NCCP TECHNOLOGY REVIEW COMMITTEE

The National Cancer Control Programme (NCCP) Technology Review Committee (TRC) was established in March 2011 and is responsible for reviewing proposals received from industry or expert groups in Ireland for funding of new cancer drugs, or expanded indications for existing cancer drugs or related predictive laboratory tests. The recommendations are based on the degree of clinical effectiveness, the acute and chronic toxicity and the cost effectiveness of the proposed technology.

Recommendations from the NCCP-TRC are brought to the Health Service Executive (HSE) Drugs Group for prioritisation in a national context. The senior management makes the final decision on funding for all new drugs/technologies.

APPLICATION AND APPROVAL PROCESS:

The process for all new applications for HSE funding approval of medicinal products, including all new cancer drugs is governed under the terms of the IPHA framework agreements of 2016 and 2021.

Applications for new therapies are initially made to the HSE's Corporate Pharmaceutical Unit (HSE-CPU). http://www.hse.ie/eng/about/Who/cpu/. The NCCP is notified by HSE-CPU upon receipt of new applications for funding approval and they simultaneously forward a copy to the National Centre for Pharmacoeconomics (NCPE). The NCPE is an autonomous agency that conducts the pharmacoeconomic assessment of pharmaceutical products for the HSE in Ireland in collaboration with the HSE -CPU.

High cost drugs/technologies and those with significant budget impact are subjected to formal pharmacoeconomic assessment. The rapid review process (initially undertaken to look at the efficacy or effectiveness of the drug) takes approximately 2-4 weeks. Many high tech drugs are then referred for a formal pharmacoeconomic assessment which is usually completed in less than 3 months.

Following formal pharmacoeconomic assessment, a full appraisal report outlining NCPE conclusions and recommendations is sent to the HSE-CPU and in the case of oncology drugs, to the NCCP, to support evidence-based decision-making on reimbursement. Further details of the NCPE Pharmacoeconomic appraisal process are available on their website http://www.ncpe.ie/submission-process/process-flochart/.

In parallel to the pharmacoeconomic assessment, the NCCP liaises with the Irish Society of Medical Oncologists / Irish Haematologists Society to nominate a clinician with relevant expertise to develop national clinical guidelines for use of the drug.

Discussions on pricing between the HSE-CPU/NCCP and the company are undertaken throughout the process.

A meeting of the NCCP TRC is convened once the clinical guidelines have been developed and the pharmacoeconomic assessment has been completed. The Committee meets on average three to four times per year and usually seeks to consider several new drug applications simultaneously.

The Committee reviews and considers the clinical guidelines and the report of the NCPE (which is an input into the process) along with the company submission and any other relevant information. Following deliberations the Committee makes a recommendation on the introduction of the drug, to the Director of the NCCP.

There are three options available to the committee:

1. To reject the drug
2. To recommend the drug for introduction
3. To recommend the drug subject to price reduction

The recommendation of the Committee does not result in funding approval. Where a recommendation is positive, the Director of the NCCP brings this recommendation to the HSE Drugs Group for discussion in a national context. Time lines for the reimbursement process are outlined in the 2016 IPHA agreement and included in Figure 1 below. Drugs subsequently prioritised for funding are then brought to the HSE Management Team/DOH who makes the final decision on funding for all new drugs/technologies.

The IPHA agreement details an annual horizon scanning process to capture items expected to be submitted for reimbursement in the following 12-18 months. This is to allow inclusion of these items in the HSE budgetary planning process. The form can be downloaded from:
http://www.ncpe.ie/submission-process/submission-of-new-medicine-horizon-scan-by-manufacturers/

Figure 1 is a summary of the process for new medicines (or new treatment indications) with budget impacts.

