



# **International comparisons of Health Technology Assessment**

A report from Breast Cancer Now  
and Prostate Cancer UK

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We’re Breast Cancer Now, the UK’s largest breast cancer charity – and we’re dedicated to funding research into this devastating disease. We believe that if we all act now, by 2050, everyone who develops breast cancer will live.



Prostate Cancer UK has a simple ambition – to stop men dying from prostate cancer. Through shifting the science over the next 10 years to focus on radical improvements in diagnosis, treatment, prevention, and support, we will stop prostate cancer being a killer.

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**It must be noted that this report does not necessarily reflect the views of the researcher, the expert advisory group or anyone interviewed as part of this research.**

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# Foreword

Enormous progress has been made in cancer treatment over the last twenty years, with the development of a new generation of drugs which can dramatically extend the lives of people with cancer.

But patients in the UK are losing out. It has become clear that the health care systems in the UK cannot cope with the development of new, expensive drugs, and sustainable access to cancer drugs has become a major issue.

Our mechanisms for evaluating new medicines are, for many reasons, stalling their delivery to those that need them. Time and time again, effective new cancer drugs have not been approved for routine use on the NHS or are taking a very long time to get to approval. Patients are not seeing the benefits of scientific progress.

This is now of real concern. Breast cancer and prostate cancer are the two most common cancers in the UK, accounting for over a quarter of all cancer cases in the UK. Over 22,000 men and women are still losing their lives to these dreadful diseases each year, and it's essential patients have access to the most effective and innovative treatments.

We believe that looking overseas provides working examples of how we could improve our levels of access without straining budgets.

In this comparative report we set out to establish whether patients in other countries have better access to cancer treatments than in the UK, and, if so, how this is being facilitated. We compare three health systems in the UK (England, Wales and Scotland) with those in five similar countries: Australia, Canada, France, Germany and Sweden.

Our research shows that, whilst no country is perfect, there are elements of other systems which could improve access for patients in the UK. Patient involvement – already strong in the UK – needs to be translated into patient access. Price flexibility is key to improving access, and speeding up the appraisals process will also deliver results.

These changes are urgently needed. Already our drug appraisal system cannot keep pace with current developments, and as we move towards an era of more personalised medicine – tailoring treatments to individual patients – significant reform will be needed to ensure these cutting-edge treatments continue to be offered on the NHS.

Ultimately, we want the UK to stop playing catch-up and start leading the way. In 2012, the Government committed to making Britain the 'best place in Europe' to receive cancer treatment. To achieve this, we need to build on the access provided in England through the Cancer Drugs Fund and introduce a sustainable system that allows new drugs to be made available to NHS patients at prices acceptable to all parties.

We hope that this report will provide much-needed food for thought for our decision makers. Men and women with prostate and breast cancer in the UK – now and in the future – deserve better and faster access to new treatments.

Baroness Delyth Morgan  
Chief Executive, Breast Cancer Now

Angela Culhane  
Chief Executive, Prostate Cancer UK

**Price flexibility is key to improving access, and speeding up the appraisals process will also deliver results.**





**Nearly 90,000 people are diagnosed with either breast or prostate cancer every year in the UK.**

## Introduction

**Prostate and breast cancer are the most common cancers in men and women respectively.**

Breast Cancer Now and Prostate Cancer UK have been working for some time to improve access to effective and innovative cancer treatments.

Nearly 90,000<sup>1,2</sup> people are diagnosed with either breast or prostate cancer every year in the UK and more than 20,000 people die every year from these types of cancer. Prostate and breast cancer are the most common cancers in men and women respectively. It is essential that people affected by these diseases have access to the most effective and innovative treatments that have been developed, especially if we are to deliver the ambitions set out in the Achieving World-Class Cancer Outcomes: A Strategy for England 2015-2020<sup>42</sup>.

Health Technology Assessment (HTA) is the method used by the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) to assess the impact of new medicines and other technologies in order to inform decision making about the availability of the technology. As charities representing patients with breast and prostate cancer, we have become deeply concerned at the number of drugs being assessed by Health Technology Assessment (HTA) bodies in the UK that are not subsequently approved for routine use on the NHS or that have taken a very long time to reach patients because of a lengthy appraisal process.

