Department of Health. *The Pharmaceutical Price Regulation Scheme 2009*, p19-20. See

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098498.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf) (Accessed on 14 Mar. 11).

<sup>24</sup> *Ibid.*, p14.

## Value-Based Pricing (VBP)

Advocates of Value-Based Pricing (VBP) believe it creates a closer link between the price the NHS pays and the value that a medicine delivers.<sup>25</sup> It works by determining a range of maximum thresholds that would be set to reflect the values that different medicines offer. Such “values” will be assessed by NICE and the benefits of medicines would be compared with the benefits that could be gained if the funds required were used to help patients elsewhere in the NHS.

These maximum thresholds would be adjusted to take into account two specific considerations. The first would be the “burden of illness” and would consider the severity of the condition that the medicine is treating and the level of unmet need of the disease area. Secondly, maximum thresholds would be established on the basis of “therapeutic innovation and improvement”, allowing for greater prices for new medicines that could represent a significant improvement relative to existing treatment. Both of these thresholds, in addition to the basic threshold, are likely to be expressed in cost per quality adjusted life year (QALY), which indicates how much extra length and quantity of life a person might gain as a result of treatment.<sup>26</sup>

## Analysing the PPRS and VBP

It is argued by the coalition government that the PPRS is not adequately stable or transparent, nor does it give clear signals about priority areas, so that research efforts are not currently directed to maximum effect.<sup>27</sup> Yet, the benefit of the PPRS seems to be that it has opened a regular dialogue between the government and the pharmaceutical industry, with this discourse now developed to a point where both sides better understand each other’s pressures. Evidence of this is seen in the pharmaceutical industry’s willingness to agree voluntary price cuts for the NHS and in the government’s acceptance of a greater number of patient access schemes. The PPRS has also shown itself to be predictable and flexible, allowing companies to know in advance what sort of

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<sup>25</sup> Department of Health. *A new value-based approach to the pricing of branded medicines*, 2010, p9. See [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_122793.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf) (Accessed on 14 Mar. 11).

<sup>26</sup> For example, 4 years lived in a health status of 1 (full health), 5 years lived in a health status of 0.8 (fairly good health) and 20 years lived in a health status of 0.2 (very poor health) are worth the same to the surveyed patients –  $4*1 = 5*0.8 = 20*0.2 = 4$  QALYs.

<sup>27</sup> Department of Health, 2010, p9.

returns they could expect from sales within the NHS and adjusting these in response to performance. It has also given assurances to industry about prices over a five-year period, which prevents the sort of *ad hoc* arbitrary price cuts that we have seen recently in other European countries, such as Greece.

The reasoning behind a move to VBP seems to be that a greater emphasis on the “value” of pharmaceuticals will allow for more innovative medicines to be rewarded at the expense of products that add little to the healthcare system. Yet, accurately determining the “value” of a medicine is likely to be incredibly difficult, as such an assessment would need to consider the savings that medicines provide to the NHS (e.g. in preventing diseases advancing to a point where expensive treatments are needed) and the importance of incentivising future innovations that continue the supply of public goods. In addition, it is also difficult for value to truly be appreciated when it is considered by a common currency, QALYs, which will only ever be compared with alternative treatments and technologies. Certainly, if many non-pharmaceutical costs in the NHS were measured by such a standard it is likely that considerable examples of low value for money would be uncovered. Therefore, if it ultimately proves problematic to accurately calculate the “value” of a medicine, then it is also unlikely that prices established by such a measurement will reflect their true value to society.

As part of a further analysis, the document will now look specifically at the prospects of innovation and patient access in a VBP system. In doing so, it will look at the likelihood that reform can achieve the stated objectives outlined earlier, i.e. a higher level of innovation and a greater, and more rapid, uptake of new innovative medicines, with the ultimate aim of improving patient outcomes.

