NICE National Institute for Health and Care Excellence

Evidence summaries: new medicines – Interim process statement

NICE process and methods
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www.nice.org.uk/process/pmg1

Contents

1 Introduction

This is not the current process. From May 2013, evidence summaries: new medicines were developed using the integrated process statement.

1.1 Introduction to the interim process statement

This interim process statement has been produced to guide the development of 'Evidence summaries: new medicines' (ESNMs). It provides an overview of the key process principles and describes all stages of the development of ESNMs. These procedures are designed to ensure that a robust, quality-assured, commentary is developed for the NHS in an open, transparent and timely way, with appropriate input from key groups.

This interim process statement of ESNMs will be superseded when the final process guide is issued later in 2012, following engagement and discussions with key groups.

1.2 Background to 'Evidence summaries: new medicines'

The National Institute for Health and Clinical Excellence (NICE) is part of the NHS. NICE's evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures, technologies and devices represent the best quality care and offer the best value for money for the NHS. Further information about NICE and its work is available on the NICE website.

The NICE Medicines and Prescribing Centre provides advice and support for delivering safety, efficiency and effectiveness in the use of medicines. The Medicines and Prescribing Centre is responsible for developing the ESNMs.

ESNMs will provide a summary of the published evidence for selected new medicines that are considered to be of significance to the NHS. This will include new indications for existing medicines and new formulations of existing medicines. The strengths and weaknesses of the relevant evidence will be critically reviewed within this summary. Importantly, the ESNM product will not constitute formal NICE guidance and this will be

clearly stated on each publication.

The context of the rest of the evidence informing the management of the licensed indication(s) or anticipated licensed indication(s) for the new medicine will also be summarised to assist local decision making.

The NHS Constitution gives patients the right to expect that decisions about the funding of medicines and treatments will be made rationally, following proper consideration of the evidence. ESNMs will help provide consistent access to the best available information on a medicine to guide local decision making, for example within a clinical commissioning group (CCG), an NHS trust, or across a local health economy. This information from NICE will help to avoid potential duplication of effort where different organisations are producing their own evidence summaries.

The topics for ESNMs will be selected in collaboration with the existing NICE topic selection programme. Two types of topics will be considered:

- A medicine recently marketed in the UK
- A medicine that may be marketed in the UK within the next 6–12 months.

In both cases, topics will only be considered for an ESNM where a NICE technology appraisal (TA) is not planned or in progress.

2 Evidence summaries: new medicines

2.1 Aims

The aim of ESNMs is to inform local planning around the managed use of medicines within a local health system. For the purposes of this interim process statement, the term 'new medicines' encompasses these areas:

- a medicine recently granted a marketing authorisation in the UK (normally within the last 6 months)
- a medicine with an existing UK marketing authorisation which has been recently licensed for a new indication (normally within the last 6 months)
- a new formulation of an existing medicine.

2.2 Key audiences

ESNMs are produced for:

- local decision-making groups involved in commissioning and funding services related to medicines (for example, area prescribing committees)
- local medicines management and horizon scanning services
- clinicians, involved in local commissioning decisions for planning purposes, for example within a CCG or NHS trust.

Note: there are restrictions on the promotion of new medicines to clinicians before receipt of a marketing authorisation. Information on yet to be licensed medicines can only be provided to clinician for use for planning purposes in their role as commissioners.

2.3 Key activities

The key activities involved in the production of ESNMs are:

- identifying and selecting the relevant and most important new medicines

- summarising the published evidence for selected new medicines
- critically reviewing the strengths and weaknesses of the evidence
- placing the new evidence in the context of the wider evidence base for the licensed indication or anticipated licensed indication(s), particularly NICE guidance, where available
- highlighting any potential implications for local decision making or clinical practice
- identifying any new evidence relevant to published ESNMs through horizon scanning, reviewing and, if necessary, updating or withdrawing ESNMs.

3 Who is involved in producing 'Evidence summaries: new medicines'?

3.1 The Medicines and Prescribing Centre

The Medicines and Prescribing Centre is part of NICE's Centre for Clinical Practice (CCP). The Medicines and Prescribing Centre consists of a programme director, associate directors and clinical, technical, project and administrative staff. For ESNMs, senior members of the medicines evidence team within the Medicines and Prescribing Centre are responsible for:

- developing and reviewing processes and methods for producing ESNMs
- in collaboration with the NICE Topic Selection team, identifying potential topics for ESNMs
- preparing ESNMs for publication, including selecting and critically appraising the evidence
- identifying and liaising with external specialist commentators to help ensure the content is relevant and useful
- providing quality assurance of the content of ESNMs
- ensuring timelines and quality assurance standards are followed
- reviewing and updating content of published ESNMs where required.

3.2 Other NICE teams

In developing ESNMs, the Medicines and Prescribing Centre works closely with members of other NICE teams, including Technology Appraisals, Clinical Guidelines, Publishing, Evidence Information Services and Guidance Information Services. Their roles will be specifically defined in the final version of the process guide.

3.3 External specialist commentators

Specialist commentator(s) and/or specialist agencies (for example, the Health Protection Agency for an infectious disease topic) will be identified to review the ESNMs ahead of publication. Specialists will be identified early in the production process and, using advance notice and careful scheduling, will provide comments within a short time frame, usually 1 week. Specialist commentators are practitioners who have significant expertise in the therapeutic area for which the new medicine is to be used. Their role is to clarify issues about the reviewed evidence and the practical implications of the information contained in the ESNM. Suggestions for reviewers come from NICE, national professional organisations and the New Medicines Community of Practice.