With this in mind, the charities jointly commissioned independent researcher Leela Barham to carry out research into international HTA systems to explore whether their systems or processes achieved patient access in a way that could be replicated in the UK.

This short report reflects what Breast Cancer Now and Prostate Cancer UK believe to be the key points to be taken from the findings of this research. This report does not necessarily reflect the views of the researcher or others involved in this research.



# Our recommendations



## Patient involvement must be strengthened to ensure that it is meaningful and impacts upon patient access.

Bodies such as NICE, the SMC and the AWMSG should carry out work to ensure that patient involvement in HTA is meaningful and does result in better access.



## HTA should not be the be all and end all

We recommend that the relevant agencies make use of this research to look at the evidence from systems internationally and assess whether there is potential to reform the systems in the UK to ensure that HTA plays a key role but isn't the whole system.



## Price flexibility must be introduced to increase access to medicines

It is clear that more flexibility around pricing is a key component through which patient access could be increased and we therefore recommend that options for this should be explored further.



## The process must be faster to allow quicker access

We recommend that any reforms to the system consider the speed of the appraisal and appeals process with a view to ensuring it is both robust and fast.



Context

Access to cancer treatments in the UK has been a continuously moving feast for the last several years as we have seen the introduction of NHS England’s Cancer Drugs Fund, discussions around the potential implementation of value based pricing (proposals to assess drugs based on the value that they provide to patients and society), changes to the Pharmaceutical Pricing Regulation Scheme (PPRS – the voluntary scheme between the Government and the pharmaceutical industry governing drug pricing) and the recent removal of drugs from the Cancer Drugs Fund.

This report comes as proposals for the future of the Cancer Drugs Fund become a reality and while there is uncertainty about its ability to deliver patient access without wider systemic reform of NICE. It also remains to be seen whether treatment can be provided at prices that are affordable to the NHS while still being acceptable to the pharmaceutical industry.

When discussing access to cancer drugs in the four nations of the United Kingdom, it is natural to ask how other countries approach treatments’ access decisions. After all, cancer patients all over the world need access to new treatments and the pharmaceutical industry is a global industry.

Our report aimed to assess levels of access to cancer drugs in other nations and provide some insight into other systems and how they differ from the systems used in England, Wales, Scotland and Northern Ireland. The other nations analysed in this research are Australia, Canada, France, Germany and Sweden. These nations were chosen because they are developed countries, with an established and mature HTA, and being included in existing research comparing

access to cancer medicines. This research was conducted during the summer of 2015 and while efforts have been made to ensure that this is up to date, findings reflect that period.

The UK does not scrimp on expenditure on cancer drugs – in the period 2010-14, spend on oncology drugs on a per capita basis increased by 67%. This was the highest increase when compared to the US, Germany, France, Japan, Italy, Canada, Spain and Korea<sup>3</sup>. While these countries differ from those used in this report, the trends regarding access to cancer treatments in other countries compared with the UK remains the same, as demonstrated in the following table.

Table notes:

**Not found**  
indicates that details about the availability of a drug are not readily available.

**Non-existent**  
indicates that the drug is not considered to have clinical benefit – this is ASMR level V (as detailed in the description of the French system). The drug may still be available but only at a lower price than the comparator.

**Not proven**  
indicates that the clinical benefit of a drug is not yet considered to be proven.

**Added benefit**  
Drugs that are considered to have a degree of added benefit may be available – this will depend on price negotiation.

Status of selected breast and prostate cancer drugs across the countries studied.

