
Objectives

Vaccines are one of the greatest triumphs of healthcare innovation. They have saved millions of lives, prevented destructive chronic illnesses and eased pressures on health services across the globe. The UK NHS constitution states that everyone has the right to receive vaccinations recommended by the Joint Committee on Vaccination and Immunisation (JCVI) under a NHS-provided national immunisation programme1.

We provide an outline of the route to potential reimbursement, using recent examples, and guidance based on lessons learnt.

Context: It should be noted that the Pharmaceutical Price Regulation Scheme (PPRS) applies as much to vaccines as it does to medicines provided that they have a brand name and marketing authorisation. The only exceptions are procurements of centrally supplied vaccines and stockpiled medicines.

Methods

Published UK articles, The Health and Social Care Act 2012, The Green Book, government records and industry records were scrutinised and summarised into an outline of the process undertaken to make vaccines available. Examples of vaccines that have been through the UK process, the challenges they have faced and potential solutions to those challenges were also examined.

Results

Some vaccine manufacturers and commentators claim that it is surprisingly difficult to navigate the UK system. The vaccine approval and funding process, including review by the JCVI, is outlined in Figure 1. There are no specific timelines for this process as it runs on a case by case basis. This is illustrated in the example in Box 1, which summarises the process of approval of meningococcal B vaccine.

The National Institute of Health and Care Excellence (NICE) and JCVI follow different approaches to the assessment of technologies as shown in Table 1 including varying degrees of public and stakeholder involvement.

Table 1: Comparison of NICE and JCVI

<table>
<thead>
<tr>
<th>Process</th>
<th>NICE</th>
<th>JCVI</th>
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<tr>
<td>Meetings</td>
<td>Public/Open</td>
<td>Private/Closed</td>
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<tr>
<td>Meeting frequency</td>
<td>Regular as required</td>
<td>Three per year (+emergency meetings)</td>
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<tr>
<td>Release models</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Evaluation scoping phase</td>
<td>Yes</td>
<td>No (some horizon scanning)</td>
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<tr>
<td>Stakeholder engagement</td>
<td>Yes (stakeholders are formally invited to submit evidence)</td>
<td>Limited (some calls for evidence and some presentations)</td>
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<td>Appeals process</td>
<td>Yes, internal NICE process for decisions</td>
<td>No, apart from judicial review</td>
</tr>
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<td>Public involvement</td>
<td>Yes, NICE Citizens Council includes members of the public</td>
<td>No</td>
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Conclusions

Companies proposing to bring vaccines to market need to pay special attention to navigating this complicated structure, well in advance.

This preparation is needed to achieve a satisfactory price, which rewards research, development and other costs, within a reasonable period. Exploring scenarios based on potential immunisation programmes and associated revenue projections could also help to inform subsequent contract negotiations.

Compared to the NICE technology appraisal process, review by the JCVI is less well defined and less transparent, with less emphasis on the manufacturer to provide evidence. This research highlights the need for manufacturers to approach review of vaccines in a similar way. There are multiple factors that affect the likelihood of positive and negative guidance including:

- Preparing a clear case of the unmet need
- Developing a robust economic case in line with NICE methodology to predict what JCVI might conclude so that assumptions can be challenged as they could be inaccurate
- Generating publications to support the evidence review
- Consultation with a wide group of stakeholders (clinicians, epidemiologists, academic groups and health economists)

References:


Presented at ISPOR 18th Annual European Congress; Milan, Italy; November 7th–11th, 2015. Poster No. PIN101