A co-production approach to implementing the Summary of Information for Patients (SIP) for medicines at NICE

# Introduction

This report has been compiled by the short-life working group formed to advise on the implementation of the International Summary of Information for Patients (SIP) for medicines at NICE as part of the implementation of the new methods and process manual for [Health Technology Evaluations published on 31 January 2022.](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation)

The short life working group consisted of patient organisations, patient experts, committee members and NICE staff:

* Heidi Livingstone, senior public involvement adviser - lead
* David Chandler, Psoriasis and Psoriatic Arthritis Alliance
* Sophie Thomas, MPS Society
* Daniel Cairns, Myeloma UK
* Dave Chuter, patient expert for Oesophageal Cancer
* Nigel Westwood technology appraisal (TA) lay committee member
* Steve O’Brien, TA committee chair
* Richard Diaz, highly specialised technology (HST) and TA associate director
* Mary Hughes and Eleanor Donegan, TA technical advisers
* Gavin Kenny, HST and TA project manager.

# Background

1. As part of the wide-ranging review of our methods and processes for health technology evaluation (HTE), a specific workstream was set up to consider the public involvement aspects of this review. The workstream’s remit was to co-design realistic proposals for changes to public involvement in NICE’s medicines and non-medicines HTE guidance (technology appraisals, highly specialised technologies, diagnostics, medical technologies and interventional procedures guidance). The output was a report *[Improving meaningful public involvement in NICE medicines and technologies guidance](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nice.org.uk%2FMedia%2FDefault%2FAbout%2FNICE-Communities%2FPublic-involvement%2FPublic-involvement-programme%2FImproving-meaningful-public-involvement-in-medicines-and-technologies-guidance.docx&wdOrigin=BROWSELINK).*
2. One of the responses to the review was to introduce a Summary of Information for Patients (SIP), which is a document written by the company who is seeking approval from NICE for their treatment to be sold to the NHS for use in England. The SIP is a plain English summary of their evidence submission written for patients to help patients, carers and parents understand the company’s submission to NICE. The SIP consists of four sections:
   1. Section 1: Submission summary   
      This includes a summary about the treatment being evaluated including an overview of the medicine and the people it is intended to treat.
   2. Section 2: Current landscape  
      This includes information about the condition being treated from the company’s perspective and includes existing treatments (if they exist) currently used for treating the condition. It may also include any patient-based evidence the company has generated.
   3. Section 3: The treatment or medicine  
      This is where the company has summarised their perspective of the details about the treatment, including how it works and how it is given or taken. They will also say if the treatment will be used in combination with any other medicines. It will include information about have effective and safe the treatment is in trials and how it might affect the quality of life for patients with the condition. The data will inform any relevant cost or financial considerations for patient in a section on health economics and value considerations.
   4. Section 4: Further information, glossary and references  
      The references include a list of publication or online sources that provide supporting evidence for the content of the SIP. The glossary is written in patient-friendly language to try to explain any complex or scientific terms included in the SIP.
3. The **Summary of Information for Patients** (SIP) template was originally developed and used at the Scottish Medicine’s Consortium (SMC) and has since been developed as an international template and guides by [Health Technology Assessment International – Patient & Citizens Involvement Group](https://htai.org/interest-groups/pcig/) (HTAi PCIG). Information about the development is available in an open-access [IJTAHC journal article](https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/development-of-an-international-template-to-support-patient-submissions-in-health-technology-assessments/2A17586DB584E6A83EA29E3756C37A14). The international SIP template has been co-created by a multi-stakeholder group of the HTAi Patient and Citizen’s Involvement Group (HTAi-PCIG), with input from industry, HTA bodies (including NICE), and patient group representatives. For more information see the HTAi website: <https://htai.org/interest-groups/pcig/resources/>.
4. The role of the short-life working group was to advise on implementing the SIP for use with patient experts at NICE. This included adapting the international template and accompanying guides for companies and patients.
5. Recommendation 14 of [*Improving meaningful public involvement in NICE medicines and technologies guidance*](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nice.org.uk%2FMedia%2FDefault%2FAbout%2FNICE-Communities%2FPublic-involvement%2FPublic-involvement-programme%2FImproving-meaningful-public-involvement-in-medicines-and-technologies-guidance.docx&wdOrigin=BROWSELINK): suggested that NICE review the support available to help navigate and understand committee documents. In addition to the monthly briefings for patient experts and the support of a NICE public involvement adviser, the SIP provides additional help for patients and lay members to understand the company submission which forms part of the committee papers. The company submission includes detailed technical information, on the condition, treatment, clinical effectiveness and cost effectiveness.
6. Introducing the SIP into NICE was included as a proposal in the methods and process consultation and was supported by a majority of stakeholders, particularly patient and carer organisations and life sciences companies. The statement in the consultation was “Companies will provide a 'Summary of Information for Patients' with their evidence submission” with a Likert scale response option, see figure 1. Figure 2 shows the breakdown of respondents to the statement by type of respondent.

