

Dated 7 January 2025: This document supersedes the version dated on 9 July 2024.

Charging Procedure for Review of Company Evidence Submissions to the Agency for Care Effectiveness

INTRODUCTION

The Agency for Care Effectiveness (ACE) of the Ministry of Health (MOH) of Singapore has been accepting evidence submissions from pharmaceutical companies since 2021. This process enabled participating companies to submit evidence for evaluation close to the anticipated date of regulatory approval by the Health Sciences Authority (HSA) and expedite funding consideration of their products compared to existing evaluation timelines¹. The procedures and guidelines that companies are expected to follow when preparing an evidence submission are available on the ACE website at <https://go.gov.sg/company-guidelines>. Since 1 January 2021, companies are charged for evidence submissions sent to ACE for full and expedited evaluations.

2. All submissions sent to ACE for full and expedited evaluation will be reviewed and critiqued by one of ACE's Evidence Review Centres (ERCs), which have experience in conducting and appraising health technology assessments (HTAs) for drug funding decision-making.
3. This document provides information about the types of fees and guidance on payment methods and refunds with regard to company evidence submissions to ACE.

CHARGING PROCEDURE

4. All companies that intend to provide an evidence submission to ACE will submit a completed pre-submission form and costing template, and discuss and confirm the type of submission and the anticipated submission timelines with ACE. More information about the pre-submission process is detailed in the procedure and guidelines for company submissions to ACE.
5. For a full or expedited evaluation, after the company registers their intent (via email to ace_submissions@moh.gov.sg) by submitting the completed pre-submission form and costing template, ACE will issue a Letter of Offer to the company seeking their agreement to have their evidence submission for the full or expedited evaluation reviewed and critiqued by an ERC and presented to the MOH Drug Advisory Committee (DAC), at the stated fee.
6. For pricing resubmission for the MOH DAC's reconsideration in relation to eligible medicines, ACE will issue a Letter of Offer to the company seeking their agreement to have their pricing resubmission reviewed by ACE and presented to the DAC, at the stated fee.
7. Once the Letter of Offer has been accepted and signed by the company and returned to ACE, it will form a contractual agreement between the company and ACE.

¹ Methods and processes for topics which are evaluated in-house by ACE technical staff and are not subject to the company-led submission process are on the ACE website at www.ace-hta.gov.sg.

8. Upon receipt of a signed Letter of Offer from a company, ACE will issue an invoice, containing a unique identifying number (i.e. invoice number) via VITAL (the Government's designated central agency for corporate shared services). Refer to Table 1 for a summary of the payment terms.

Table 1: Payment Terms of the Charging Procedure

Type of Fee	Review and Critique of Submission for Full Evaluation	Review and Critique of Submission for Expedited Evaluation	Pricing Resubmission
Due date of fee payment	All fees must be paid in full within <u>30 calendar days</u> from the date of invoice. Payment in instalments or by milestones is not permitted.		
Late payment	A reminder will be sent to companies approximately <u>one week</u> before the due date of within 30 calendar days.		
	If payment is not received on time, any company submission provided by the company will not be accepted until full payment is received. In the event of extended delays, the evaluation timelines will be revised and the topic will be rescheduled to a later DAC meeting date.		

9. ACE will accept payment in Singapore dollars via Electronic Bank Transfer (e.g. telegraphic transfer) or any other payment method as per the instructions provided in the invoice. The invoice number must be entered in the free-text portion of the transaction when payment is made.

10. ACE is not responsible for any fee charged during the payment process (including any fee charged for any telegraphic transfer). If withholding taxes are imposed by any tax authority on any payment to ACE, the company is responsible for making payment of such taxes directly to the relevant authority on a timely basis. All other additional costs and taxes incurred by ACE for receiving an overseas payment, such as bank processing fees for telegraphic transfers or foreign currency, should also be borne by the company. When making a telegraphic transfer, the charge code should be indicated as "OUR" in the payment instruction.

FEE SCHEDULE

11. Table 2 outlines the fees with effect from 7 January 2025. All fees stated in Table 2 are inclusive of Singapore's Goods and Services Tax (GST) at a prevailing rate of **9%**, which is payable by the company.

Table 2: Fees for Review of Company Evidence Submission to ACE

S/N	Type of Fees	Fees with effect from 7 January 2025
1	Review and Critique of Submission for <u>Full</u> Evaluation	SGD111,834 including GST
2	Review and Critique of Submission for <u>Expedited</u> Evaluation	SGD45,889 including GST
3	Pricing Resubmission	SGD5,450 including GST

12. The fees for S/N 1 and 2 take into account the time and personnel required by the ERC to complete a written critique of the evidence submission and to review additional information or analyses provided by the company in response to clarification questions. Administration

and review fees for ACE staff involved in the evaluation process and presentation to the DAC will now be charged to companies.

13. The fees for S/N 3 take into account the time spent by ACE staff to review the company submissions and prepare the necessary reports for consideration.

14. There will strictly be no waiver or exemption of fees or any part thereof.

REFUNDS

Submission for Full and Expedited Evaluations

15. Refunds will not be provided in any circumstances once the submission has been sent to the ERC for critique.

16. ACE may approve refunds for reasons acceptable to ACE in its sole discretion (which must be substantiated in writing and with the relevant supporting documents), provided that the submission has not been sent to the ERC. An acceptable reason would include (i) the proposed technology fails to achieve regulatory approval for example by the Health Sciences Authority (HSA), or (ii) the company no longer intends to make the technology commercially available in Singapore. In the event that a refund is provided to the company, the contractual agreement between the company and ACE will be terminated with effect from the date of the refund.

17. If a company initially pays the fee for a full evaluation but subsequently switches to or requests an expedited evaluation, ACE will refund the difference in fees only if the submission has not been sent to the ERC for critique, and an expedited evaluation is considered by ACE to be appropriate. In this instance, ACE will issue a new Letter of Offer to the company to reflect the new contractual agreement between the company and ACE.

Submission for Pricing Resubmission

18. No refunds will be provided to the company for any pricing resubmission under any circumstances.

REVISION OF FEES

19. Where applicable, fees are charged based on the time spent by personnel required by the ERC and/or ACE to conduct the review and prepare the reports for funding consideration. ACE may amend the fees as required and will publish the revised fees on the ACE website. Any changes to the fees will be applied prospectively, with the company obliged to pay the fees that are in effect when the Letter of Offer is issued.

CONTACT INFORMATION

20. Any enquiries should be directed to ace_submissions@moh.gov.sg.