Briefing Book Guidance for Company

General Points for Preparing a Briefing Book:

- Use the official template to submit a Briefing Book (BB) to NICE Scientific Advice (SA) in **Microsoft Word format**.
- The manufacturer/sponsor may insert their logo on the title page.
- Replace information in brackets [ ] with relevant information on your product/company
- The length of the briefing book should be no more than 50 pages (excluding annexes). This is a maximum and should not be considered a target. There is no lower limit on the number of pages in the briefing book, as long as the required information is covered in significant detail.
- The size of the briefing book file must not exceed 10Mb. Essential information from self-standing documents such as study protocols or reports should be incorporated into the briefing book. The documents themselves may be submitted separately as appendices or annexes. Please do not embed these documents directly into your briefing book.
- The template should be used as a guide and judgement exercised as to which sections are relevant to the product for which advice is being sought.
- Additional sections may be inserted into the BB when required. Where relevant data are missing, this should be explained and an indication given as to when they may become available.
- Questions to NICE SA should be followed by an explanation of the company's position. The wording of the questions should be clear and concise.
- It is not necessary to reference all statements in the BB; however, references should be provided if they relate to the methodology being proposed or the questions asked.
- Do not include preclinical data unless it is specifically relevant to the questions
- NICE Scientific Advice cannot provide advice on marketing or pricing.
- The Health Technologies Adoption Programme (HTAP) can participate in advice projects and advise on overcoming potential barriers to implementation within the NHS

Selected section-specific points

3.1 Indication(s) for use:

- Briefly outline the disease condition(s), patient population(s), position(s) in the treatment pathway(s) and clinical context within which you envisage your product being used.

3.2 Treatment Options and Relevant Guidelines:

- Current clinical care pathway and any variations across the NHS
- NICE or relevant UK guidance
- Current clinical outcomes
- Include details of equivalent of similar products (drugs, devices, procedures) in established use in the NHS for the condition
- Include new products on the horizon in advanced stages of development, if known

3.4 Regulatory Status:

- Details of CE mark and date granted or when expected
- Class of product – I, IIa, IIb, III
- EC directive the device is (or is intended to be) covered by – medical device (2007/47/EC), active medical device (90/385/EEC), in-vitro diagnostic medical device (98/79/EC)
- Notified body providing approval
- Any other indications for which the product is approved
- Has the MHRA been notified of the intention to undertake a clinical investigation (for non-CE marked products)? If yes, please provide the clinical investigation plan. If not, anticipated date for notifying MHRA[1]
- Intellectual property – details of any patents held by, or filed for, the technology[2]

[1] If the product requires clinical evidence, it is suggested that you approach NICE Scientific Advice before you notify the MHRA. This will allow you to take the advice into consideration when developing your clinical investigation plans and ensure these generate regulatory and HTA relevant endpoints/data.
[2] A condition of MTEP considering a technology is that it is novel. A granted patent is legal proof of novelty. Not having a patent would not prevent notification to MTEP.

- Has the technology been launched and is it available to the NHS?
- Details of the use of the technology outside the UK
- Has an evaluation of the technology been previously completed, is one being carried out, or is one planned for the future by any other national organisation within the UK?

4.1 Product properties:

- Brief description of the device/diagnostic
  - Mechanism of action[3] - how does the medical device/diagnostic work?
- Scientific or medical principles upon which the technology is based
  - How much evidence is available to support the proposed mode of action of the technology?
  - Claimed performance of the technology in humans
- Lifespan of product
- Features that make the technology innovative or a significant modification when compared with other technologies of its type

4.2 Proposed use:

- How is it used to treat, diagnose of otherwise assist management?
  - Is it used in combination with another technology or as part of a surgical procedure?
  - Who uses/administers it - patients, healthcare professionals, laboratory scientists?
- Frequency of use
- How results are made available or displayed (particularly in the case of tests)
- Compatibility with other NHS systems currently in use (if applicable)

[3] Mode of action is not a requirement for MTEP notification, but any sponsor that does not understand how their technology works is unlikely to receive positive guidance from NICE or endorsement from the clinical community. Knowledge of the mode of action helps to indicate the plausible promise for a technology, and will include elements of physiology, medical physics, and clinical engineering.

4.3 Intended use and Target Population:

- Target population to be treated/tested.
- Clinical context – the clinical condition or problem the device or diagnostic is intended to influence
- Specify product positioning in current NHS clinical practice and in the pathway of care (e.g. first line, second line, third line, screening pre-treatment, monitoring during treatment, etc.).
- Aim of treatment (preventative, curative, palliative, symptomatic, disease modifying).
- Are there any potential equality issues?