Figure 1

Figure 1: Pie chart shows the summary of total responses to the survey question about whether companies should provide a Summary of Information for Patients.
80% agreed or strongly agreed that the SIP should be provided.
7% did not think that the SIP should be provided
10% neither agreed nor disagreed that the SIP should be provided
1% (one person) responded they didn't know.



**Figure 2**

**Type of respondent to the SIP statement**

|  |  |
| --- | --- |
| **Type of respondent** | **Number of responses** |
| Patient and carer organisation | 42 |
| Pharmaceutical company | 38 |
| Other such as ABPI | 14 |
| NICE committee member | 3 |
| Individuals | 2 |
| NHS | 2 |
| NICE (Public Involvement) | 1 |
| Unknown | 1 |
| Total responses | 103 |

1. The two key issues identified in the consultation responses were:
   1. the timing of the SIP: when would it be submitted and given to patients
   2. respondents wanted more information on the SIP and how it would be used.
2. Other issues included;
   1. the wish for plain English summaries to be produced at all stages of guidance development, especially the External Assessment Group Report and at the technical engagement stage
   2. quality control – including to mitigate against marketing or promotion
   3. level of detail – and whether it would include information about health economics
   4. learning from NICE pilots and use of the SIP at the SMC
   5. include patient organisations in the development and evaluation of the SIP
   6. how would the SIP be evaluated
   7. the wish for one SIP across HTA bodies

# Short-life working group

1. NICE decided to set up a short-life working group to advise NICE in implementing the first stage of the SIP for medicines. The working group met 5 times from January – March 2022 and comprised of equal numbers of patients (patient organisation members, patient experts and lay members) and NICE staff.

## Formation

1. Non-staff members of the short-life working group were invited to submit expressions of interest to NICE to join the working group. An email was sent out to all the stakeholders on the Stakeholder Insight Group - an email group open to any stakeholders who wished to engage in the process consultation.
2. We asked for expressions of interest from people from patient organisations or individual patient experts with previous experience of working at NICE, preferably in medicines appraisals who have provided written submissions to NICE. We were looking for one person representing each of the following disease areas: cancer, non-cancer and rare disease. We received 9 expressions of interest. We included another patient place to keep the patient to NICE ratio even, as a chair of an evaluation committee volunteered (and was accepted) to join the working group.
3. The working group consisted of 1 person from a rarer cancer organisation, 1 person from a non-cancer organisation, 1 person from a rare disease organisation and 1 rarer cancer patient expert, 1 technology appraisal lay member, 1 technology appraisal committee chair, 1 senior public involvement adviser, 1 associate director covering both highly specialised technology (HST) and technology appraisals (TA), 1 project manager covering TA and HST, and 2 technical advisers (covering the same role in the group). The members from patient organisations had all also had experience of being patient experts (3 on TAs and 1 on HSTs).

## Aims

1. NICE had 3 aims for the short-life working group:
   1. To amend the international guides for patients and companies for use with patient experts at NICE
   2. To advise on how to evaluate the SIP
   3. To advise on the communication and education around the SIP to companies and patient organisations and experts.

