# Annex 3: Company evidence submission template to support evaluation by ACE

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| **COMPANY EVIDENCE SUBMISSION FOR SUBSIDY CONSIDERATION** |
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| **Instructions for submission**This is the template for submission of evidence to the Agency for Care Effectiveness (ACE). The evidence provided in this submission will be taken into consideration by the ACE technical team if the submitted evidence follows the prescribed format and instructions in this form, and may be presented to the MOH Medical Technology Advisory Committee (MTAC) to inform the subsidy decision. **Companies should endeavour to only submit good quality, ideally comparative evidence with appropriate comparators**. Companies should carefully consider the evidence they wish to submit and are strongly advised against a data dump to avoid any protraction or delay in the evaluation of their product(s). Submissions that do not follow the prescribed format or instructions in the respective sections can be excluded from consideration. MOH and MOH MTAC are not obligated to accept any evidence submitted by companies in its subsidy decisions. |
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| **SECTION A - APPLICANT INFORMATION** |
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| Name of company: |   |
| Name of product manufacturer (if different from applicant company): |   |
| Point of contact: |   |
| Designation: |   |
| Contact number: |   |
| Email address: |    |
| Date of submission: |   |

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| **PLEASE INDICATE SUBMISSION CLASSIFICATION** |
| *Please tick (✓) one of the following on confidentiality of submitted information:* |
| This submission contains **NO** information provided in confidence. |  |
| This submission contains **SOME** confidential information clearly marked as **CONFIDENTIAL**. |  |
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| **1. Clinical need** |
| <State clearly the indication(s) applied for consideration. Define the proposed population and any relevant sub-populations. Please estimate the number of patients who would benefit from this product. Describe the expected place of the proposed product in the local treatment pathway for the indication(s) applied. Explain how the proposed product may change the existing pathway if it is subsidised. For a proposed product with multiple indications applied for consideration, present the pathways separately as necessary.> |
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| **2. Summary of clinical effectiveness and safety evidence** |
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| **Fields with an asterisk (\*) are compulsory. Please do not exceed 2,000 words (excluding references) for this section. Please provide the references (including relevant PDFs) and word count appropriately.** |
| Comparator\* | <By default, all applications must identify at least one comparator unless there a strong basis for not doing so. This may be a product or the current treatment or therapy that is most likely to be replaced by the product in the application.> |
| Summary of clinical effectiveness and safety evidence\* | <Provide a brief overview of the key trials which demonstrate the clinical effectiveness of the model for the relevant HSA-registered indication for this submission. Include a summary of any adverse reactions and safety evidence.><A brief summary of key results from non-randomised comparative evidence sources (including real world data), registry data that provide additional evidence to supplement randomised trials can be included. Evidence from animal studies or cadaveric studies are out of scope.><If there is a total of more than 10 studies identified for clinical effectiveness and safety per product group, please summarise and submit the top 10 studies with best quality and most appropriate study design. Preference should be given to good quality, comparative evidence that clearly demonstrates superiority in relevant patient outcomes. If non-comparative evidence is included, please distinguish them clearly in a separate paragraph in the summary write-up.><Where possible, please distinguish studies containing the product(s) under submission from other studies of mixed or other brands > |
| Summary of cost-effectiveness evidence (including costs)\* | <ACE prefers cost-effectiveness evidence expressed in incremental cost-effectiveness ratios using cost per quality-adjusted life year gained unless there are compelling arguments to use another outcome variable. Please provide details of measurable evidence of cost savings (due to improved patient outcomes, e.g. reduction in hospital stay) to the Singapore public healthcare system achieved through the use of the model. Where applicable, please include the estimated charge of the procedures involved in the use of product(s).> |
| Details of any ongoing studies | <Provide details of all ongoing studies from which additional clinical effectiveness evidence is likely to be available in the next 12 months for the indication being evaluated. Details include estimated completion date, estimated publication date and preliminary findings from these ongoing studies.> |
| Concluding remarks (if any) | <The submitting party can include brief concluding remarks at the end of the evidence submission.> |