Joint Committee on Health
Houses of the Oireachtas
Leinster House
Dublin 2

27th March 2018

OPENING STATEMENT

Implications for this country of the adoption of COM(2018)51, a Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

Role of the NCPE

The NCPE conducts rigorous, evidence based Health Technology Assessments (HTAs) to inform decision makers on the reimbursement of pharmaceuticals and vaccines in Ireland. The NCPE assessment considers the clinical effectiveness and health related quality of life benefits and all relevant costs including potential savings from reduced healthcare resource use (e.g. hospitalisation), which a new treatment may provide and whether the price requested by the manufacturer is justified. A budget impact analysis is also required in addition to the status of HTAs in other jurisdictions. The NCPE process also facilitates submissions by patient groups who wish to have their views taken into consideration. The NCPE will then advise the HSE in relation to the clinical effectiveness, cost effectiveness [value for money] and budget impact associated with the specific pharmaceutical product. The final decision on reimbursement of any drug is made by the HSE, considering all relevant evidence and recommendations, in line with the provisions of the Health (Pricing and Supply of Medical Goods) Act 2013.

The NCPE process is well established and there are standardised criteria for the evaluation of pharmaceutical products. All assessments are conducted in accordance with published general HTA guidelines produced by the Health Information and Quality Authority [HIQA] and internal NCPE assessment guidelines. The pharmacoeconomic process is outlined in the 2016 Framework Agreement on the Supply and Pricing of Medicines (available at: https://www.hse.ie/eng/about/who/cpu/iphaagreement2016.pdf).

NCPE Involvement in European initiatives and cooperation

The NCPE is committed to, and heavily involved in European cooperation, participating in various collaborations including the European Medicines Agency Joint Scientific Advice Process, numerous IMI-funded initiatives, and of course

the EUnetHTA collaboration in HTA. The NCPE are full partners to the current and final EUnetHTA Joint Action (JA3), and are involved in the four main work packages. These involve cooperation in the following areas:

- Early scientific advice to manufacturers and post-market evidence generation
- Production of Joint Relative Effectiveness Assessments
- Guidelines Development and Quality Assurance
- Implementation

The NCPE are providing meaningful contributions to many EUnetHTA outputs such as the prioritisation of work tasks for JA3 across work packages, companion guides for the conduct of HTA, and are currently co-authoring the Topic Identification, Selection and Prioritisation horizon scanning program for the current and future models of cooperation.

Furthermore the NCPE have provided expert advice to the Department of Health regarding collaborative pricing and reimbursement initiatives at a European level, such as the Valetta and Beneluxa initiatives.

Overall the NCPE have invested significant resources in cooperative European projects over the last number of years, and welcome the publication of the commission proposal on the regulation of HTA.

Implications of the European Commission Proposal to Develop a regulation promoting cooperation in the area of Health Technology Assessment

On 31st January 2018, the European Commission put forward a proposal to develop a regulation around HTA, and specifically to require the mandatory cooperation of member states in the area of joint clinical assessment.

The Commission have described the intention and scope of the Regulation. The purpose is to address impediments to market access between member states, avoid duplication of work for HTA bodies and overcome the challenges of voluntary HTA cooperation by creating permanent infrastructure and funding to support joint activity.

Specifically, the proposal focuses on joint work on clinical aspects of HTA while the assessment of more context specific economic issues and decision-making on pricing and reimbursement will remain at Member State-level. Member States will continue to draw conclusions on the overall added value of the assessed health technology based on the joint clinical assessment report and the assessment of non-clinical aspects of the technology.

The NCPE welcome the proposal and consider that there is potential for efficiency gains for our organisation and potentially the broader health service, if implemented in a timely manner.

However the NCPE consider that there are a number of important issues which require detailed clarification before these potential efficiency gains could be realised, including the following:

- Whether it will be mandatory for pharmaceutical companies to submit evidence as part of this process. As much of the relevant clinical evidence is held by the companies, their participation is considered to be critical.
- The coordination of the publication of the joint clinical assessments and the product launch date in Ireland. Product launches and reimbursement applications are often made in Ireland some time after receipt of EU marketing authorisation. Efficiency gains may be lost if product launch is later than the date of marketing authorisation, and reassessment due to the availability of new clinical evidence is required
- Efficiency gains may not be realised if the primary language of the new body is not English.

The NCPE understand that these clarifications may not be available until after the Regulation has been enacted, and are produced as part of the secondary legislation process. Thus at this point it is not possible for the NCPE to confidently assume that this process will yield significant efficiency gains for the NCPE in the assessment of clinical effectiveness of new drugs.

The committee has specifically requested information on how the proposed Regulation may affect the approval of orphan drug products in Ireland and the likely impact on drug pricing in the member states. The draft Regulation does not distinguish orphan drugs or propose any specific processes for orphan drugs, and in its current format is unlikely to affect the approval process for orphan drug products in any way. Drug pricing and reimbursement is outside the scope of the Regulation, and it contains no reference to formal cooperation in this area. The NCPE consider that the proposed Regulation should not prevent or impede international cooperation on pricing and reimbursement.

NCPE 27th March 2018