## Benefits of implementing the SIP

1. The working group agreed that there were many benefits for implementing the SIP at NICE, whilst stressing that its use by patient experts is optional. Benefits include helping patient experts:
   1. as a source of background reading to help with participation.
   2. understand of the issues at the technical engagement stage (if used during the evaluation)
   3. understand the company submission and thus help with the committee papers and discussions.

## Concerns about implementing the SIP

1. A few concerns were raised about implementing the SIP and these were:
   1. Timing – this was out of scope for phase one – see below
   2. Governance – the SIP is written by the company and not independently verified. To mitigate against any concerns of marketing or promotion by the company the patient guides will make clear firstly, who the author of the SIP is and secondly, that patients are asked to compare the SIP with their experience. Additionally, members of the Public Involvement Programme at NICE would read the SIP before it is made available to patient experts for obvious marketing and promotion as advised by the HTAi PCIG group when developing the international SIP.

## Out of scope

1. The use of the SIP as background information to help inform patient organisation’s written submissions for medicines evaluation to NICE was out of scope for phase 1 of the implementation of the SIP for medicines, as it involves further consideration of NICE’s timelines. However, thoughts and recommendations from the working group are included in the recommendations section of this report. Implementing the SIP for patient organisations will be addressed in phase 2.
2. The positioning of the SIP is also out of scope, for the same reason. However, thoughts and recommendations from the working group are included in the recommendations section of this report.
3. Plain English summaries of other documents were also out of scope.
4. Development and use of the SIP outside NICE – this is the work of HTAi PCIG project group working on the implementation of the SIP.

# Outputs

## Documents

1. The outputs of the group based on tailoring the international template and guides for use at NICE were:
   1. A SIP template for companies
   2. A guide for companies
   3. A guide for patient experts
   4. A guide for patient organisations supporting patient experts.
2. In developing these outputs the working group covered the issues raised during the process consultation mentioned above (8b,c,d,e,f)

## Recommendations – in scope

1. The working group was asked to advise NICE how the use of the SIP should be evaluated for the first year. This included when to evaluate it and with whom.
   1. Patient experts were to be asked questions about the SIP after their attendance at committee meetings as part of the experience survey that they already receive
   2. Companies will receive a survey at the end of the first year of the SIPs use
   3. Once a and b have been completed, and depending on the results, a webinar to bring patients and companies together to talk about the results and future improvements to the SIP could be held.
2. The working group were asked to advise on how to communicate and educate stakeholders including patient organisations, patient expert and pharmaceutical companies about the SIP and they advised:
   1. Making the template and guides available on the NICE website
   2. Producing a short YouTube video about the SIP
   3. Including support about the SIP for patient organisations and patient experts in both the monthly training and support already provided to patient organisations and patient experts including ongoing support provided by the named public involvement adviser for a particular evaluation.

## Recommendations – out of scope

1. The working group had recommendations outside the scope of the group. There were:
   1. That timelines are amended so that patient organisations could receive the SIP and use it before completing their submissions, should they wish
   2. That NICE consider asking the companies for an early version of the SIP at scoping stage as part of the scoping documentation
   3. That NICE considers producing a document (other than the final scope) after scoping, as the outcome of the scoping consultation and workshop (if there is one) and incorporating comments on the company’s early SIP
   4. That an early version of the SIP is provided to all stakeholders at the invitation to participate stage in the timeline so that it is of maximum benefit to other stakeholders such as patient organisations
   5. Annual training for HST and TA committees on how best to talk to patient experts (in the same way that health and safety training gets repeated annually).

# Next steps

1. For medicines evaluations starting from 1 February 2022, companies are asked to provide a SIP which will be shared with patient experts to support their participation.
2. NICE is asked to implement the recommendations on evaluation (22 above) and communication (23 above).
3. NICE is asked to consider the recommendations in point 24, prioritising 24a *That the deadline for non-company submissions should be moved later so that patient organisations could receive the SIP and use it before completing their submissions, should they wish.*