	England	Wales	Scotland	Australia	Canada	France	Germany	Sweden
Abiraterone (Zytiga) for prostate cancer	Approved	Approved by NICE	Approved by SMC both before and after chemotherapy	Approved and subsidised	Approved	Considered to have minor benefit	Considered to have considerable benefit	Approved
Bevacizumab (Avastin) for breast cancer	Not available on CDF, not approved by NICE	Not approved	Not approved	Approved and subsidised	Not found	Not considered to have added benefit	Not found	Not found
Cabazitaxel (Jevtana) for prostate cancer	On CDF, restricted approval from NICE – under re-appraisal	Not assessed	Restricted approval – under re-appraisal	Approved and subsidised	Not found	Considered to have minor benefit	Hint of added benefit	Not found
Enzalutamide (Xtandi) for prostate cancer	Approved	Approved by NICE	Approved	Approved and subsidised	Approved	Non-existent	Considerable added benefit	Not approved
Everolimus (Afinitor) for breast cancer	On CDF, not approved by NICE	Approved	Approved	Approved and subsidised	Approved	Non-existent	Not approved	Not approved
Pertuzumab (Perjeta) for breast cancer	On CDF, not approved by NICE	Not assessed	Not approved	Approved and subsidised	Approved	Moderate benefit	Not proven	Not found
Radium-223 dichloride (Xofigo) for prostate cancer	Approved by NICE under restriction, with before docetaxel access provided by the CDF	Not found	Approved both before and after docetaxel	Approved but not yet subsidised	Not found	Not found	Not proven	Not found
Trastuzumab emtansine (Kadcyla) for breast cancer	On CDF, not approved by NICE	Not assessed	Not approved	Approved and subsidised	Approved	Important	Major added benefit	Not found
Eribulin (Halaven) for breast cancer	On CDF, not approved by NICE	Approved	Approved	Approved and subsidised	Approved	Non-existent	Not proven	Not found
Lapatinib (Tyverb) for breast cancer	Not approved by NICE, removed from CDF	Approved	Not approved	Approved and subsidised	Not approved	Non-existent	Not proven	Not found

Table accurate at the time of publication.

# Key points of other systems

Below is a brief overview of key elements of the other systems analysed in this research. This does not consider every factor that may impact the availability of new drugs but provides a brief outline of the key points.

## Australia



HTA is carried out by the Pharmaceutical Benefits Advisory Committee (PBAC).

Pharmaceutical companies have to pay a fee to PBAC per submission<sup>15</sup>.

PBAC makes a distinction between drugs that are considered superior to the comparator and those that are considered non-inferior<sup>16</sup>.

PBAC recommendations are used in negotiations between the Pharmaceutical Benefits Pricing Authority (PBPA) and companies. Products with a budget impact likely to be over AUS\$20million a year also need approval from the Cabinet of Australia<sup>17</sup>.

Approved drugs are then listed on the Pharmaceutical Benefits Scheme which provides government subsidised medicines, although patients still have to pay a contribution.

Research has shown no correlation between ratings and prices for cancer drugs<sup>31</sup>.

## Canada



HTA is carried out by the Pan-Canadian Oncology Drug Review (pCODR) which sits within the Canadian Agency for Drugs and Technologies in Health (CADTH). pCODR applies in all provinces except Quebec.

pCODR recommendations inform price negotiations which are done on a provincial basis.

Negative recommendations do not necessarily mean that the drug won't be made available – individual provinces may make the drugs available, either on their formulary or through special access programmes. Negative recommendations are likely to lead to price negotiations so that companies can secure a position on the formulary<sup>18,19</sup>.

Agreements on a provincial basis can bring benefits such as increasing access to new medicines. However, they can also raise postcode lottery issues between provinces<sup>20</sup>.





HTA is carried out by the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care or IQWiG).

IQWiG looks at clinical and cost effectiveness and makes recommendations to the Gemeinsamer Bundesausschuss (G-BA or Federal Joint Committee) who then make an assessment of a drug. G-BA has six months to produce their assessment and award a rating to the product. Drugs can be rated in the following categories:

- A. Major extent of benefit
- B. Considerable extent of benefit
- C. Minor extent of benefit
- D. Not quantifiable extent of benefit
- E. No additional benefits shown
- F. Benefit less than the alternative

G-BA ratings are used to inform negotiations between the National Association of Statutory Health Insurances to set a reimbursement price. The reimbursement price then replaces the list price<sup>22</sup>.