### Innovation

It is clear that the PPRS is not allowing for a greater uptake in new innovative medicines in the NHS, at least in comparison with other major healthcare systems. This is because innovation is not

adequately rewarded within the NHS through the way it prices pharmaceuticals. The coalition government agrees with this assessment and believes that the solution is to differentiate between 'more valuable' and 'less valuable' pharmaceuticals products. In doing so, it focuses on incremental innovations, which it argues are more easily found and which it believes deter the type of significant investment that can achieve breakthroughs in performance.<sup>28</sup>

Yet, such an argument panders to the myth that a) incremental innovation is not real innovation and b) that pharmaceutical companies focus more on incremental innovation because of commercial convenience. In reality, however, all scientific progress, not least in the area of pharmaceuticals, is based on a foundation of looking for improvements to existing products. So-called "breakthrough" medicines are not created out of thin air, rather they rely on a gradual progression of discovery that necessitates incremental innovation.<sup>29</sup> In addition, continually improving medicines provides added benefits to patients, by improving safety, efficacy and side effects, as well as allowing for greater choice in available products – e.g. a single pill per day rather than multiple pills or more user-friendly drug delivery systems – which can vastly improve patients' quality of life. Therefore, whilst it is of course important to identify the most innovative medicines and reward them adequately, it is wrong to treat all other new products as worthless and assume that they offer no value for money to the NHS or improved quality of life for patients. Innovation should not be merely characterised as "good" or "bad" as this is too simplistic a distinction.<sup>30</sup>

It is also a mistake to believe that VBP in the NHS could change the focus of global pharmaceutical companies' R&D strategies towards areas of unmet clinical needs. The belief that varying levels of maximum reimbursement ceilings imposed by the UK government will incentivise industry to redirect its R&D investments does not take into account the current realities of the business model of biopharmaceuticals. The UK represents just 3.5% of the global market for pharmaceuticals and it is unlikely that global pharmaceutical companies will amend their long-term

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<sup>28</sup> Ibid, p9.

<sup>29</sup> International Policy Network. *Pharmaco-evolution: The benefits of incremental innovation*, 2005, p4. See <http://www.who.int/intellectualproperty/submissions/Pharmaco-evolution.pdf> (Accessed on 14 Mar. 11).

<sup>30</sup> Stockholm Network. *If it Ain't Broke, Don't Fix it*, 2008, p44. See <http://www.stockholm-network.org/downloads/publications/Innovation.pdf> (Accessed on 15 Mar. 11).

investment strategies in order to secure a higher maximum price in the UK market, particularly since such products will ultimately not enter the market for another 15 years.

Whilst it is clear that improvements need to be made to how the NHS rewards and encourages innovation, VBP does not offer a better way for doing this than the system which is currently in place. In fact, the reforms currently proposed are likely to focus unnecessarily on lowering the price of drugs that the government believes have no value. In doing so, VBP will reduce revenue for manufacturers and thus counterproductively decrease the amount reinvested in R&D. The reforms would also install a dangerous concept, whereby governments are relied upon to decide what the investment priorities of the pharmaceutical industry should be. It has always been difficult to predict future healthcare needs in order to accurately direct investments, yet to allow politicians to make such decisions could further muddy the waters. Industry should maintain a primary role in this respect as it is best placed to: a) anticipate the potential benefits and returns across global markets, b) compare this to the cost they will commit during the development process and c) decide whether it is right to risk private capital in such an endeavour.<sup>31</sup>

### Patient access

Ultimately, any reforms to the healthcare system should aim to improve outcomes for patients. In particular, the Conservative Party in opposition was very keen to shift the focus of the NHS towards measuring the actual outcomes patients experience as a result of their treatment, as opposed to targets focused only on narrow processes.<sup>32</sup> Their definition of an “NHS outcome” was the recorded result from the care that a patient experiences, for example long-term survival rates from cancer, which would move the NHS away from “top-down” government diktats.<sup>33</sup>

With respect to pharmaceuticals, reforms to the current system should have the definitive outcome for patients of broadening the availability of medicines, many of which have hitherto

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<sup>31</sup> Centre for Health Economics (University of York). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*, 2011, p15. See <http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP60.pdf> (Accessed on 15 Mar. 11).

<sup>32</sup> Conservative Party. *NHS Autonomy and Accountability*, 2009, p4. See <http://www.conservatives.com/pdf/NHSAutonomyandaccountability.pdf> (Accessed on 14 Mar. 11).

