Joint Committee on Health

Meeting
Wednesday 21\textsuperscript{st} November 2018

Opening Statement
By

John Hennessy
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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 preparation for today has focused on the Committee’s report on this issue in February 2018, and on measures taken or underway to address the recommendations contained in the report.

In relation to recommendation 4, I wish to confirm that discussions have commenced with the Pharmaceutical sector in relation to clarity on pricing and measures to speed up the negotiation process. These discussions have also explored the issue of risk sharing and post approval review, in order to ensure at on-going expenditure is justified by evidence of clinical effectiveness.

In relation to recommendation 6 and 7 – a high degree of communication already exists between the HSE, patient advocacy groups and the Pharmaceutical Industry. Steps have been taken to strengthen this engagement through additional resourcing at NCPE and CPU level, which enables representations to be considered at HTA stage. Routine engagement with the Pharmaceutical Industry is also in place and the composition of the Drugs Group has been expanded to include patient representation and more clinical expertise in the area of Rare Diseases, Medicine for Older Persons and Medical ethics.

The HSE has also written to Hospital Group CEOs in relation to the importance of having a clear understanding in place and informed consent arrangements prior to the commencement of clinical trials / compassionate access programmes.
The establishment of a specific budget for High Tech and Orphan Drugs is also being examined, however to a large extent this is already in place in that High Tech and most Orphan Drugs are funded centrally at present rather than through individual hospital budgets.

The measures now underway to strengthen the representation of Rare Diseases in the assessment process and to involve patient representation and medical ethics should also refine the process in the manner recommended by the Committee.

The issues highlighted in recommendation 10 are being pursued further with the HRB, which appears to be the most obvious route to influence research in collaboration with the University Sector.

In relation to recommendation 12, the HSE has established a National Rare Disease Technology Review Committee. The role of the Committee is to enable clinicians and other stakeholders to input into the assessment process and (in the post HTA phase) to review proposals, prescribing guidelines etc. for consideration by the Drugs Group (similar to the NCCP Therapeutic Review Committee). Such guidelines will where appropriate include recommendations in relation to the prescribers who should be enabled to access Orphan Medicines. I will ask my Colleague Professor Barry to elaborate more on the work of this group.

A model of Care has also been prepared by the HSE’s Clinical Programme for Rare Diseases, which aims to improve access to care for patients with rare conditions and improve value and quality in this area.
The process for evaluating applications was covered in detail at our meetings in 2017, 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 point to bear in mind is that the legislation requires the HSE to have regard to the cost effectiveness and the clinical benefits of the product being applied for.

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

As you are aware the HSE currently spends in excess of €2b per year on Drugs and Medicines, and on a per capita basis the Irish Health Service continues to be one of the highest spenders on medicines in the OECD area, with expenditure still increasing annually.

I will now hand over to Professor Barry for further detail on the Rare Diseases Technology Review Group.

Thank you.