Procedures for company submissions for funding consideration of medicines and cell, tissue and gene therapy products

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ACE
agency for
care effectiveness

Record of updates

Date	Version	Summary of changes
December 2020	1.0	Publication of initial procedures and guidelines for company submissions to ACE.
March 2022	1.1	Updated to clarify the ERC critique process and include information about process for companies to discuss risk-sharing agreement with ACE for their products, and to revise the MOH Drug Advisory Committee's terms of reference. Minor additions, wording changes and amendments of Figures throughout the document have also been made to improve the clarity of the text.
March 2023	1.2	Minor additions, wording changes and amendments of Figures throughout the document and templates have been made to improve the clarity of the text and streamline processes.
September 2023	1.3	Minor additions and wording changes throughout the document have been made to improve the clarity of the text and streamline processes.
January 2024	1.4	Updated to clarify the pricing resubmission process, re-registering submission intent, pre-submission meetings, ERC's response to the company response template and including a detailed change record for changes made to the evidence submission.
April 2024	1.5	Minor changes regarding submissions for related indications and updated reference links.
October 2024	1.6	Updated to include CTGTP List. Minor additions and wording changes have also been made to improve the clarity of the text and streamline processes.
October 2026	2.0	Updated to incorporate abridged evaluation pathway, clarify the pricing resubmission process, include new guidance on risk-sharing agreements and incorporate the charging procedure previously published as a separate document, clarify literature search requirements, and revise key company response timelines. Revisions have been made to improve clarity of the text. The guide has also been separated into two documents for ease of reference. (A) Procedures for company submissions for funding consideration of medicines and cell, tissue and gene therapy products (B) Guidelines for company submissions for funding consideration of medicines and cell, tissue and gene therapy products

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Foreword

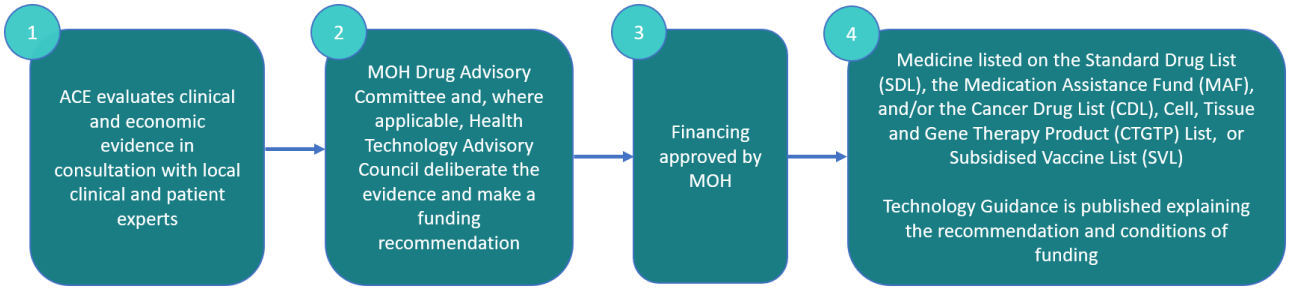
Established by the Ministry of Health (MOH) in 2015, the Agency for Care Effectiveness (ACE) is Singapore's national health technology assessment (HTA) and clinical guidelines agency. ACE evaluates health technologies and develops guidance to support evidence-based, value-driven care and national funding decisions.

The MOH Drug Advisory Committee (DAC) makes funding recommendations for medicines, vaccines and cell, tissue, and gene therapy products (CTGTPs). The Health Technology Advisory Council (HTAC) also provides recommendations for high-cost, high-impact health technologies with broader system or policy implications. All funding recommendations are subject to approval by the MOH (Figure 1).

Government subsidies for medicines are available through the Standard Drug List (SDL) and the Medication Assistance Fund (MAF). The SDL includes low- to moderate-cost medicines that are essential for the management of common conditions, while the MAF typically includes moderate- to high-cost medicines that have been assessed to be clinically effective and cost effective. Subsidies are also provided for CTGTPs listed on the CTGTP List, and for vaccines on the Subsidised Vaccine List (SVL).

Further information on government healthcare subsidies is available on the MOH website. For cancer medicines, the Cancer Drug List (CDL) specifies the indications eligible for MediShield Life and MediSave claims, applicable claim limits, and subsidy status for MOH-funded cancer drug treatments.

