



Your Ref: P-04-527

11th September 2014

Mr William Powell AC/AM
Chair, Petitions Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA

For the attention of Stephen George, Committee Clerk

Dear Mr Powell

I refer to your letter dated September 2014 requesting further information on the All Wales Medicines Strategy Group's (AWMSG's) appraisal processes for evaluating cancer medicines.

The remit of AWMSG is to advise the Minister for Health and Social Services on the managed entry of all newly licensed medicines, or licence extensions of existing medicines, for use within NHS Wales. AWMSG takes into account the future work programme of the National Institute for Health and Care Excellence (NICE) when considering whether a medicine will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intends to publish final technology advice (Single Technology Appraisal or Multiple Technology Appraisal) for the same medicine and indication(s) within 12 months of the date of marketing authorisation. AWMSG advice is interim to that of NICE, should NICE subsequently publish final technology appraisal advice. Exceptions to this rule have been made on occasions when there has been a request by clinicians for mandatory advice ahead of NICE: For example, the prostate cancer medicine, abiraterone, was routinely available to patients living in Wales four months ahead of patients living in England.

In January 2014 AWMSG adopted a new approach intended to address some of the issues relating to equity of access in relation to new medicines for patients in Wales. It applies in circumstances when the National Institute for Health and Care Excellence (NICE) does not recommend a medicine for use within the NHS on the grounds of cost-effectiveness and the medicine is subsequently funded within England via alternative national commissioning routes (including the Cancer Drugs Fund). An opportunity now exists for the marketing authorisation holder to make an application for the medicine to be appraised by the All Wales Medicines Strategy Group (AWMSG). The application must include a Wales Patient Access Scheme (WPAS), but may also include additional information which may not have been submitted to NICE, or information specific to NHS Wales (perhaps highlighting a specific patient population or other societal benefit/s).

It is important that any 'additional evidence' showing added value or benefit to NHS Wales over and above that considered by NICE is clearly identified, highlighted by the marketing authorisation holder, and reflects the context of an AWMSG appraisal which applies clinical and cost-effectiveness, in addition to a broad strategic, societal and patient perspective to its recommendations. It is also important that confirmation and full details of the alternative funding route within the NHS in England is provided. This approach has been implemented and will be reviewed by AWMSG in March 2015.

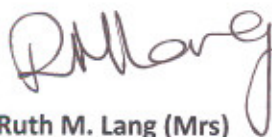
In advising whether a medicine should be routinely available, AWMSG takes into account evidence of clinical-effectiveness, cost-effectiveness, clinical expert and patient/patient carer views, in addition to societal and budget impact issues. The appraisal process is open, transparent and robust - the holder of the marketing authorisation (normally the applicant company) submits their best available evidence to support the use of the medicine, has opportunity to comment on the critique of the evidence, is invited to attend the public meeting and given opportunity to input into discussions. This process is the same for all medicines irrespective of a patient's condition, thus enabling equity of access to medicines that are considered by AWMSG to be both clinically-effective and cost-effective. In addition, a process exists in Wales for health board clinicians to make decisions for individual patients in exceptional circumstances, which is outside the role and remit of AWMSG.

My role as Head of Liaison & Administration in the All Wales Therapeutics & Toxicology Centre is to provide secretariat services and administrative support to the AWMSG. It would therefore be inappropriate for me to provide my personal views in relation to the matters raised by the petition more generally. I would, however, be more than happy to chat through any aspect of the AWMSG appraisal process to assure you that the appraisal process in Wales is rigorous, fair, transparent and equitable.

Please don't hesitate to contact me if you require any further information.

Kind regards.

Yours sincerely



Ruth M. Lang (Mrs)

Head of Liaison & Administration

All Wales Therapeutics & Toxicology Centre