Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Joint Committee on Health

Meeting

Wednesday 12th July 2017

Opening Statement

By

John Hennessy

National Director

Primary Care

Good morning Chairman and members of the Committee and thank you for the invitation to attend this meeting to discuss 'Orphan' Drugs. I am joined by my Colleagues, Professor Michael Barry, Clinical Director of the National Centre for Pharmacoeconomics and Mr Shaun Flanagan, Chief Pharmacist, HSE Corporate Pharmaceutical Unit.

Schemes and Legislation

The HSE is responsible for the reimbursement of medicines under a number of statutory schemes, such as the GMS (Medical Card Scheme), the Long Term Illness scheme and the Drugs Payment Scheme. With the inclusion of medicines purchased for hospital care, the expenditure on Medicines by the HSE comes to approximately €2b per annum.

The Legislation which deals with applications received for new medicines from Pharmaceutical companies is the Health (Pricing and Supply of Medical Goods) Act 2013.

This Act requires the HSE to consider detailed criteria when making decisions around reimbursement and/or pricing.

Specifically, Section 19(4) of the Act states that "*The Executive shall not make a relevant decision*[i] *except in accordance with the criteria specified in Schedule 3".*

Schedule 3 goes on to list the criteria as follows;

1. The health needs of the public.

2. The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services.

3. The availability and suitability of items for supply or reimbursement.

4. The proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks.

5. The potential or actual budget impact of the item or listed item.

6. The clinical needs for the item or listed item.

7. The appropriate level of clinical supervision required in relation to the item to ensure patient safety.

8. The efficacy (performance in trial) effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies), and

9. The resources available to the HSE.[ii]

Application Process

The process for dealing with applications for a new medicine typically involves the following stages:

- The HSE Corporate Pharmaceutical Unit receives the application from the pharmaceutical company as per Section 18(1) of the Act.

- The Corporate Pharmaceutical Unit commissions the NCPE to conduct a health technology review of the new medicine.

- The medicine is subjected to a preliminary rapid review.

- High-cost products and those with significant budget impact are subjected to formal pharmacoeconomic assessment.

- Similarly, products where concerns arise in relation to value for money are selected for formal pharmacoeconomic assessment.

- All such pharmacoeconomic assessments are carried out in compliance with published HIQA Guidelines.

- Companies submit a dossier for consideration i.e. the company gets the opportunity to put forward its best case for consideration by NCPE.

- Following assessment, a full appraisal report outlining the NCPE conclusions and recommendations is sent to the Corporate Pharmaceutical Unit.

- The appraisal report sets out detailed information on the clinical evidence for the benefits associated with or claimed for the new medicine and the robustness of that evidence.

- Information on cost-effectiveness and the probability of cost effectiveness at a range of thresholds (e.g. €20,000 per Quality Adjusted Life Year (QALY), €45,000/QALY, €100,000/QALY and occasionally at even higher thresholds is also provided.

- In the case of oncology drugs a report is also sent to the National Cancer Control Programme for consideration under the NCCP Therapeutic Review Process.

- The Corporate Pharmaceutical Unit leads on any commercial negotiation with the individual pharmaceutical company.

- The full assessment report, the outputs of any commercial negotiations and any other relevant information is then considered by the HSE Drugs Group, which is the expert body in place to make recommendations to the HSE Leadership Team on New Medicines applications.

- The HSE Leadership Team or Directorate is the final decision making body.

- The Act requires that the HSE provides a formal notice of any proposed decision to the applicant company and requires that the HSE considers any representations received from an Applicant company in advance of making a formal (final) decision on pricing and reimbursement.

The Legislation passed by the Oireachtas in 2013 does not make separate provision for ‘Orphan’ Drugs. Consequently, the processes and procedures do not make separate provision for distinct criteria on the assessment of ‘Orphan’ Drugs.

However, the HSE has in the past been an early adopter of new medicines, including in this category, and especially where clear evidence of clinical benefits to patients can be demonstrated and value for money assured.

The HSE is committed to providing access to as many medicines and other services as possible from within the resources provided.

Internationally, there appears to be a growing trend towards providing market authorisations on the basis of evidence which previously might have been insufficient to support authorisation.

In parallel, greater responsibilities are also being placed on Health Services to ensure that cost effectiveness is clearly considered as part of the assessment process.

The challenge for reimbursement agencies (such as the HSE) is that the evidence on efficacy, cost and budget impact is often insufficient to determine such cost effectiveness.

In addition, the pricing strategy adopted by some pharmaceutical companies adds to the challenges, with prices demanded often running to hundreds of thousands of euro per patient per annum. On occasion, these prices can be demanded for medicines for which there may only be preliminary clinical information available to support the benefits claimed. This is leading to serious affordability problems for health services in Ireland and internationally.

My colleague Professor Michael Barry from the National Centre for Pharmacoeconomics (NCPE) will outline details of the HTA process, after which we will endeavour to answer any questions the Committee may have.

Thank you.

---

[i] Relevant decision means a decision to reimburse, or, not to reimburse

[ii] In addition, before agreeing the price of a medicine, the HSE must take into account the following criteria:

- The equivalent relevant prices (if practically available) of the item in all other Member States where the item is marketed.
- The relevant prices of therapeutically similar listed items.
- The potential therapeutic benefits of the item for patients likely to use the item.
- The potential budget impact of the item.
- The ability of suppliers of the item to meet patient demand.
- The resources available to the Executive, and
- The terms of any agreement in place between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.