Figure 1: High-level steps for evidence generation and decision-making for medicines, vaccines and CTGTPs



Under the company-led process, companies can request the evaluation of eligible medicines and CTGTPs for funding consideration and submit evidence to ACE. This enables evaluations to be conducted close to the anticipated date of HSA regulatory approval, facilitating timely funding decisions and improving patient access to clinically necessary treatments.

Find out more about ACE at www.ace-hta.gov.sg/about-us.

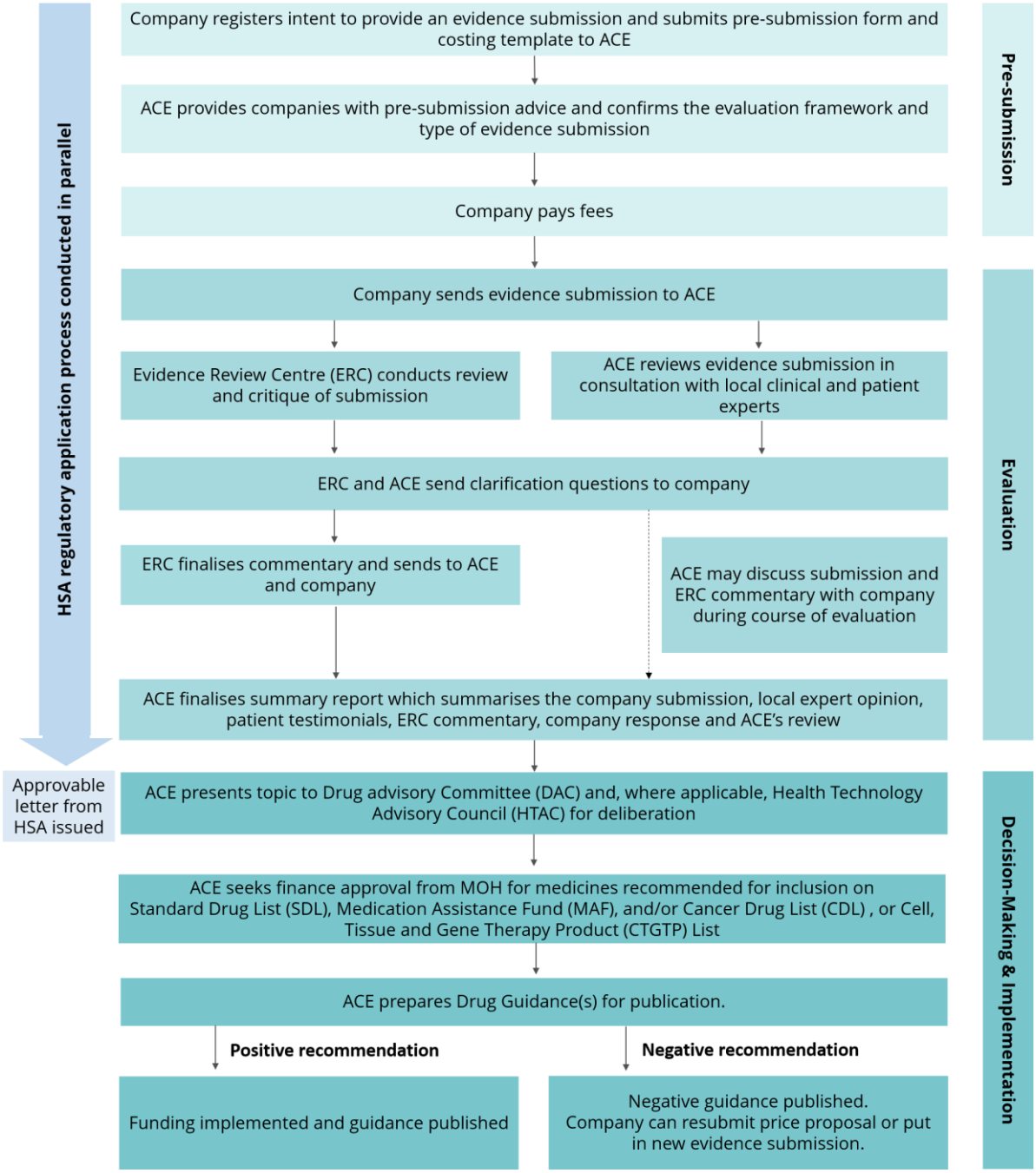
Abbreviations and acronyms

Term	Definition
ACE	Agency for Care Effectiveness
ALPS	Singapore's public healthcare supply chain and procurement organisation
CDL	Cancer Drug List
CDS	Cancer Drug Subcommittee
CTGTP	cell, tissue and gene therapy product
CMA	cost-minimisation analysis
CUA	cost-utility analysis
DAC	Drug Advisory Committee
ERC	Evidence Review Centre
HSA	Health Sciences Authority (Singapore)
HTAC	Health Technology Advisory Council
ICER	incremental cost-effectiveness ratio
LOA	Letter of Acceptance
LOU	Letter of Undertaking
MAF	Medication Assistance Fund
MOH	Ministry of Health, Singapore
NICE	National Institute for Health and Care Excellence (England)
NOO	notification of outcome
PAP	patient assistance programme
PBAC	Pharmaceutical Benefits Advisory Committee (Australia)
PVA	price-volume agreement
RSA	risk-sharing agreement
SDL	Standard Drug List
QALY	quality-adjusted life year
TGA	Therapeutic Goods Administration (Australia)

Introduction

This document outlines the company-led submission process (Figure 2), including the key procedures, timelines, stakeholder roles, and the decision-making framework used by the DAC to make national funding recommendations. It covers the evaluation process from pre-submission through to implementation of funding decisions. The company-led submission process currently applies only to medicines and CTGTPs.

Figure 2: Overview of company-led submission process



Section 1 Pre-submission process

Application process

Eligible applications

1. A company can propose to submit evidence for a:
   - **new medicine or CTGTP** – a new active ingredient that has been submitted to the Health Sciences Authority (HSA) for regulatory approval or has been approved by HSA; or
   - **new indication** – a new clinical condition or broader patient population that has been submitted to HSA for regulatory approval or has been approved by HSA for an existing medicine or CTGTP.

