Opening Statement by Dr Kathleen Mac Lellan, Director National Patient Safety Office, Department of Health to the Oireachtas Health Committee
Health Technology Assessment
28th March 2018

Thank you Chairman and members of the Committee for the invitation here today. I am accompanied by Finian Judge and Laura Nagle from the Department's primary care division. I will endeavour to set out for the Committee the importance placed on Health Technology Assessments or HTAs in Ireland, the processes that we have in place for their delivery and some considerations with regard to the Commission's proposal.

From a policy perspective, the Department regards the availability of high quality, timely and cost-effective HTAs as an extremely important factor in the delivery of health services. HTAs can help provide answers such as is this medicine a better treatment for a certain disease? Will this new scanner really lead to a better diagnosis? Does this innovative surgery improve the patient's treatment? In summary, it is a procedure for assessing the added value of new medicines and medical devices.

The importance of ensuring that resources are directed correctly within the health service, to where they can provide the most benefit, cannot be overstated. HTAs are therefore a key element in the ongoing evolution of the Irish health system and one of the vital inputs used to inform decision makers when considering whether and when to commence using a particular new medical technique or treatment, or indeed, on occasion, when it can be considered that a treatment has become obsolescent and can be withdrawn from use.

Currently in Ireland, HTAs are primarily conducted by two bodies, the Health Information and Quality Authority, HIQA, and the National Centre for Pharmacoeconomics, the NCPE, who are both present here today and will be able to provide further detail on the technical aspects of HTA and specific considerations that they may have with regard to the proposed EU Regulation. It is the NCPE that provides HTA advice to the HSE Drugs Group on drugs for reimbursement under the Community Drugs Schemes.

In addition to undertaking HTA on a national basis, Ireland has long been involved in international cooperation efforts. At present, there are two EU HTA cooperation mechanisms, the EC Health Technology Assessment Network and the European network of HTA known as EUnetHTA.

The impact of the proposed EU Regulation on drug pricing in the EU Member States
The joint work proposed under the Regulation will focus only on clinical aspects of Health Technology Assessments. The assessment of more specific HTA domains including economic, organisational, ethical and decision making on pricing and reimbursement will remain a Member State competence. Assessment of these domains could be carried out jointly by Member States on a voluntary basis but this would lie outside the remit of the Regulation.

How are Orphan Drugs assessed and reimbursed in Ireland

I believe that the Committee had particular queries in relation to issues surrounding orphan drugs, and drug pricing more generally, and I will now turn to these areas. In that respect the Department has received the Committee's Report on the Evaluation of Orphan Drugs, which is under examination.

The HSE has statutory responsibility for medicine pricing and reimbursement decisions under a number of publicly funded community drug schemes including the General Medical Services (GMS), Long Term Illness scheme (LTI), Drug Payment Scheme (DPS) and the High Tech arrangement, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013.

In considering an application for reimbursement, the Act requires the HSE to consider detailed criteria when making decisions around reimbursement and pricing, including the health needs of the public, clinical need, cost effectiveness, potential or actual budget impacts, safety, efficacy, effectiveness and added therapeutic benefit versus standard therapies, availability and suitability, the level of clinical supervision and the resources available.

The legislation as passed by the Oireachtas in 2013 does not make separate provision for orphan drugs. Likewise, there is no separate provision or distinct criteria on the assessment of orphan drugs.

HSE decisions are supported by HTAs which systematically assess whether a drug is both a clinically effective and a cost-effective health intervention. Currently, most new medicines, including orphan medicines undergo HTAs. The NCPE has a standardised process and criteria for the evaluation of pharmaceutical products, including orphan drugs. The final decision for reimbursement is made by the HSE Drugs Group and/or HSE Leadership.

I understand that one of the recommendations in the Committee's report is to change the process and criteria for the assessment of Orphan Drugs. As the Committee has acknowledged, this would require legislative change.

Conclusion

From a policy perspective, we view the Commission's proposal as in keeping with the approach that has been taken for the last several years, multiplying the relatively small HTA capacity which Ireland operates through uniting with other European agencies, and gaining access to the assessments which our partners have completed. The financial support of the Commission for this HTA work is also noteworthy.

Ireland has been an active participant in these HTA cooperation mechanisms. The Regulation has been brought forward by the European Commission due to the fact that the current arrangements will expire in the coming years, and a revised approach will be required for the period beyond 2020. The proposal will see cooperation among Member States in relation to the production of joint relative effectiveness assessments reports, which are reports focused only on the clinical aspects of a particular technology.

These reports would then be used by individual Member States as the basis of their economic assessments, which in turn would inform decisions in relation to pricing and reimbursement.

In our contacts with the Commission including the visit of November last, Ireland, while outlining its general support for the regulation, has emphasised the importance of ensuring that the quality of the assessments that would be undertaken by the various national bodies are of a sufficient standard. The need for access to the relevant information from technology companies and for the HTA to be timely has also been expressed.

Our understanding is that the process of undertaking HTA will continue to be driven by the Member States, particularly those with experience of HTA. Methodologies and tools to be used by the agencies undertaking HTA will be agreed.

There are potential benefits and efficiencies within these proposals where a small country like Ireland will be able to access, participate in and lead HTAs across Member States. This will hopefully minimise duplication and build a stronger HTA function across Europe. The Department recognises that Ireland has a good reputation across Member States in relation to HTAs and indeed has played a leadership role in establishing strong standards for HTA assessment.

In conclusion, there are many benefits for Ireland with this proposal including early access to robust evaluation of clinical evidence. However, key to this is trust in the proposed joint working arrangements for HTA across Member States and this will require adherence and monitoring of minimum quality assurance standards for HTAs.

Thank you Chair for the opportunity for presenting this opening statement and we will endeavour with our HIQA and NCPE colleagues to address the Committee's considerations.

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