I would like to thank the Chairman and the Committee for the invitation to attend the meeting this morning to discuss the Report on Evaluating Orphan Drugs. I am accompanied by Mr John Hennessy, HSE National Director Acute Strategy and Planning, Mr Shaun Flanagan, Chief Pharmacist in the HSE Corporate Pharmaceutical Unit and Professor Michael Barry, clinical director of the National Centre for Pharmacoeconomics.

In March of this year the Department of Health received the Committee’s report on evaluating orphan drugs which included a number of significant recommendations around the assessment and reimbursement process for orphan drugs. Some of those recommendations concerned the policy and statutory framework underpinning the process with the remainder focussing on the evaluation and reimbursement process, including the clinical criteria deployed in that evaluation.

At the outset I want to say that the 2013 Act is a very comprehensive piece of legislation which provides for a range of important matters, one of which is the criteria which the Health Service Executive shall have regard to when making reimbursement decisions for new medicines. It also includes provisions on interchangeable products; rules around the
establishment and maintenance of the reimbursement list; and provisions in relation to reference pricing.

The Committee in its Report has focussed on that part of the Act which concerns the evaluation process for new medicines, for inclusion on the reimbursement list. In that respect, I wish to inform the Committee that since the publication of the Committee’s Report, the Department has been engaging with the HSE and the NCPE, in seeking to address the various recommendations contained in the Report on the framework and process for assessing orphan drugs.

I am going to address those recommendations which were directed at the Minister or Department of Health and my colleagues from the HSE and the NCPE will address those recommendations around the evaluation and reimbursement process including the clinical criteria that pertains to that evaluation.

The Minister for Health is satisfied that the Oireachtas has put in place a robust legal framework in the Health (Pricing and Supply of Medical Goods) Act 2013, for the assessment and reimbursement of medical goods. The Act gives full statutory powers to the HSE to assess and make decisions on the reimbursement of all medicines and includes detailed criteria which the Executive is required to have regard to when making those decisions. The Act has put in place a clear statutory framework by which new products must be assessed by the HSE and ensures that decisions are made on an objective and scientific
basis. The Act provides for a fair, transparent and rigorous process for the assessment of all drugs which has delivered tangible results for patients. The Minister is satisfied that there are no legislative barriers to the reimbursement of orphan drugs as distinct from any other drugs and is further satisfied that the ruleset that pertains to the assessment of all drugs does not discriminate against orphan drugs. In fact the criteria that applies to the evaluation process, which is contained in Schedule 3 of the 2013 Act, allows sufficient scope for the HSE to take on board the particular circumstances that pertain to orphan drugs and my colleagues from the HSE/NCPE can elaborate further on that.

The Committee in its report rightly identifies that increasingly drugs are being developed to target very rare conditions and that these drugs often come with very high list prices. In that respect, the HSE is required under the Act to have regard to the funding challenge that these drugs represent. It does this by drawing on the criteria contained in the Act including the potential or actual budget impact of the drug in question and the cost effectiveness of meeting health needs by supplying a particular item rather than providing other health services. These are difficult decisions but recognise the core challenge of the availability of finite resources in the face of ever competing demands.

The Committee recommended the appointment of an independent person to conduct a review of the current process and its role in orphan drug availability. In that respect I wish to inform the Committee that the Department is preparing to undertake a review of the governance arrangements that apply to the internal HSE process. That review will examine
the systems, structures and resources which support the decision-making process in relation to reimbursement.

The Committee in its report expresses support for collaboration with other EU member states. In that respect, the Minister is very much in agreement with the Committee. In fact the challenge of accessing innovative medicines at affordable prices is one shared by most, if not all, developed countries. Demographic change will have to be managed along with a continually growing pipeline of new and innovative medicines, many of which come with asking prices that risk being unaffordable and unsustainable. It is estimated that in the region of 45 new molecules are due to receive market authorisation in Europe each year over the next five years. It is in this high-tech space, including orphan drugs that the greatest challenges will arise in the years ahead. Already expenditure on the High-Tech arrangement, through which the majority of new, high-cost medicines, including orphan medicines, are funded, has increased from about four hundred million euro in 2012 to close to seven hundred million euro this year. That level of growth presents a major challenge for Government and the HSE and is the reason why Ireland is working with other countries in Europe to develop common solutions to what is a universal problem.

A significant development since the publication of the Committee’s report was Ireland joining the Beneluxa Initiative on pharmaceutical policy in June 2018. This collaboration will support the Minister’s objective of cooperating with other European countries to identify workable solutions, in an increasingly challenging environment, to secure timely
access for patients to new medicines in an affordable and sustainable way. As the Committee acknowledges in its report, this is a long-term strategy but a strategy that we expect will complement existing domestic policy in this area.

To conclude, I want to emphasise that while the Department has not undertaken a formal review of the Act in its entirety, it has in conjunction with the HSE and the NCPE considered in detail the Committee’s report and the various recommendations contained in it.

There has been substantial engagement between the Department, the HSE and the NCPE on each of the recommendations and I am pleased to be able to report that, apart from the policy developments that I have outlined, there have been a number of significant changes at operational level to the assessment and reimbursement process within the confines of the 2013 Health Act, which address a number of the recommendations in the Committee’s report.

I will hand over to my colleagues in the HSE/NCPE to elaborate on those developments.