2. New strengths or formulations of already listed or previously evaluated medicines or CTGTPs are not eligible and should be requested by public healthcare institutions during the annual call for topics as described in ACE's Drug and Vaccine Evaluation Methods and Process Guide.

3. Companies are not required to prepare evidence submissions for biosimilars. Biosimilars of medicines listed on the CDL are considered for subsidy through the ACE-ALPS joint tender process. Where a biosimilar is not subsidised, the company may submit a pricing resubmission for consideration for listing on the CDL without subsidy.

Registering intent to submit evidence

4. A company can register its intent to submit evidence to ACE once a regulatory application for marketing approval has been submitted to HSA. Companies are encouraged to engage ACE early and, where appropriate, in parallel with the regulatory review process. Registration deadlines, submission timelines and DAC meeting dates are published on the ACE website.

5. Each submission should generally relate to a single indication for one medicine or CTGTP. A submission may cover a multi-drug regimen for a single indication. Multiple unrelated indications for the same medicine or CTGTP should be submitted separately.

6. To register its intent, a company must submit the completed Company Pre-submission Form and Costing template to ace_submissions@moh.gov.sg.

7. The Company Pre-submission form should provide sufficient information for ACE to understand the proposed submission and provide pre-submission advice. This includes the proposed evaluation framework, relevant comparator(s), key supporting evidence, regulatory status, and planned submission timeline. Companies may also identify technical, process or other evaluation issues that they wish to discuss with ACE.

8. The form should be completed with reference to the **Guidelines for company submissions for funding consideration of medicines and CTGTPs**. Information provided to ACE will be treated as confidential.

9. Companies seeking to proceed with a previously deferred submission must re-register their intent before the applicable registration deadline for the relevant DAC meeting.

Pre-submission advice

Provision of pre-submission advice

10. ACE will review the completed *Company Pre-Submission Form* and *Costing Template* and provide pre-submission advice, where appropriate. Advice may be provided by email or through a pre-submission meeting, depending on the nature and complexity of the proposed indication.

11. Where a meeting would facilitate discussion, ACE will arrange one with the company. Meetings will generally be prioritised for complex submissions and companies that are new to the company-led submission process.