4.4 Comparator:

- The standard intervention against which the technology is compared – usually a similar or equivalent technology used in current clinical practice and defined in existing NICE guidance, or clinical guidelines form other UK bodies

- List all technologies which are similar or equivalent to the technology and how these differ from the technology in terms of their functionality

4.5 Clinical Data Available to Date[4]:

- Describe clinical studies performed to date and provide results if available
- If the administration of the product is associated with the use of a diagnostic test, a medical device or a medical procedure, provide relevant information, e.g. describe if:
    - Additional monitoring is required for the product
    - Additional resources and training is required
    - Adverse effects and management
- Have different, independent research groups proven utility for the product?
- Is there evidence in English language journals?
- Does the evidence include expert testimony from healthcare professionals working in the NHS?

[4] Include primary clinical and secondary research evidence on efficacy, effectiveness, usability and safety outcomes. Include clinical studies (with intermediate outcomes) of any design (experimental or observational) and any costing/ health economics studies, including non-UK studies.

4.6 Patient safety and risks:

- Potential adverse events for patients, healthcare system staff and facilities, reporting data available from all sources

4.8 Summary of Patient Engagement Information:

- Briefly describe if you have engaged with patients and/or patient organisations as part of your product development programme, and the nature of that engagement

  - If so, what issues/questions have you explored with patients/patient organisation groups e.g. real world applicability, limitations of the studies, outcomes of importance to patients, mode of administration, clarity of definitions etc.
  - Advice from patients or patient organisations used in the development of the technology – patients' preference, views on acceptability etc.

  - Have any issues with patients using the device been identified?

5. Product Value Proposition (s):

- This section of the BB is mandatory. Describe value propositions for the product and how the study evidence will be used to support these

5a. Potential additional patient benefit

- Extent to which your product has measurable benefits to patients over technologies, treatments or management currently in use within NHS in terms of its impact on quality or quantity of life

5b. Potential healthcare system benefits

- Extent to which your product has measurable benefits to the healthcare system over technologies, treatment or management currently in use within NHS

5c. Potential benefits for the sustainability agenda

- Extent to which your products is likely to contribute to the sustainability agenda – less energy usage, less waste etc.

6. Proposed Clinical Development Programme[5],[6].

- For each study, describe the objective, design (randomisation, blinding, etc., if relevant), location(s), frequency and duration of use, comparator(s), number of subjects and description of studied population and end point(s). Provide a trial diagram if available. Specifically describe:

- **Patient population** (inclusion and exclusion criteria, patient characteristics). How many patients will be included and what is the justification for the number

- **Subgroups** identified (provide justification)

- Selected **comparators** (provide justification)

- **End points** (primary, secondary, other). All scales and scores that will be used for end point measurement should be presented and their validity should be reported

- Study duration and follow-up

- Relevant methodologies and analyses of study data

- Data gaps expected in the evidence at the time of the initial evaluation. Provide plans to address these data gaps

7. Proposed economic evaluation:

This section is optional if no questions on economic evaluation are submitted to NICE Scientific Advice.

- Include a description and critique of the key assumptions related to the model structure

- Justify the chosen model structure in line with clinical pathway of care, list of assumptions and health states. Consider including a diagrammatical representation of the model structure

[5] Consider carefully what type of evidence your product requires. This will depend on the class of your product and not all MedTech products need clinical trials as other forms of evidence may be sufficient to demonstrate patients and health system benefit claims.

[6] As a minimum a diagnostic tests would need data on diagnostic accuracy, sensitivity, specificity, predictive values and clinical utility evidence.

- Describe sources of clinical evidence and how data from the clinical trial programme will be used in the analysis

- Define and justify time horizon and assumptions used in the analysis. Describe outcome measures. State clearly if expert opinion was used to inform any of the model parameters

- State how resources are identified, measured and valued for the technology and comparator

- Describe any proposed sensitivity analyses

9. Adoption

Fill in this section if you are also seeking advice from HTAP on adoption issues.

- Clinical issues could include
    - No clinical advocate/champion/user
    - Clinical resistance to change practice
    - No perceived need to change/adopt
- Financial issues could include
    - No obvious source of funds to purchase technology
    - Cost/benefit argument not clearly understood or acknowledged
    - Technology reduces commissioner costs but increases provider costs
    - 'Silo budgeting'- benefits realised in different place than costs incurred
- Logistical issues could include
    - Product not in NHS Supply Chain
- Workforce issues could include
    - Technology could require a change in clinical responsibilities e.g. from doctor to nurse
    - Technology could require a significant increase in clinical responsibility for a particular group of staff e.g. nurses
    - Technology may require/drive a change in setting of care e.g. from hospital to primary or community care

Further information relating to the content of the briefing book can be provided and discussed in a teleconference with NICE Scientific Advice.