HTA is carried out by the Tandvårds- Och Lakemedelsformansverket (Dental and Pharmaceuticals Board or TLV). The TLV is responsible for setting the national price and reimbursement status of medicines<sup>23</sup>.

There is no predefined threshold for cost effectiveness. This is determined by disease severity<sup>24</sup>.

TLV recommendations are drawn upon to inform decisions on usage and budget made by the County Councils although County Councils<sup>34</sup> can reimbursement a drug not recommended by TLV<sup>35</sup>.

Although in theory there is free price setting in Sweden, in practice the system limits the level of price that is consistent with health needs and cost effectiveness<sup>35</sup>.

There have also been performance based risk sharing agreements in cancer, specifically for bevacizumab where the costs of use above a cap is covered by the company<sup>35</sup>.

There is debate in Sweden about variation in access to new cancer medicines arising from differences between the regions reflecting the responsibility of County Councils to fund new medicines<sup>25</sup>.





HTA is carried out by the National French Authority for Health (Haute Autorité de Santé – HAS).

Rapid HTA is conducted on drugs, focused on the assessment of added clinical benefits, the Amélioration due Service médical Rendu (ASMR). ASMR has five levels – from Level I (major clinical benefit) to Level IV (minor clinical benefit), with Level V implying no clinical benefit<sup>26</sup>. ASMR is the most important assessment for both pricing and reimbursement<sup>27</sup>. Efficacy of a drug and disease severity are particularly important criteria, which gives cancer drugs a high likelihood of obtaining reimbursement<sup>35</sup>.

HAS findings are considered mandatory and are used by the Comité Economique des Produits de Santé (CEPS) to inform price negotiations<sup>28</sup>.

Drugs with an ASMR rating of I to III can claim a price in relation to those in Germany, UK, Spain and Italy as well as waivers from special discount agreements. Drugs rated IV can secure a higher price than comparators if they can demonstrate cost savings, those with V have to accept lower prices than comparators.

ASMRs are granted by indication, so it's possible for a drug to have more than one ASMR. If this is the case, CEPS will negotiate a weighted net price based on the sizes of the different patient populations<sup>40</sup>.

## Are other systems better?

Drawbacks have been identified with some of the other systems analysed in this research.

Research has suggested that patients in Australia wait longer to gain subsidised access to cancer medicines than counterparts in UK, Canada, France and Germany<sup>29,30</sup>. It has also been suggested that HTA in Australia has failed to evolve in response to changes in the developments seen in medicines and diagnostics<sup>29,31</sup>.

There are debates around the system in Germany as well, particularly in relation to the guidance produced and evidence that IQWiG will accept. IQWiG has been criticised by industry for being 'vague' in the case of cabazitaxel for prostate cancer in 2012, which can make it difficult for companies to know what they need to submit to convince IQWiG of the benefits of their drugs<sup>32</sup>.

There has also been debate particularly around what matters to patients. In cancer, there have been different views expressed with the German Association for Haematology and Oncology regarding progression-free survival (PFS) as an important endpoint but G-BA disagreeing and often not taking PFS into account<sup>32</sup>.

Issues have been raised in both Canada and Sweden that price negotiation takes place at either a provincial or county council level and therefore inequities can result across the country<sup>30,37</sup>.



# Recommendations



## Recommendation 1: Patient involvement must be strengthened to ensure that it is meaningful and impacts upon patient access.

One of the key themes from the research is the involvement of patients in making decisions about access to cancer drugs. We believe there is much to be gained from involving patients in HTA – the decisions made in HTA directly affect patients and therefore patients should be included in this decision making process<sup>4,5,6,7,8</sup>. It has also been suggested that patient involvement in HTA may increase the relevance of research<sup>9</sup>, improve the quality of decision-making by considering the experiences of those directly affected by a condition or who have experience of a particular treatment<sup>3,10,11,12</sup> and bring greater transparency to the process, thus encouraging confidence in the decision<sup>9,13,14</sup>.