12. Pre-submission advice generally takes place **8 to 16 weeks** before the planned evidence submission date.

Scope of pre-submission advice

13. Pre-submission advice is intended to support companies in preparing an evidence submission that addresses ACE's evaluation requirements. Companies should identify key issues, evidence gaps, areas of uncertainty and anticipated challenges relevant to the proposed submission.

14. Discussions may cover the proposed evaluation framework, evidence requirements and approaches for addressing uncertainties, including potential pricing arrangements, risk-sharing agreements, or other funding arrangements.

15. Advice provided by ACE during the pre-submission meeting is non-binding and does not influence the DAC's and, where applicable, HTAC's consideration of the submission or guarantee a positive funding recommendation.

Proceeding with the submission

16. Following completion of the pre-submission advice process, the company should inform ACE whether it intends to proceed with the evidence submission.

17. Where the company confirms that it intends to proceed, ACE will issue a **Letter of Offer,** setting out the applicable evaluation fee and terms of the evaluation.

18. For companies submitting evidence to ACE **for the first time**, ACE will also issue a perpetual Confidentiality Agreement to facilitate the exchange and safeguard of confidential or commercially sensitive information.

19. ACE will provide the evaluation timeline and key milestones requiring company input, including deadlines for responding to clarification requests and completing factual accuracy checks. Failure to meet these timelines may result in the evaluation being deferred to a subsequent DAC meeting.

20. Companies may contact ACE if additional questions arise while preparing their evidence submission.

Charging procedure

Evaluation fees and payment

21. Once the Letter of Offer has been accepted, ACE will issue an invoice for the applicable evaluation fee. The fees in **Table 1** are inclusive of GST.

Table 1: Applicable evaluation fees

Type of fee	Fee, including GST
Review and critique of submission for full evaluation	SGD 111,834
Review and critique of submission for expedited evaluation	SGD 45,889
Review of submission for abridged evaluation	SGD 16,350
Pricing resubmission	SGD 5,450

22. Companies must pay the applicable evaluation fees in full within 30 calendar days of the invoice date. Instalments or milestone payments are not permitted. No fee, or any part of a fee, will be waived or exempted.

23. ACE will accept the evidence submission only after payment has been received. Delays in payment may result in a revised evaluation timeline and consideration at a later DAC meeting.

24. Payment must be made in Singapore dollars using the payment method specified in the invoice. The company must bear all charges and taxes associated with payment, including telegraphic-transfer fees, bank-processing fees, foreign-currency charges and any applicable withholding tax.

Refunds

25. Fees for abridged evaluations and pricing resubmissions are non-refundable.

26. For full and expedited evaluations, no refund will be available once the submission has been sent to the ERC. Before this point, ACE may, at its sole discretion, consider a substantiated written request for a refund, including where regulatory approval has not been obtained or the technology will no longer be made commercially available in Singapore. Where a refund is approved, the contractual agreement between the company and ACE will terminate on the date of refund.

Changes to fees

27. ACE reviews fees periodically to ensure they continue to reflect the costs of conducting each evaluation. ACE will publish any revised fees on the ACE website before any changes take effect. Revised fees apply prospectively.

28. Enquiries may be sent to ace_submissions@moh.gov.sg.

Section 2 Submitting evidence to ACE

Confidentiality

29. The company is responsible for highlighting information that is academic-in-confidence or commercial-in-confidence within their submission in accordance with the instructions in **Guidelines for company submissions for funding consideration of medicines and CTGTPs**. It is not acceptable to classify an entire submission as "confidential" and information that is published or in the public domain should not be marked as confidential.

Handling information submitted by a company

30. ACE will use its best efforts to prevent unauthorised use, disclosure or dissemination of information deemed confidential or commercially sensitive by the company and will use such information solely for the purpose of evaluating the submission.

31. ACE follows the MOH's policies and procedures to ensure appropriate management, storage and disposal of sensitive information.

Copyright legislation

32. Companies must provide full-text copies of articles cited in their submission and ensure that appropriate copyright permissions have been obtained for electronic copies shared with ACE and the ERC.

