Inquiry into progress made to date on implementing the Welsh Government's Cancer Delivery Plan: Sanofi response

4 April 2014

Sanofi welcomes the decision of the Health and Social Care Committee to undertake an inquiry into the Cancer Delivery Plan and the progress that it has made to date. This document sets out Sanofi's view on progress on the Cancer Delivery Plan, with a particular focus on the ambition to "deliver fast, effective treatment and care".

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

1. Monitoring of progress

1.1. We agree that accountability on the delivery of the Cancer Delivery Plan will be critical to assure its success. We therefore supported the ambitions set out in the Welsh Assembly last year that:

- Local Health Boards should publish their cancer delivery plans and annual reports on their websites to ensure public scrutiny of their plans.
- Local Health Boards should ensure that cancer services are timely, person-centred and that people's clinical and wider non-clinical needs, including access to financial advice and support, are met.
- The Welsh Government should provide annual updates to the National Assembly for Wales on the progress of the implementation of the Cancer Delivery Plan[1].

1.2. *Recommendation: The Health and Social Care Committee should ensure that plans are in place to regularly monitor and support scrutiny of progress on the Cancer Delivery Plan at a national and local level.*

2. Inequalities in access to effective treatment and care

The Cancer Delivery Plan made commitments to find and treat cancer quickly and effectively using the latest, effective drugs and technology and to speed up the introduction of known effective new treatments and technologies. Despite this commitment there remain inequities in access to treatment across Wales, as well as between Wales and other countries in the United Kingdom.

2.1. *Inequalities within Wales*

- For cancer medicines that have not been approved by the National Institute for Health and Care Excellence (NICE) the main funding route is through the Individual Patient Funding Request (IPFR) process.

- There are significant variations in IPFR approval rates between the different health boards in Wales. This runs counter to the former Health and Social Services Minister's stated desire for, "consistent and fair outcomes for patients throughout Wales."[2]

- The Rarer Cancers Foundation has highlighted that there was a 33% chance of getting a particular cancer drug in Cardiff compared to a 57% chance elsewhere in Wales[3]. There needs to be a greater degree of consistency in the delivery of cancer treatment across Wales.

- *Recommendation: The ongoing review of the IPFR process should seek to ensure consistency across health boards in Wales. This should focus on understanding the reasons why some health boards' fall below the national average in approving applications.*

2.2. *Inequalities across the United Kingdom*

- There are growing inequalities in access to cancer medicines between Wales and England. NICE develops guidance on cancer medicines that applies in both Wales and England. In recent years there has been an increase in the number of cancer medicines rejected by NICE. This led in 2010 to the introduction of a £200 million per annum Cancer Drugs Fund in England – providing access to medicines which were otherwise not routinely available. There are currently 41 medicines available on the Cancer Drugs Fund which clinicians can prescribe to their patients. No such access mechanism is available in Wales, and as a result of there is a growing inequality between patients in Wales and in England.

- NICE has launched a consultation on value based assessment. We are concerned that the proposals as set out may not improve the number of positive appraisals for cancer medicines by NICE and therefore render access to cancer treatment in Wales progressively worse should there be no reliable fall back mechanisms.

- *Recommendation: The Health and Social Care Committee should explore the potential implications of the proposed value-based assessment on access to cancer medicines in Wales.*

- There is research that documents the paucity of access to cancer medicines in Wales:

- A report published by the Rarer Cancers Foundation (RCF)[4] in 2011 found that there are now profound differences in the availability of newer cancer medicines between England and Wales. The report argued that people in Wales are five times less likely to get access to a newer cancer drug than their neighbours in England, and that comparable levels of access for people in Wales could be delivered at a cost of only £1 per person in Wales per year.

- Research from the University of Bristol concluded that patients with cancer in England are up to seven times more likely to be prescribed expensive cancer drugs than fellow patients in Wales. The researchers compared the prescription of 15 cancer drugs in both countries to show the divide created by the introduction of the CDF in 2010[5].

- *Recommendation: The Government should ensure that data on availability of cancer medicines in Wales is routinely collected and published.*

3. Improving access to cancer medicines in Wales

3.1. There are a number of ongoing reviews in Wales which could improve access to medicines in Wales and England. These include:

- Review of the appraisal of orphan and ultra-orphan medicines
- Review of IPFR process
- Update to the AWMSG appraisal process

3.2. In addition to the consistency of application of the IPFR process as set out above, changes are needed if the IPFR process is to support access to the medicines which clinicians wish to prescribe for their patients. A frequent criticism of the IPFR process has been its focus on the need to demonstrate clinical exceptionality i.e. 'is evidence supplied to explain why the clinical presentation of this patient is unusual and different to that expected for this disease and this stage of the disease? Is evidence supplied to explain why the clinical presentation means that the patient will gain a greater clinical benefit from the treatment than another patient with the same disease at the same stage?'[6] If this criteria remains in place following the current IPFR review then we are unlikely to see any increase in access. Scotland has recently reviewed their Individual Patient Treatment Request (IPTR) system and has recommended that it be replaced with a new Peer Approved Clinical System.

3.3. *Recommendation: The IPFR review should review and reform the exceptionality criteria. The negative human, and practical impact, it has on access should be assessed.*

3.4. We have welcomed the recent moves by the All Wales Medicines Strategy Group (AWMSG) to better understand and react to the inequalities caused by the Cancer Drugs Fund in England. The introduction of a new ability to submit applications to the AWMSG for medicines that have been turned down by NICE, but which have an alternative funding mechanism in England (for example the CDF), could offer an opportunity to reduce inequalities. Rapid implementation of the process will be necessary to successfully overcome these barriers. There should be an expectation that the process is able to increase the number of positive approvals of medicines.