3.4 Manufacturers

When a topic is selected for the ESNMs programme, NICE will inform the manufacturer of the medicine of its intention to produce an evidence summary and the expected timeframe. NICE will contact the manufacturer to invite them to provide data to support the production of the evidence summary.

The manufacturer will be invited to comment on an early draft of the evidence summary, and, using advance notice and careful scheduling will provide comments within a short time frame, usually within 1 week. The manufacturer has the opportunity to comment on matters of factual accuracy, and respond to any specific questions from NICE about any information they submitted to inform the summary.

3.5 The NICE Medicines and Prescribing 'New Medicines Community of Practice'

The New Medicines Community of Practice is a group consisting of about 300 healthcare professionals who are actively involved in local decision making bodies such as area prescribing committees. The group was established by the Medicines and Prescribing Centre to support those NHS staff who have a role in managing the introduction of new medicines within health communities. Their aim is to facilitate the sharing of information, knowledge and wisdom around new medicines to assist local decision making.

The New Medicines Community of Practice is facilitated in 2 ways: via an electronic discussion group and by invitation to 3 face-to-face meetings each year. These meetings

consider the available technical data on new medicines in development, as well as matters of process and implementation.

The New Medicines Community of Practice advise the prioritisation of topics for ESNMs (see section 4.1), and – in conjunction with the NICE technology appraisals team – identify external specialist commentators, who may come from the Community of Practice itself.

3.6 Conflicts of interest

NICE staff, members of the New Medicines Community of Practice and specialist commentators will be required to comply with the NICE code of conduct on conflicts of interest. For more information about how NICE deals with conflicts of interest, please see NICE's code of practice for declaring and dealing with conflicts of interest.

4 Topic identification, prioritisation and scoping

4.1 Topic identification and prioritisation

The topics for ESNMs will be selected in collaboration with the existing NICE topic selection programme. Two types of topics will be considered:

- a medicine recently marketed in the UK
- a medicine that may be marketed in the UK within the next 6–12 months.

In both cases, topics will only be considered for an ESNM where a NICE technology appraisal (TA) is not planned or in progress.

Stage 1: Identify potential topics

The NICE topic selection process is the primary route for the identification of significant new medicines. Potential topics for a NICE ESNM are being identified at various points during the topic selection and technology appraisal process and can come from:

- the National Institute for Health Research Horizon Scanning Centre (NHSC) non-prioritised list (a list of topics identified by the NHSC that are not considered significant enough to consider as a potential technology appraisal)
- topics that are not prioritised for development into technology appraisal guidance
- topics referred to the technology appraisal programme that will not publish an appraisal consultation document (ACD) within 6 months of launch
- terminated technology appraisals.

The NICE topic selection prioritisation criteria include the size of population affected, severity of disease, potential resource impact and claimed therapeutic benefit.

Stage 2: Prioritise topics

Three times each year, the NICE Medicines and Prescribing Centre will present a list of those medicines identified in stage 1 to members of the New Medicines Community of Practice. Members will advise NICE on the likely clinical and service impact of these new medicines. The purpose of this stage is to engage with those who have a role in managing the introduction of new medicines within health communities, with their advice informing stage 3 of this topic selection process.

Stage 3: Formal approval of topic for review

A final, prioritised list of topics is then compiled by the NICE Medicines and Prescribing Centre using the NICE topic selection prioritisation criteria (based on the size of population affected, severity of disease, potential resource impact and claimed therapeutic benefit), taking into account the advice from the New Medicines Community of Practice. The CCP Director is asked to formally approve the shortlist. Once approved, the manufacturers of the medicines will be informed of the intention to produce these ESNMs and the topics are added to the NICE Forward Planner, as well as being added to the 'Coming soon' section of the Medicines and prescribing page on the NICE website.

4.2 Scoping of individual topics

The NICE Medicines and Prescribing Centre will hold an internal scoping meeting for each ESNM topic to:

- confirm key contacts at the pharmaceutical manufacturer
- identify specialist commentators (via the New Medicines Community of Practice and other existing NICE networks)
- identify terms for a literature search to identify published clinical trial data that reflect the possible indication for the medicines, usually phase III trials.
- confirm arrangements for identifying:
  - proposed or likely indication
  - relevant published trials or other data to support the (possible) indication
  - likely licensing and marketing timeline
  - proposed cost and course of treatment

- evidence of clinical effectiveness
- safety issues
- treatment alternatives
- likely place in therapy
- incidence and prevalence of (likely) indication (to inform an estimation of use).

5 Production

5.1 Equality and diversity considerations

ESNMs are developed in accordance with the NICE equality scheme.

5.2 Process and timescales

ESNMs are not formal NICE guidance and therefore are not subject to the same intensity of process as other NICE products.

Table 1 shows the key steps in the development of ESNMs.

Table 1 Key steps of development of an ESNM with timelines

Key step	Timescale
Literature search and/or contact manufacturer for data	Week 0
Scope topic and begin authoring of ESNM	Week 2
Internal check of initial draft	Week 3
Send draft to manufacturers and specialist commentators for review	Week 4
Review comments received and revised draft produced	Week 5
Technical check of content by senior adviser	Week 6
Final check of content by associate director	Week 6
Editorial check of content by NICE Editorial team	Week 7
Guidance Executive sign off	Week 8
Inform manufacturer of date that ESNM will be published	Week 8
Publication on NICE website	Week 9

6 Review

The process for the review of ESNMs will be considered during the development of the final process guide. In the meantime, the need for review of any published ESNM will be dealt with as necessary.

7 About this interim process statement

This interim process statement was used to develop evidence summaries: new medicines published up to 21 May 2013, but evidence summaries published after this date have used the integrated process statement.

For published 'Evidence summaries: new medicines', see the list on the NICE website.

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