Types of evidence submissions

33. Companies can submit evidence to ACE as either a **Full Evaluation**, **Expedited Evaluation or Abridged Evaluation**. The appropriate type of submission will be confirmed by ACE during the pre-submission advice process. All submissions must adhere to the structure and information requirements described in **Guidelines for company submissions for funding consideration of medicines and CTGTPs.**

Submissions for full evaluation

34. A full evaluation is required for a submission which includes a cost-utility economic model to support a claim of cost-effectiveness or cost-utility, when a company intends to demonstrate that the medicine or CTGTP under evaluation is:
    - therapeutically superior to the comparator, but likely to result in additional costs to the healthcare system, or
    - therapeutically inferior to the comparator but likely to result in lower costs to the healthcare system.

Submissions for expedited evaluation

35. An expedited evaluation is required for a submission which includes a therapeutic claim of non-inferiority and the use of the medicine or CTGTP is anticipated to result in equivalent or lower costs to the healthcare system compared to the comparator. A cost-utility analysis should not be included in a submission for expedited evaluation; however, companies may choose to include a cost-minimisation analysis (CMA) where applicable. In the event a complex CMA is submitted by the company, full evaluation fees may be charged to the company, as determined by ACE, to cover the cost of the additional time needed by the ERC to complete their commentary.

Submissions for abridged evaluation

36. An abridged evaluation may be considered for selected medicines if they fulfil the following guiding principles:
    - A relevant overseas HTA agency assessment is available (e.g. NICE [England], PBAC [Australia]),
    - Funding can be determined without a cost-effectiveness analysis, e.g. through price referencing, and
    - The budget impact is reasonable or potentially cost saving.

37. Under the abridged evaluation, a cost-utility or cost-minimisation analysis is not required. Submissions will be reviewed by ACE without an ERC review, allowing them to be tabled at a DAC meeting one cycle earlier than submissions undergoing a full or expedited evaluation.

38. ACE will determine whether a proposed submission is suitable for abridged evaluation. Where an ERC review of the clinical evidence is required, ACE will advise the company of the revised evaluation route, fee and timeline.

Request for Proposal (RFP)

39. As part of the submission, companies are required to submit their **best cost prices** (i.e. the prices at which they sell the medicine or CTGTP to public healthcare institutions) in a Request for Proposal (RFP) template. Details of risk-sharing agreements (RSAs) and the impact of any proposed arrangements on the effective cost price should be clearly stated. The proposed effective price should align with the economic and budget impact analyses in the submission. In instances where a company is required to submit more than one RFP throughout the evaluation process, any new proposal submitted shall supersede previous proposals.

Submission process

40. Submissions and all correspondence during the evaluation should be sent by the agreed timeline via email(s) to ace_submissions@moh.gov.sg. If a file size exceeds email limits, the company should discuss alternative secure file transfer arrangements with ACE. The submission should include a signed cover letter (an electronic signature is acceptable) from the company which contains the following information:
    - Type of submission (full, expedited or abridged evaluation)
    - Medicine or CTGTP and indication under evaluation
    - Confirmation of whether an economic model has also been provided (if applicable)
    - Name(s) of third-party consultant(s) appointed to prepare the evidence submission (if applicable)
    - Names and contact information (email and phone number) of company representatives (primary contact and an alternative) that ACE can contact regarding the submission.

