STATEMENT
BY
THE WELSH GOVERNMENT

TITLE The Individual Patient Funding Request Review

DATE 21 March 2017

BY Vaughan Gething AM, Cabinet Secretary for Health, Well-being and Sport

Last July I announced the establishment of an independent review of the IPFR process. The purpose of the review was to look afresh at the clinical criteria, usually referred to as "clinical exceptionality", used to make IPFR decisions and the potential to reduce the number of IPFR panels in Wales.

My approach to this review has been to be open, inclusive and transparent from the outset involving all political parties, the public and the NHS in Wales. For example:

- Health opposition spokespeople have been fully involved in the whole process, including briefing sessions with the chair of the review group at the outset and conclusion of the review;

- The patient perspective featured strongly – two patients were members of the review group and discussion sessions were held across Wales for patients, their families and carers and patient organisations; and,

- The pharmaceutical industry, health boards and clinicians participated fully giving their views on how the process could be improved.

I published the report in January as soon as it was available to provide everyone with the earliest opportunity to consider the findings and recommendations. In parallel, my officials have been discussing the report with health boards, the

Association of the British Pharmaceutical Industry (ABPI) Cymru Wales and our medicines experts at the All-Wales Therapeutics and Toxicology Centre (AWTTC).

The consensus is that this is a helpful report that makes thoughtful and pragmatic recommendations that will help health boards to deal with what are sensitive and very often complex decisions. I am particularly pleased that the patient voice has centre stage in the report.

I will now deal with the review group's recommendations on the issues they were asked to consider:

Clinical Exceptionality

Clinical exceptionality has been the underpinning principle upon which IPFR decisions have been made across the UK. It is not a well understood concept and is open to varying interpretation. This is discussed fully in the report with practical recommendations to reform the IPFR decision criteria which have been broadly welcomed.

The proposed changes cover situations where there is a recommendation from the National Institute for Health and Care Excellence (NICE) or the All-Wales Medicines Strategy Group (AWMSG) and where a recommendation from NICE or AWMSG has not been made. The review group recommends a new two-part test covering:

- Significant clinical benefit to the patient; and,
- Value for money.

This means assessing the degree of clinical benefit expected by the treatment and whether the cost of the treatment is in balance with the expected benefits.

Number of Panels

In relation to whether the number of IPFR panels should be reduced, the review group concluded the risks inherent in moving to a single panel or reducing the number of panels negated any compelling argument for change. The review group has however, made other helpful recommendations to support health boards in making further improvements to the process. This includes clarifying commissioning policies and embedding IPFR policy within those frameworks and

strengthening the central expert support, quality assurance and governance function of the AWTTC.

Implementation

Health boards, supported by AWTTC, have already begun the initial work to reform the clinical decision criteria with the aim of making this change to the guidance by May. Today, I have written to health board chairs to confirm the arrangements for implementing all of the recommendations by September.

Health boards will always have to make difficult choices about the relative clinical benefits versus the cost and value for money at an individual patient level, balanced against the health needs for their local population. IPFR decisions will therefore always be sensitive. However, taken together, all of the recommendations when implemented will have a positive impact on the IPFR process, making it more easily understandable and less prone to being misused.

The IPFR process has a place within the policy framework for access to treatment for relatively small numbers of individuals. For the majority of the population, we will continue to place the appraisal process at the centre of our evidence-based approach; ensuring people have access to clinically and cost effective treatment. The new £80 million treatment fund I announced in January supports this approach by providing earlier access to new, medicines recommended by NICE or the AWMSG.

The review group endorses our policy position of placing appraisal at the heart of decisions on the routine availability of treatment. They also highlight the importance of appraisal as the best way to evaluate clinical effectiveness and value for money. In particular I welcome their recommendation that the pharmaceutical industry should submit their medicines for appraisal as soon as possible after licensing to ensure a timely and transparent appraisal of the clinical benefits.

We have a good relationship with industry and the Association of the British Pharmaceutical Industry (ABPI) Cymru Wales. The ABPI and individual companies engage with us and AWMSG on the appraisal agenda and the wider new medicines work. The ABPI contributed to the review group's work and are supportive of implementing the report's recommendations. I will continue to support and encourage industry to work with us and the NHS in Wales to ensure the earliest possible access to innovative treatments.

I would like to finish by thanking the review group for their effort and commitment in tackling a highly complex area, compassionately and intelligently and delivering their recommendations within a challenging timeframe.