Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **Access to Medicines**

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This Written Statement explains the Welsh Government's approach to ensure people in Wales can access innovative and cost-effective medicines. It also serves to announce the outcome of the review commissioned into the Individual Patient Funding Request (IPFR) process.

Demand for healthcare continues to increase and the emergence of new and very often high-cost medicines places further pressures on our finite resources. The challenge is to make sure we only invest in medicines where the proven benefit is in balance with their cost, thereby ensuring we do not invest in medicines not proven to deliver high-value outcomes. This is why we must also take an evidence-based approach to determine which treatments should be routinely available in the NHS. It provides everyone with assurance investment is focused on bringing about clear health, social and economic benefits, regardless of what disease they or their loved ones have the misfortune to suffer.

To deliver this evidence-based approach we invest substantially in our own medicines appraisal process, which is undertaken by the All Wales Medicines Strategy Group (AWMSG). Its work complements that of the National Institute for Health and Care Excellence (NICE) and brings together an expert panel of health professionals, scientists, patient advocates, the pharmaceutical industry and lay representatives to assess new and existing medicines to ensure evidence-based, cost-effective medicines are available to all people in Wales.

AWMSG and NICE provide authoritative and expert advice on the management of medicines. To date, AWMSG has issued guidance on 205 medicines, of which 167 have been approved for use in the NHS in Wales. Some of these medicines were appraised in advance of NICE guidance and clearly demonstrate we have an effective, evidence-based process to make new medicines routinely available. The success of this approach has been confirmed in a recent study by Chamberlain et al, which compared access to cancer medicines in England and Wales. Published in the British Journal of Cancer in February 2014, the findings included:

- Wales had a faster uptake of the medicines most recently launched and subsequently recommended by NICE;
- Medicines deemed not cost-effective by NICE were more frequently prescribed in England than in Wales;
- The Cancer Drugs Fund in England did not expedite access to new cost-effective cancer medicines when compared to Wales;
- In England there is provision of less-evidence based treatment and/or more unlicensed treatment, when alternative, more cost-effective treatments exist.

To adopt an evidence-based approach informed by rigorous appraisal requires the pharmaceutical industry to engage with AWMSG. To improve the likelihood of a favourable appraisal outcome by AWMSG we established, in April 2012, a Wales Patient Access Scheme. This helps to ensure cost discounts on new medicines can be considered by AWMSG during its appraisals and further opens up the opportunity for more new, cost-effective medicines to be routinely available in Wales. To date, seven new medicines have been made available using this scheme and we are looking at how to encourage more pharmaceutical companies to participate and offer medicines at a cost in line with their clinical outcomes.

The conventional approach to appraising medicines has proved challenging in respect of rare diseases where patient numbers are very low. These medicines are normally referred to as orphan and ultra-orphan medicines. While the NICE highly specialised technologies programme aims to cover some ultra orphan-medicines - and the intention is to adopt this advice where appropriate - there remains a gap in developing the evidence base for orphan and ultra-orphan medicines. This is why a review of the appraisal process for these particular treatments has been commissioned. The report has been consulted on and the chair of AWMSG has been asked to undertake the work required to develop and implement a whole-system approach to the identification, appraisal and monitoring of this group of medicines; the aim being to ensure that patients with rare diseases have fair and equitable access to appropriate, evidence-based treatments

The report into the appraisal of orphan and ultra-orphan medicines and a summary of consultation responses received is available at:
http://wales.gov.uk/topics/health/publications/health/reports/orphan/?lang=en

I am also pleased to announce the early access to medicines scheme, which has been developed by the Medicines and Healthcare Products Regulatory Agency (MHRA), will apply in Wales. It will make a small number of new medicines available at the earliest possible stage where the MHRA has advised they are safe and it is appropriate to do so. The scheme is aimed at new medicines which will treat serious or life-threatening diseases where no effective treatment currently exists.

Where a medicine or treatment has not been appraised or approved for use in the NHS in Wales, a clinician can apply for it to be made available under the IPFR

process[1]. This process allows access to treatments where there is clear evidence a patient will benefit because of some exceptional clinical circumstances.

In October last year, I commissioned a review of the IPFR process to ensure the system is robust and working properly. The review group has now completed its work and concluded it does support rational, evidence-based decision making for medicine and non-medicine technologies which are not routinely available in Wales.

The group has also made a number of recommendations to strengthen the IPFR process, including enhanced transparency and inter-panel consistency. Its report is available at http://wales.gov.uk/consultations/healthsocialcare/funding/?lang=en and we will now carry out an eight-week public consultation into the group's recommendations.

Taken together, the elements outlined above provide a comprehensive and coherent appraisal to the complex and challenging issue of determining access to new treatments in Wales, which are rooted in evidence, shaped by clinical outcomes and tested against the core principles of openness, fairness and consistency.

[1] The IPFR process covers both medicine and non medicine technologies