Submission check by ACE

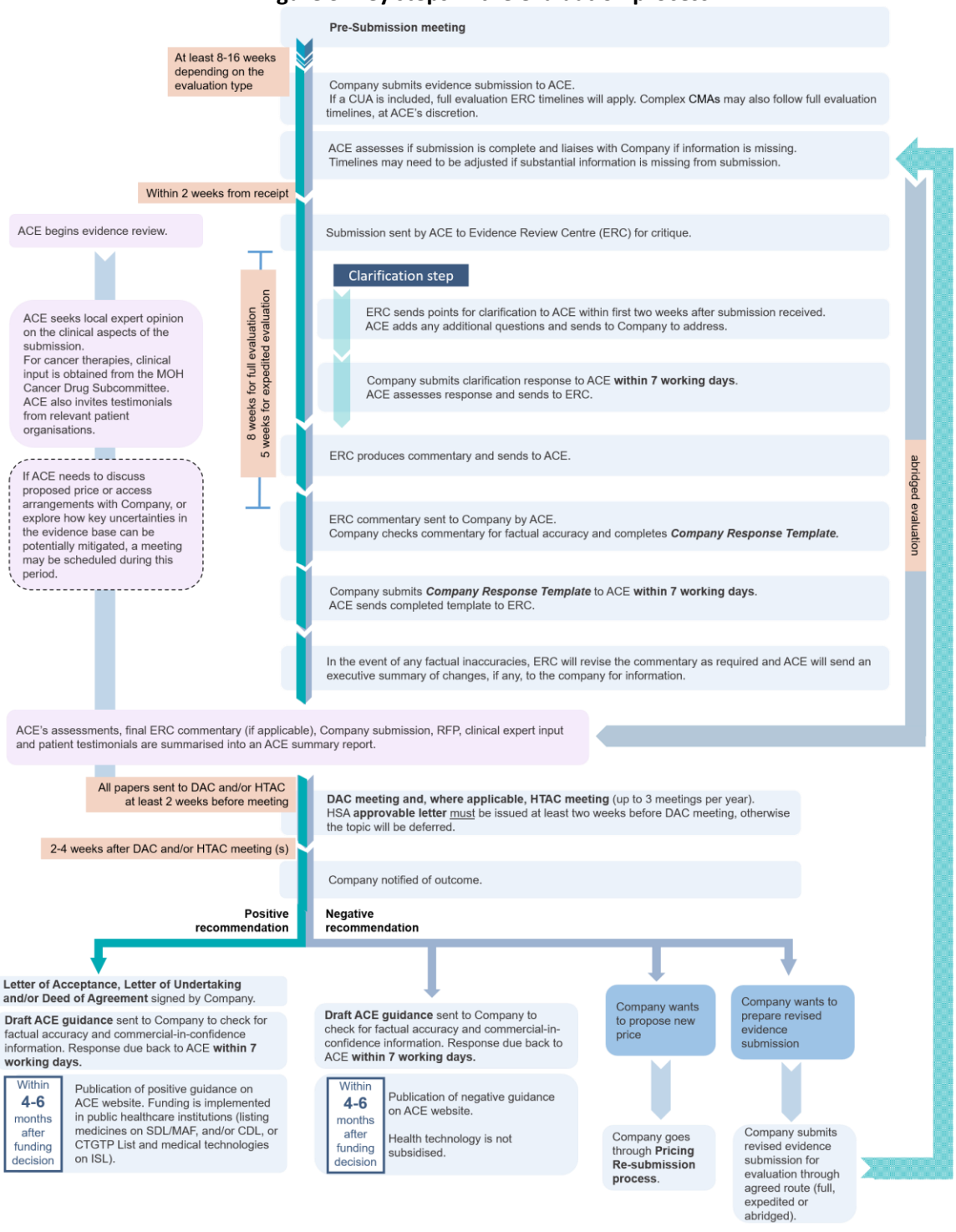
41. ACE will acknowledge receipt and review the submission to identify any missing files or key information. If a submission is considered incomplete and/or not fit for purpose, it will not be accepted, and the company will be advised to revise it. In this situation, the company may choose to withdraw the submission or advise ACE when a revised submission will be provided so that evaluation timelines can be amended accordingly.

Section 3 Review of evidence submission

Overview of the evaluation process

42. The key steps of the evaluation process are shown in Figure 3. Timelines indicate the minimum time needed for each step and may vary depending on the quality of the submission and whether additional time is required by the company to prepare further analyses to address uncertainties identified by ACE or the ERC.

Figure 3: Key steps in the evaluation process



Clinical and patient expert advice

43. ACE may seek advice from relevant local healthcare professionals and patient organisations to inform its assessment of clinical need, local practice and the evidence submission. For cancer medicines and CTGTPs, ACE may also seek advice from the MOH Cancer Drug Subcommittee (CDS). Non-Disclosure Agreement and Conflict of Interest requirements apply to all parties consulted.

ERC review and critique

44. Full or expedited submissions are sent to one of ACE's ERCs which have experience in conducting and critically appraising HTAs for decision-making. Companies are unable to request a specific ERC to review their submission. The ERC will be given **5 weeks** to review an expedited evaluation submission and **8 weeks** to review a full evaluation submission (including economic model).

Clarification request

45. Within the first two weeks after receiving a submission, the ERC will advise if any clarification or additional analyses are needed. ACE will collate these with questions from the ACE technical team and send them to the company to address within **7 working days**. The company's response will be sent to the ERC upon receipt.