3.5. *Recommendation: The All Wales Medicines Strategy Group should ensure that it has the resource to rapidly assess medicines that have been rejected by NICE.*

3.6. While each of the reviews highlighted above offers opportunities to improve access, there is no overarching strategy on access to medicines in Wales.

3.7. The recent review into access to medicines in Scotland resulted in an overarching strategy, with leadership from the Cabinet Secretary for Health and Wellbeing, which has now identified clear mechanisms for improving access to medicines in Scotland. Oversight for implementation remains with the Cabinet Secretary for Health and Wellbeing.

3.8. *Recommendation: The Government should undertake a comprehensive review of access to medicines in Wales – incorporating the HTA and IPFR processes, as well as medicines that currently fit into neither process. This should include consideration of the assessment of the measures that are being introduced in Scotland to improve access to medicines in Wales.*

4. Expenditure on treatment for cancer

4.1. The Welsh Government has argued that Wales spends £4.50 more per head of population than England on cancer treatment. However these figures have been challenged by the Rarer Cancers Foundation who found that the Welsh Government spends £1000 less per patient than England on cancer treatment. Further work is needed in order to fully

understand the current situation regarding expenditure on cancer patients in Wales, and how this compares with England.

4.2. *Recommendation: The Health and Social Care Committee should seek to understand the most up to date data on:*

- *Expenditure on cancer per cancer patient in each country in the UK*
- *Current expenditure on medicines verses forecast expenditure broken down by health board*

5. Targeting Research

5.1 Sanofi welcomes ambitions within the Cancer Delivery Plan to ensure Local Health Boards and NHS Trusts foster a strong culture of research, in particular to offer all appropriate patients access to relevant clinical trials. However, we are increasingly aware of examples where trial placement in Wales has not been possible due to standardized control-arm 'gold standard' treatments not being available. The short term implication of this is that appropriate patients cannot access innovative treatments and clinical trials. Longer term Wales' research portfolio and investments are at risk, together with the recruitment and retention of leading academics in Wales.

5.2 Programmes such as Commissioning through Evaluation[7], introduced last year in both Scotland[8] and England[9], aim to improve access to services which are not currently routinely funded by the NHS because the existing evidence base does not yet demonstrate sufficient clinical and cost-effectiveness. These programmes have facilitated patient access to treatments such as Selective Internal Radiation Therapy (SIRT). This type of programme has yet to be adopted in Wales and there have been no indications of commitment to, or timelines for, adoption.

5.3 The Welsh Government has made significant investments in initiatives such as the Wales Cancer Bank, the Cancer Genetics Biomedical Research Unit, the Experimental Cancer Medicine Centre, the Wales Gene Park, the Cancer Research UK centre, and the Cancer Registered Research Group. In addition, recent advances allowing clinicians to stratify patients on the basis of the molecular characteristics of their tumours provide the possibility of patients receiving targeted treatments with fewer side effects and better outcomes. However, investment in newer, targeted medicines in Wales needs to be symbiotic with this research investment to ensure that effective treatment, improved patient outcomes and further research opportunities are realised.

5.4 *Recommendation: The Health and Social Care Committee should seek to better understand the impact of access to medicines on trial viability in Wales through formal discussions with clinicians and researchers.*

5.5 *Recommendation: The Minister for Health and Social Care should commit to the introduction of a form of commissioning through evaluation in line with the rest of the UK so that patients have fair and equitable access to agreed treatments via this route.*

5.6 *Recommendation: The Government should develop and deliver a policy on Stratified Medicines including the commitment to improve access to targeted medicines in line with research advances.*

[1] Welsh assembly debate, 12/06/13

[2] 'Exceptional Cymru? An audit of the progress made in improving access to treatment for people with rarer cancers in Wales' by Rarer Cancers Foundation, April 2011

[3] BBC Radio interview with Rarer Cancers Foundation, 17/10/2013

[4] 'Nations divided? - An assessment of variations in access to cancer treatments for patients in England, Scotland and Wales', by Rarer Cancers Foundation, August 2011

[5] 'Cancer prescribing in England and Wales: the impact of the CDF' by C. Chamberlain, S. M. Collin, P. Stephens, J. Donovan, A. Bahl and W. Hollingworth in British Journal of Cancer

[6] 'All Wales Policy on Individual Patient Funding Requests IPFR Decision Making Guide', by Cardiff and Vale University Health Board, September 2011

[7] NHS England, (6 March 2014), 'NHS England expands its innovative Commissioning through Evaluation programme. Available online at: http://www.england.nhs.uk/2014/03/06/comm-eval/ [Accessed 3 April 2014]

[8] NHS Scotland, (21 November 2013), 'NHS National Services Scotland 'Innovative Radiotherapy Funding Approved'. Available online at: http://www.nhsnss.org/supplementary_pages/news_detail.php?newsid=260 [Accessed 3 April 2014]

[9] NHS England, (20 November 2013), 'NHS England announces hospitals chosen to take part in new initiative aimed at increasing access to radiotherapy'. Available online at: http://www.england.nhs.uk/2013/11/20/sirt-comm/ [Accessed 3 April 2014]