<sup>33</sup> Conservative Party. *Outcomes not Targets*, 2007, p15-16. Download <http://tinyurl.com/6c85bv3> (Accessed on 14 Mar. 11).

been unattainable for most patients in the NHS. Aside from the direct benefit that such medicines can have to individual patients, it needs to be appreciated that not allowing innovative medicines into the NHS jeopardises future R&D and trialling within the UK.

Unfortunately, the rationing of healthcare treatments has become a prominent feature of the NHS, as certain medicines have been made unavailable to patients because of a cost-effectiveness assessment made by NICE. In acknowledgement of the devastating effect that this can have for patients, the coalition government introduced a Cancer Drug Fund once it came to power. This fund “enabled patients to access the cancer drugs their doctors think will help them”<sup>34</sup>, providing an opportunity for drugs rejected by NICE to be provided on a short-term basis.

Yet, there seem to be very few guarantees from these reforms in regard to patient access. After all, the maintenance of pricing ceilings in itself implies that patients will still be denied medicines that are deemed too expensive. In fact, it is entirely plausible that the current basic threshold, of £20,000 to £30,000 per QALY, could remain the point at which the NHS refuses to reimburse drugs. In addition, the intention of terminating both the Cancer Drug Fund and patient access schemes once VBP comes into effect, does away with two safeguards that could have provided a short-term solution if patients continued to be denied treatments. Both of these schemes provide a “back door” to treatments when the system of pricing and reimbursement is unable to help patients, without which patient access could become more limited.

## 5. Policy Recommendations

Given the above-described gap between the stated intentions of pharmaceutical pricing reform and what is realistically going to be achieved, the Stockholm Network believes that the architects of a VBP system for pharmaceuticals in the UK should go back to the drawing board. Certainly, the principles behind reform are worthwhile and important and we recommend that such

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<sup>34</sup> UK Cabinet Office. *The Coalition: our programme for government*, 2010, p25. See [http://www.cabinetoffice.gov.uk/sites/default/files/resources/coalition\\_programme\\_for\\_government.pdf](http://www.cabinetoffice.gov.uk/sites/default/files/resources/coalition_programme_for_government.pdf) (Accessed on 14 Mar. 11).

standards be maintained in future. In particular, the following are welcome additions to policymakers' lexicon when discussing healthcare reforms:

1. When determining the current worth of pharmaceuticals to the healthcare system a wider assessment should be conducted than is currently the case;
2. Broader and in particular more rapid access to new innovative medicines needs to be achieved for patients in the UK; and
3. Physicians should be allowed greater autonomy to decide which treatments are appropriate in consultation with their patients (the move to GP commissioning is likely to be significant in this regard)

However, despite this, there are unfortunately a number of assumptions that policymakers would be wise to reconsider before embarking on healthcare reforms:

1. Pharmaceutical prices are unreasonably high and the NHS budget is unnecessarily burdened as a result;
2. Incremental innovation implies that manufacturers have turned their back on the risky pursuit of breakthrough innovation in favour of an easy commercial gain; and
3. The state is better placed than the market to determine which R&D investments are likely to result in worthy products that benefit the public good.

Moving forward, the Stockholm Network argues that such principles can be maintained and such assumptions may be dismissed without the need for the significant structural reform that VBP will engender. Whilst this submission is by no means a whole-hearted tribute to the current PPRS arrangement, certain merits of the PPRS deserve to be considered, given that this system has existed now for 54 years. In particular, it would be better if impetus for this reform was informed by constructive criticism from within the system itself. "Better the devil you know" in regards to the PPRS at least provides the platform upon which more targeted and delicate reforms may truly achieve their stated objectives.

## 6. Response to consultation questions

The document will now provide answers specifically to the questions laid out in the consultation document. As the Stockholm Network is an independent think tank and not a representative of the pharmaceutical industry, it will be unable to provide constructive assistance to the more technical questions, therefore it will only attempt to provide feedback in areas on which it has direct competence.

1. Are the objectives for the pricing of medicines set out in Section 3 of this document – better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS – the right ones?