46. If substantial additional analyses are required, or errors in the economic model require additional time to rectify, the company can discuss with ACE if a short extension is permitted. Any extended delays may result in the evaluation being rescheduled to a later DAC meeting. Any changes made to the evidence submission should be accompanied with a detailed change record.

Preparation and review of ERC commentary

47. The ERC will use a standardised template to prepare a commentary of the company evidence submission, economic model (if provided), and clarification responses in line with ACE's reference case described in the **Guidelines for company submissions for funding consideration of medicines and CTGTPs**. The ERC will be responsible for the content and quality of the commentary.

48. Once complete, ACE will send the commentary to the company for **factual accuracy checking**. Companies should use the **Company Response Template (not exceeding 5 pages)** to address any key clinical and economic issues highlighted by the ERC, and record any factual inaccuracies identified. The completed template should be returned to ACE within **7 working days**. No new information or analyses will be accepted at this stage.

49. In the event of any factual inaccuracies, the ERC will revise the commentary as required. ACE will send the company an executive summary of the ERC's response to the Company Response Template for information. Companies are not allowed to submit a revised price proposal after the ERC commentary is completed.

ACE summary report

50. ACE will prepare a summary report for the DAC, drawing on relevant information including the clinical and economic evidence, local expert opinion, patient testimonials, the company evidence submission, ERC commentary and the company's response, and any pricing proposals or risk-sharing agreements submitted by the company.

51. The summary report is an internal document and not shared with the company.

Section 4 Funding decisions

Drug Advisory Committee

52. The DAC is an expert committee that appraises the clinical and cost effectiveness of medicines, vaccines and CTGTPs. The DAC provides funding recommendations to MOH, including any conditions or criteria for subsidy and, where relevant, MediShield Life coverage for cancer treatments and CTGTPs. It comprises senior clinicians (specialists and general practitioners) and pharmacists from public healthcare institutions, and senior regulatory affairs and healthcare finance representatives from MOH. It is chaired by the MOH Director-General of Health (DGH) and usually meets up to three times per year.

Factors informing funding decisions

53. The DAC considers the full range of clinical and economic evidence available. The weight given to different types of evidence depends on their quality, generalisability to Singapore clinical practice, associated uncertainty, and relevance to the medicine or CTGTP and indication under evaluation. In general, greater weight is given to evidence derived from high-quality studies designed to minimise bias.

54. Based on the available evidence, the DAC makes funding recommendations considering the following core decision-making criteria:
    - Clinical need of patients and nature of the condition;
    - Clinical effectiveness and safety of the technology;
    - Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
    - Budget impact.
    - Organisational feasibility (where appropriate) – the potential impact of adopting the technology, including barriers to uptake.

55. Additional factors, including social, cultural, and ethical issues, and other value judgments, may also inform the DAC's funding considerations.

DAC recommendations

56. Unless a company intends to seek funding for an off-label use of a registered medicine or CTGTP under exceptional circumstances, a medicine or CTGTP cannot be considered by the DAC until it has regulatory approval from HSA, or the company has received an **approvable letter** from HSA **at least two weeks prior to the DAC meeting**, and formal approval is expected no later than 3 months after the meeting. The company is required to notify ACE once final approval is granted by HSA.

57. Based on its assessment of the evidence and consideration of the relevant decision-making criteria, the DAC may recommend or not recommend funding for the medicine or CTGTP, including for a defined subgroup if such a recommendation is supported by the evidence and feasible to implement in clinical practice.

58. If the DAC considers a cancer medicine for funding, the DAC Chairman and Minister for Health will

subsequently determine if it should be included on the Cancer Drug List (CDL) and its corresponding claim limits under MediShield Life and MediSave.

Health Technology Advisory Council

59. The HTAC is an independent professional body that supports MOH in determining whether financial support for high-cost, high-impact health technologies is appropriate. It comprises eminent individuals in their respective disciplines, including professionals from public and private sectors across disciplines such as healthcare and economics. HTAC reviews the clinical and cost-effectiveness assessments made by the DAC and provides funding recommendations to MOH.