HTA agencies in the UK are widely regarded by many others internationally. Both NICE and the SMC involve patients at all stages of HTA. Out of the other HTA systems analysed for this research, only Canada had an equally robust system of patient engagement. The French HTA system does not include any patient involvement at all and the systems in Germany, Australia and Sweden include patient involvement but not to the same extent of those in the UK.

However, patient involvement is clearly not translating into patient access in the UK. Patients in the other countries studied for the report generally enjoy greater levels of access to cancer drugs than those in the UK. This research found that trastuzumab emtansine (Kadcyla) for secondary breast cancer is routinely available in Germany, Canada, Sweden and France. While it is currently available in England on the Cancer Drugs Fund, it was recently considered for delisting from the Cancer Drugs Fund and it has not

been approved by NICE, the SMC or the All Wales Medicines Strategy Group (AWMSG) meaning that it is not available in Scotland, Wales or Northern Ireland.

Patient groups such as Breast Cancer Now and Prostate Cancer UK believe that it is important for patients to be involved in the HTA process and that there should be evidence of how this contributes to decisions on patient access. NICE and the SMC are well regarded internationally in terms of their patient involvement processes and this is something that both organisations should be proud of.

However, it is natural to question the impact of patient involvement in HTA if it is not resulting in access to the drugs that patients need and say they want. This is particularly important when considering cancer treatments as many of those being assessed by HTA are intended for advanced forms of the disease. Patients who can speak knowledgeably about these treatments or what it is like to live with advanced cancer are people who have the disease and therefore have limited time left. These patients and the patient organisations who facilitate their involvement in HTA may therefore question whether this is a good use of time for people who have limited time left if it does not have the potential to impact on the outcome of HTA.

**So, we recommend that bodies such as NICE, the SMC and the AWMSG carry out work to ensure that patient involvement in HTA is meaningful and can enable better access.**



## Recommendation 2: HTA should not be the be all and end all

In the absence of short-term fixes like the CDF, the HTA processes in the UK determine whether or not a drug will be made available routinely on the NHS.

These assessments evaluate the clinical and cost effectiveness of a drug and make recommendations about whether paying for the drug is a good value for limited NHS funds. In other words, in practice the HTA becomes the whole system. When compared to other health systems, this fundamental role of HTA in the UK access systems appears to be unique.

In other countries which have better patient access, HTA plays a role but is only one part of a wider process. In most cases, recommendations from HTA agencies are used to inform negotiations between governments and pharmaceutical companies.

Negotiations also take other factors into account, such as overall budgetary impact, the extent of clinical benefit and severity of disease. Our research suggests a link between the role of HTA in the system and level of patient access.

**We recommend that the relevant agencies make use of this research to look at the evidence from systems internationally and assess whether there is potential to reform the systems in the UK to ensure that HTA plays a key role but does not become the whole system.**





### Recommendation 3: Price flexibility must be introduced to increase access to medicines

A key point of all of the other systems analysed in this research is the importance of flexibility around pricing. HTA systems in the UK allow for pharmaceutical companies to offer discounts to the NHS in the form of Patient Access Schemes. The prices offered through these schemes are confidential and do not impact on a drug's list price. Patient Access Schemes are usually offered when a company submits their product to an HTA agency in the UK for assessment but it appears that for many cancer drugs these schemes are rarely sufficient to allow drugs to be made available on the NHS.

In cancer, there is often scope for new cancer drugs to have therapeutic value well beyond their initial indication. This presents a challenge in determining the value that a new drug can bring at the time that the first indication is appraised. It is also more generally the case that a significant proportion of the value of new medicines is realised after patent expiry.

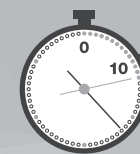
There is evidence of the changing value of cancer medicines over time. For example, in paclitaxel and docetaxel, researchers conclude that the incremental cost effectiveness ratio (ICER) of a drug can substantially decrease over the life cycle. That means that cost effectiveness at launch could be a poor indicator of the long term value of the drug. Long term follow up or real world evidence may show a treatment to be more cost effective than it initially seems. In addition, innovation in oncology is often seen in the form of small, incremental steps, and therefore decision makers should take a longer-term perspective when considering the value of new cancer drugs.

