How are topics selected and prioritised by NICE and what might be the options if a technology is not selected?

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Objectives

In contrast to the Scottish Medicines Consortium, NICE does not evaluate all new medicines as they reach the market, but uses a set of specific selection criteria. Where a technology is not selected for assessment the affected products may face difficulties in achieving payer and physician uptake even if alternative reimbursement routes are available. This is because the funding for NICE approved medicines is mandatory and takes precedence over other routes generally. We aimed to evaluate the process used by NICE in selecting topics for appraisal and how companies can increase their chance of a NICE assessment. Furthermore, we considered the challenges associated with the alternative routes to reimbursement for products not selected for NICE assessment.

Methods

We reviewed the topic selection methodology and compared the number of marketing authorizations (MA) in 2010-2014 from the European Medicines Agency (EMA) database[1] versus the number of products reviewed by NICE[2,3]. Furthermore, we reviewed the alternative routes to reimbursement for manufacturers where they are not subject to a NICE technology appraisal.

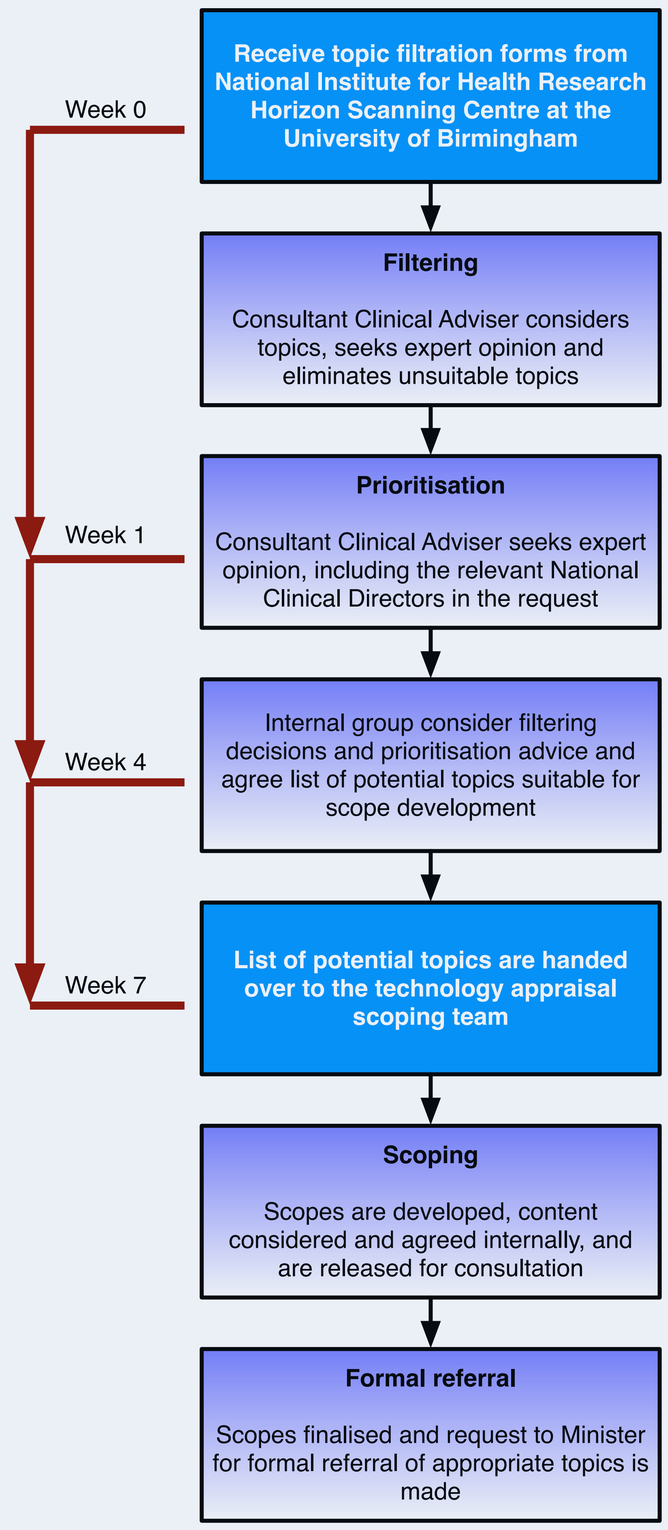
Results

38% of orphan products and 54% of non-orphan products receiving MA in 2010-2014 have been assessed or are under assessment by NICE. An important aspect of the NICE topic selection process, which is outlined in Figure 1, is that any information published by NICE about topic selection is with the specific agreement of the company. Selection is heavily dependent on patient and clinical advocacy. In the event that NICE does not conduct an assessment or a negative recommendation is obtained, there are four alternative routes to reimbursement:

1. The Cancer Drugs Fund (CDF)

The CDF list currently contains 37 products covering over 60 indications although following review, more products are expected to be removed from the CDF list.

Figure 1: Overview of the NICE topic selection process



2. Commissioning through evaluation (CTE)

This route is unlikely to achieve broad funding and should be considered as a last resort. The principle was to have specialist hospitals take part in a new, innovative commissioning approach, aimed at increasing access to services or treatments not currently routinely funded by the NHS. In practice, a very small number of procedures have been funded, within a limited number of selected centers, and within a limited time frame.

3. Commissioning policy

Currently, there are over 20 NHS England policies to support the commissioning of products and associated services; and over 100 awaiting review with no clear time frames for a decision.

4. Individual funding requests (IFRs)

IFRs are for patients with exceptional clinical circumstances that are not already covered by existing policies. The process can be time consuming and is only appropriate if there are fewer than 20 patients in England or the annual cost of treatment per patient is less than £150,000.

Where none of the above options apply or are unsuccessful, companies may be forced to rely on local commissioner approvals, individual hospitals within clinical commissioning group (CCGs) boundaries or, ultimately, legal redress. The common characteristic accompanying success is strong clinical support from the relevant NHS England clinical reference group and powerful patient lobbying.

Conclusions

The current position, whether caused by delay or a positive decision by NICE not to review, is considered unsatisfactory both for patients and manufacturers. Alternative routes to market are associated with very long delays, uncertainty and the possibility of access for patients only on a regional level leading to the 'postcode lottery' which NICE was originally tasked to reduce. There is an issue of how NICE, CDF and NHS England policies will work together in the future. There are several options for remedy such as a more comprehensive product review programme, but this could lead to further delays as NICE has limited resource and a growing workload.

There are 3 actions a company can take to increase the likelihood of a NICE review:

- Contact the National Institute for Health Research Horizon Scanning center at the University of Birmingham (UK) to raise awareness of a product that may be made available in 1-3 years
- Register on UK PharmaScan, and upload as much information on the product and likely indication as early as possible
- Ensure that clinicians with payer responsibility are aware of any potential budget impact through development and dissemination of an advanced budgetary notification.

A final step to consider is judicial review, but this should be considered carefully as it can be expensive and lengthy, and even success does not guarantee a different outcome.

References:

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2. MAP BioPharma HTA database and trends analysis. Selected charts available at: http://www.mapbiopharma.com/
3. NICE recommendations obtained from the NICE website: http://www.nice.org.uk/guidance/published?type=ta

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