Section 5 Guidance and funding implementation

Post-Committee processes

Drafting ACE guidance

60. Following the DAC and, where applicable, HTAC meeting, ACE will draft a guidance document outlining the recommendation(s), rationale, and key clinical and economic evidence informing the DAC's and, where applicable, HTAC's deliberations. Guidance documents are produced for full or expedited evaluations, covering both positive and negative recommendations, and are published on the ACE website before funding implementation. A plain English summary (PES) may also be produced for patients and the public.

61. **Commercial-in-confidence information is not published**. Where applicable, cost-effectiveness and annual budget impact results will be presented in ranges rather than as exact values.

62. **Cost-effectiveness results will be presented using the following ranges:**
    - Dominant (i.e. cost saving and health improving);
    - 0 to <SG$15,000/QALY gained; then
    - SG$15,000 to <SG$45,000/QALY gained; then
    - SG$45,000 to <SG$75,000/QALY gained; then
    - SG$75,000 to <SG$105,000/QALY gained; then
    - SG$105,000 to <SG$135,000/QALY gained; then
    - SG$135,000 to <SG$165,000/QALY gained; then
    - SG$40,000 increments to SG$365,000 (i.e., SG$165,000 to <SG$205,000/QALY gained, SG$205,000 to <SG$245,000/QALY gained etc.); then
    - >SG$365,000/QALY gained.

63. **Annual budget impact to the healthcare system will also be presented in ranges, such as:**
    - Cost saving
    - <SG$1 million
    - SG$1 million to <SG$3 million
    - SG$3 million to <SG$5 million
    - SG$5 million to <SG$10 million
    - >SG$10 million

64. Academic-in-confidence information is generally not redacted from the published guidance. However, ACE may consider redaction where the company identifies a commercial risk. Information already publicly available, including in overseas HTA reports, is not considered confidential.

65. Companies will receive draft ACE guidance ahead of publication and have **7 working days** to identify factual inaccuracies and confirm that the guidance does not contain information that poses a commercial risk.

Notification of outcome

66. ACE will issue the company a ***Notification of Outcome*** (NOO) advising it of the DAC's and, where applicable, HTAC's recommendation. Companies should not distribute the information in the NOO indiscriminately before the date of funding implementation.

Letter of Acceptance, Letter of Undertaking and/or Deed of Agreement

67. Where funding is recommended, ACE may issue a ***Letter of Acceptance*** (LOA), ***Letter of Undertaking*** (LOU) and/or ***Deed of Agreement*** setting out the agreed price, any applicable expenditure cap or risk-sharing agreement, and the conditions for funding. These are legally binding agreements.

Resubmission following a negative recommendation

68. For medicines or CTGTPs not recommended because of uncertain or unacceptable cost-effectiveness or budget impact, and for medicines being considered for reclassification from MAF to SDL, companies may submit an improved price and/or price-volume agreement proposal through the pricing resubmission process. New clinical study data or revised economic models are typically not required.

69. Where DAC and, where applicable, HTAC provide explicit guidance with a negative funding recommendation and the company submits a proposal that meets all elements of that guidance within the stipulated deadline, funding may be implemented within the implementation window associated with the original meeting.

70. Other pricing resubmissions, including proposals that do not fully align with the DAC's and, where applicable, HTAC's guidance, will be considered at a subsequent meeting. If recommended, funding will occur at the earliest within the implementation window associated with that subsequent meeting. Companies should refer to the key process deadlines on ACE's website when planning resubmissions.

71. Pricing resubmission fees apply to each medicine or CTGTP-indication pair and are payable separately for each indication included in a resubmission. Companies should avoid indiscriminate submission of minimally improved proposals. Delays in registering intent, paying the applicable fee or submitting the proposal may result in consideration at a later DAC and, where applicable, HTAC meeting.

72. Where new or updated clinical evidence needs to be evaluated, the company must provide a revised evidence submission, and the applicable evaluation fee will apply. This may include cases where funding was not recommended because of substantial uncertainty regarding clinical effectiveness or safety, limitations in the evidence base, or economic-model issues that cannot be readily resolved.

Funding implementation

73. Funding implementation typically occurs 4 to 6 months after a positive funding recommendation, subject to MOH financing approval and completion of the applicable agreement. ACE will advise companies of the relevant implementation timeline and requirements.

The Agency for Care Effectiveness was established by the Ministry of Health Singapore to drive better decision-making in healthcare through health technology assessment, clinical guidance, and education.

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