It is our belief that these objectives are welcome additions to the lexicon of health policymakers. For too long now patients in the UK have been denied access to the innovative medicines that they need and which patients in many other European countries have been able to attain. Any reforms that aim to amend reimbursement in the NHS should first and foremost focus on this challenge in the system and endeavour to guarantee patients that the medicines which they and their physicians feel are necessary for them can be acquired. Furthermore, the UK should also be looking to establishing itself as a breeding ground for new innovative medicines, in line with the investment in R&D that already takes place within the domestic pharmaceutical industry. In doing so, the UK could significantly improve outcomes for patients and thus better realise the value that medicines have within the NHS and society at large.

7. Do you agree that – compared to the current situation – we should be willing to pay an extra premium to incentivise the development of innovative medicines that deliver step changes in benefits to patients but pay less for less innovative drugs?

It is of course important to identify the most innovative medicines and reward them adequately, therefore a premium upon the most innovative medicines would provide a useful tool for

acknowledging those innovations that significantly improve patient outcomes. Yet, it is wrong to do this at the expense of other products that are mistakenly assumed to offer no value for money to the NHS or improved quality of life for patients. Innovation should not be merely characterised as “good” or “bad” as this is too simplistic a distinction. Incremental innovations play an important role in the development of breakthrough medicines and can themselves offer additional benefits to patients. It is also a mistake to assume that global pharmaceutical companies are likely to amend long-term R&D priorities in favour of reform in one domestic market and that politicians are best placed to decide these priorities rather than industry itself.

10. What measure should we use to define the weightings? Options might include using the existing Quality Adjusted Life Years (QALY) measure, patient experience and expert opinions or some combination of these.

It is the Stockholm Network’s belief that the use of QALYs is too narrow a measure for deciding the value of medicines. Whilst QALYs may offer policymakers a convenient common currency to compare one treatment to another, they do not always take into account the multiplicity of medicinal benefits and the need to consider pharmaceutical value beyond simply what is currently available. The reforms accept the need for broadening the scope when assessing medicines, and this is welcomed, yet such extensions will be ineffective if they continue to be defined by such a narrow yardstick. Instead, wider assessments of value should be introduced in parallel with a greater range of measurements, which could be used to combine different elements of value during an assessment and before a decision of reimbursement.

12. What approach should be taken under value-based pricing where insufficient evidence is available to allow a full assessment of the value of a new medicine?

Stockholm Network research has shown that patient access schemes, or risk-sharing, could provide a useful interim measure for medicines that have as yet been unable to exhibit their effectiveness. However, such schemes should not look like the ones that have previously been

used in the NHS, as these have often been fig leaves for imposing price cuts rather than for widening access or increasing innovation. Instead, effective patient access schemes should truly appreciate risks on both sides of the negotiation and thus adequately address both price and performance concerns. They should allow the opportunity for manufacturers to prove that their products can provide benefit in “real world” situations and not simply be a method used by governments to obtain a discount. Effective patient access schemes like this would be a very useful complement to pricing reforms that adequately encourage innovation and broaden patient access. The Stockholm Network is therefore concerned to see that both patient access schemes and the Cancer Drug Fund will not be continued after 2014 and that no adequate measures have been proposed to protect patients who may be denied treatments.

16. Will the approach outlined in this document achieve the proposed objectives of better patient outcomes, greater innovation, a broader and more transparent assessment and better value for money for the NHS?

It is difficult to see the stated objectives of these reforms being realised whilst they continue to be based on mistaken assumptions. In particular, on innovation, a greater understanding of the pharmaceutical industry will encourage policymakers not to focus too strictly on always trying to obtain lower prices for pharmaceuticals brought about by incremental innovation. Furthermore, by accepting the realities of the global pharmaceutical business model, policymakers could find better ways to encourage greater innovation domestically. Finally, the ability of patients to access different treatments is unlikely to be achieved if policymakers take on an entrenched rationale that further decreases UK expenditure on pharmaceuticals as a whole, and specifically on innovative pharmaceuticals. Instead, they would do well to recognise the comparatively low price that the UK government is currently placing on pharmaceuticals, which ignores the high significance that they have in treating patients in the NHS. Without dispelling these assumptions it is hard to see the stated objectives being achieved to their full potential.