Joint Committee on Health

Meeting

Wednesday 8th November 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.

The focus today is on the:-

(i) The process for evaluating Orphan Drugs and

(ii) Reasons for potential delay in reimbursing approved drugs.

The process for evaluating applications was covered at the July meeting so I won't repeat this other than to emphasise again that the criteria for assessment are as detailed by the legislation (the Health (Pricing and Supply of Medical Goods) Act 2013, and as set out specifically in Section 19(4) of the Act.

The important points to bear in mind is that the legislation requires the HSE to have regard to the cost effectiveness and clinical benefits of the product being applied for and that the legislation does not make specific provision or permit a different rule set to be applied in the case of Orphan Drugs.

Nevertheless, particular features that relate to Orphan conditions are obviously considered during the assessment process, and factors such as the clinical effectiveness of the product and the number of potential patients affected are clearly set out in the reports compiled.

In the case of approved medicines – the reasons for delay are mainly logistical in terms of putting in place the conditions that may be attached to the approval - or Finance for instance in the case of products that confer clinical benefits but provision does not currently exist in the Service Plan for the budgetary implications of an approval.

This occurred in 2017 for instance in the case of products for the treatment of Cystic Fibrosis, Cancer, Heart Failure and a number of other conditions.

Delay can also occur in cases where the clinical benefits demonstrated by the trial studies are marginal but the prices charged are substantial – and products may be referred back for further negotiations on price. Companies are encouraged to submit their applications based on the final price, but experience has shown that further price adjustments can still become available after decisions are notified.

I trust this information is of assistance and my colleagues and I will endeavour to answer questions the Committee may have or provide any further information required.

This concludes my opening statement.

Thank you.