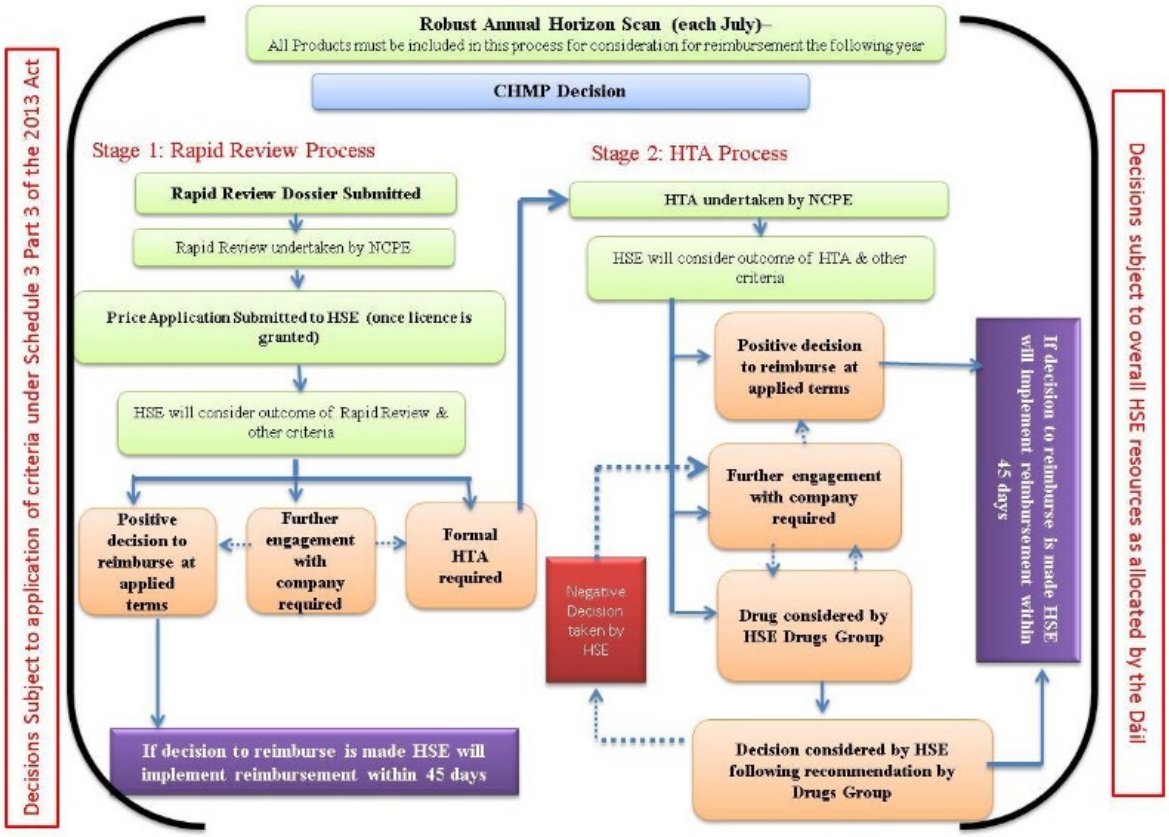

Figure 1: Summary of the process for new medicines (or new treatment indications) with budget impacts (Source: IPHA)

Additional questions relating to the NCCP Technology Review Committee can be emailed to oncologydrugs@cancercontrol.ie

The following drugs (for the indications as detailed in their associated treatment regimen) and predictive technologies were recommended for approval by the TRC to the HSE Drugs Group and subsequently approved for reimbursement:

2011	Oncotype DX
2012	Ipilimumab, Abiraterone
2013	Cabazitaxel, Axitinib, Mifamurtide, Vemurafinib
2014	Afatinib, Bosutinib, Brentuximab vedotin, Crizotinib, Dabrafenib, Decitabine, Enzalutamide, Eribulin mesylate, Pertuzumab, Ruxolitinib, Vandetanib
2015	Obinutuzumab, Pixantrone, Radium 223, Regorafenib, Siltuximab, Trastuzumab emtansine
2016	Ceritinib, Ibrutinib, Lenvatinib, Nab-paclitaxel, Pembrolizumab, Pomalidomide, Ponatinib
2017	Alectinib, Idelalisib, Nintedanib, Nivolumab, Nivolumab – Ipilimumab, Olaparib, Trifluridine and Tipiracil, Vismodegib
2018	Carfilzomib, Cobimetinib, Daratumumab, Ixazomib, Palbociclib, Trametinib, Venetoclax
2019	Atezolizumab, AvelumAB, Binimetinib/ Encorafenib, BlinatumomAB, Brigatinib Cabozantinib, Dacomitinib, DinutuximAB beta, InotuzumAB ozogamicin, Lorlatinib, Obinutuzumab Ribociclib, Tivozanib
2020	GemtuzumAB ozogamicin, Osimertinib, Pertuzumab, Venetoclax –rituximab
2021	Lutetium oxodotreotide (Lu177), Midostaurin, Niraparib, Polatuzumab vedotin, Talazoparib, Tisagenlecleucel (CAR-T), Trametenib/ dabrafenib
2022	Axicabtagene ciloleucel (CAR-T), Darolutamide, Entrectinib, Fedratinib, Neratinib, Phesgo®(Pertuzumab, and trastuzumab) Venetoclax-obinutuzumab, Zanubrutinib
2023	Mogamulizumab