Systems in other nations have built price flexibility in to allow access to new and innovative treatments. For instance, in France, drugs are rated based on the clinical benefit they provide and ratings are granted by indication. Prices are determined by rating, meaning that the price is determined by the average benefit that the drug provides across indications. In Australia, recent changes have been made to the system to allow for managed entry schemes and pay for performance pricing arrangements.

The difficulties around assessing value of new cancer drugs suggest that this is an area where flexibility in pricing could be particularly beneficial. This could include allowing prices to be increased or decreased based on follow up data from trials or allowing different prices for different indications. These deals could be negotiated confidentially, thus protecting the list price which is used as a reference price for many other markets. This could have the impact of allowing new cancer drugs to be made available in the UK at prices that the NHS can afford, whilst still supporting the British pharmaceutical industry.

Proposals for the reform of the Cancer Drugs Fund do not appear to allow for any further flexibility on pricing and reimbursement and therefore it is likely that drugs will continue to fail to meet the cost effectiveness thresholds set out by HTA bodies.

**While this research did not analyse closely the mechanisms through which prices are negotiated in other countries, it is clear that more flexibility around pricing is a key component through which patient access could be increased and we therefore recommend that options for this should be explored further.**



### Recommendation 4: The system must be faster to allow quicker access

A frequent criticism of the NICE technology appraisal process is the length of time it takes. It is generally accepted that NICE appraisals take at least a year from start to finish and they do not always start at the point of licensing. When appeals are lodged, the process takes much longer than this.

For example, in the case of trastuzumab emtansine for metastatic breast cancer, the draft scope, (the first document in the process) was published on 4 April 2013. However, because of the length of the appeal process, the Final Appraisal Determination was not published until 17 November 2015<sup>38</sup>.

In other countries, including France, Canada and Sweden, there is a maximum time period between submission to the HTA agency and the publication of a recommendation. This varies between 90 and 120 days<sup>40,26,36</sup>. The new appraisal and funding system that will be brought about by reform to the Cancer Drugs Fund in England commits to NICE publishing final guidance within 90 days of marketing authorisation being granted<sup>41</sup>. It is now up to NICE to set out how it will resource this new commitment.

In Germany reimbursement is available at the point of licensing<sup>39</sup> and this is a key point of the new Cancer Drugs Fund<sup>41</sup> which we hope will match the early access to many drugs achieved by its predecessor. This is critical if patients in England are to experience the early access that patients in other nations enjoy and which is achieved through quick decision making.

**We recommend that any reforms to the system consider the speed of the appraisal and appeals process with a view to ensuring it is both robust and fast.**



# Conclusion

## The current system in the UK is not fit for purpose – we can learn from other countries

The current systems in the UK are not currently working for cancer patients – new and innovative cancer drugs are not being made available through the routine access route or are taking a very long time to become available. Patients in England have been able to access many new cancer treatments through the Cancer Drugs Fund. However, the future of the Cancer Drugs Fund is uncertain and access to those drugs currently funded through the Fund is unclear.

Recent changes to the system in Scotland mean that some new cancer drugs have now been approved for use on the NHS in Scotland. However, further work is needed to ensure that the Scottish system is sustainable. The Scottish Government has recently committed to carrying out a review of the system to ensure that cancer drugs can be made routinely available to patients who need them\*.

This research looked at other systems of access in France, Germany, Sweden, Canada and Australia to compare levels of access and different approaches to HTA.

While no system is perfect, there are certainly aspects of other systems that could be considered for implementation in the UK to improve levels of access. While systems in the UK are renowned for levels of patient involvement this does not appear to result in the increased access that patients need. Other systems allow flexibility in pricing and have greater access for patients. The UK should look to adopt more flexible pricing systems while still allowing for meaningful patient involvement.

## The UK should look to adopt more flexible pricing systems while still allowing for meaningful patient involvement.

\*More details on Breast Cancer Now and Prostate Cancer UK's positions in relation to the appraisal of end of life and orphan treatments in Scotland are contained in their responses to the Scottish Medicines Consortium Review during summer 2016. Available by contacting the charities directly.





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