

NCCP TECHNOLOGY REVIEW COMMITTEE

The National Cancer Control Programme (NCCP) Technology Review Committee 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.

A positive recommendation from the NCCP-TRC is brought to the 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 Health Service Executive (HSE) funding approval of medicinal products, including all new cancer drugs is governed under the terms of the 2016 IPHA agreement.

<http://www.ipha.ie/alist/ipha-hse-agreement.aspx>

Applications for new therapies are initially made to the HSE's Corporate Pharmaceutical Unit (CPU).

<http://www.hse.ie/eng/about/Who/cpu/>. The NCCP is notified by 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 Health Service Executive (HSE) in Ireland in collaboration with the HSE Corporate Pharmaceutical Unit (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 Corporate Pharmaceutical Unit (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 CPU/NCCP and the company are undertaken throughout the process.

A meeting of the NCCP Technology Review Committee 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 National Cancer Control Programme.

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.

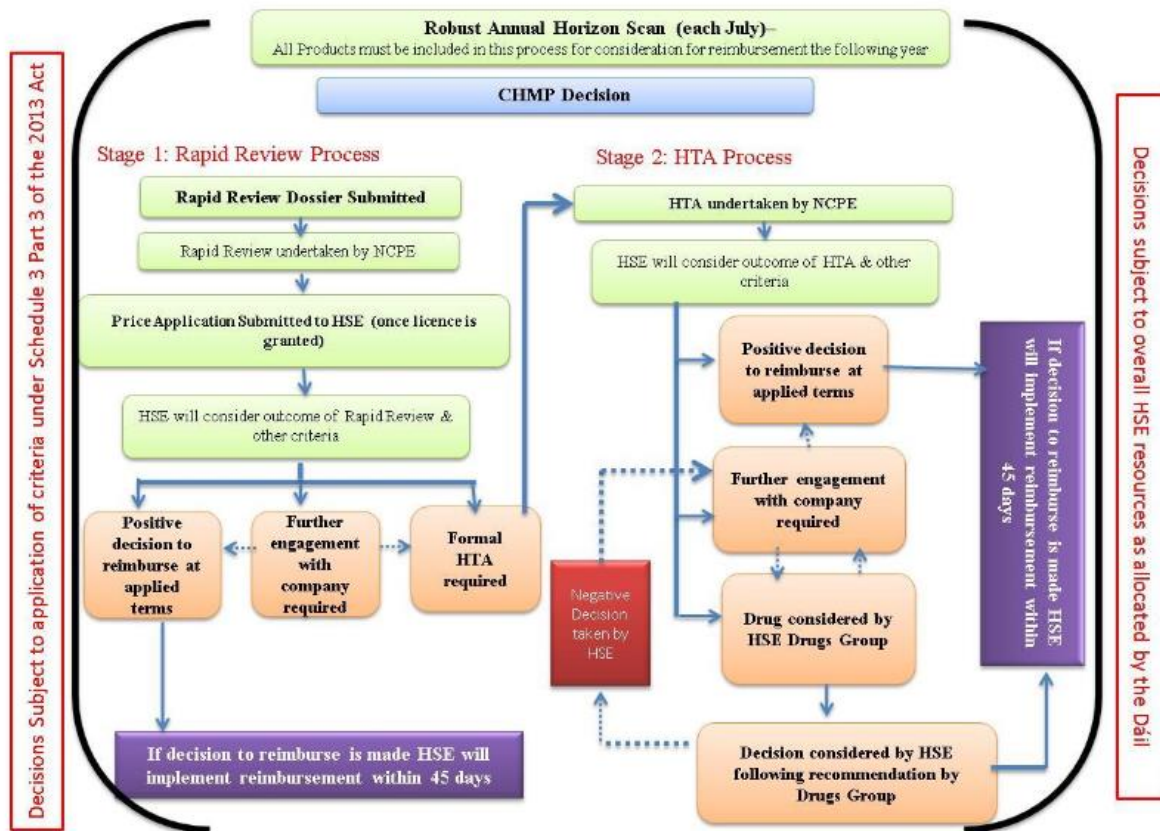


Figure 1: Summary of the process for new medicines (or new treatment indications) with budget impacts (Source: IPHA)

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 protocol) and predictive technologies were recommended for approval by the Technology Review Committee to the HSE Drugs Group and subsequently approved for reimbursement:

- 2011 Oncotype DX
- 2012 Ipilimumab, Abiraterone
- 2013 Cabazitaxel, Axitinib, Mifamurtide, Teysuno, Vemurafinib
- 2014 Afatinib, Aflibercept, Bosutinib, Brentuximab vedotin, Crizotinib, Dabrafenib, Decitabine, Enzalutamide, Eribulin mesylate, Pertuzumab, Ruxolitinib, Vandetanib
- 2015 Abiraterone, Obinutuzumab, Pixantrone, Radium 223, Regorafenib, Siltuximab, Trastuzumab emtansine
- 2016 Ceritinib, Enzalutamide, Ibrutinib, Lenvatinib, Nab-paclitaxel, Pembrolizumab, Pomalidomide, Ponatinib
- 2017 Alectinib, Idelalisib, Nintedanib, Nivolumab, Nivolumab – Ipilimumab, Obinutuzumab, Olaparib, Trifluridine and Tipiracil, Vismodegib
- 2018 Carfilzomib, Cobimetinib, Daratumumab, Ixazomib, Nivolumab, Palbociclib, Pembrolizumab, Trametinib in combination with Dabrafenib, Venetoclax
- 2019 Alectinib, Atezolizumab, Avelumab, Binimetinib in combination with Encorafenib, Blinatumomab, Brigatinib, Cabozantinib, Dacomitinib, Dinutuximab beta, Inotuzumab, Lorlatinib, Obinutuzumab, Ribociclib, Tivozanib
- 2020 Brigatinib, Carfilzomib, Daratumumab, Osimertinib, Pertuzumab, Ribociclib, Venetoclax.