

***Dated on 5 January 2024:*** This document supersedes the version dated on 20 January 2023. The fees stated will take effect from 1 January 2024.

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

### **INTRODUCTION**

The Agency for Care Effectiveness (ACE), Ministry of Health (MOH) 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 timelines<sup>1</sup>. 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. With effect from 1 January 2024, there will be one new type of fee imposed on companies namely, pricing resubmission for MOH Drug Advisory Committee (DAC)'s reconsideration.
4. This document provides information about the three types of fees and guidance on payment methods and refunds.

### **CHARGING PROCEDURE**

5. All companies that intend to provide an evidence submission to ACE will submit a pre-submission form and discuss and confirm the type of submission and the anticipated submission timelines. More information about the pre-submission process is detailed in the procedure and guidelines for company submissions to ACE.
6. Once the type of submission is finalised or company wants to resubmit its pricing proposal for DAC's reconsideration, ACE will issue a Letter of Offer to the company seeking their agreement on the following at the stated fee:
  - to have their evidence submission for the full or expedited evaluation reviewed and critiqued by an ERC; or
  - to have their pricing resubmission reviewed by ACE.

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.

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<sup>1</sup> 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](http://www.ace-hta.gov.sg).

7. 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). 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
<b>Due date of fee payment</b>	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.		
<b>Late payment</b>	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.		

8. 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.

9. ACE is not responsible for any fees charged during the transfer process. If withholding taxes are imposed by the tax authorities on any payments to ACE, the company is responsible for making payment directly to the relevant authorities on a timely basis. Any 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 the telegraphic transfers, the charge code should be indicated as “OUR” in the payment instruction.

## FEE SCHEDULE

10. [Table 1](#) outlines the fees with effect from 1 January 2024. 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 1 January 2024 <sup>2</sup>
1	Review and Critique of Submission for <u>Full</u> Evaluation	<b>SGD91,792.13 including GST</b>
2	Review and Critique of Submission for <u>Expedited</u> Evaluation	<b>SGD38,876.67 including GST</b>
3	Pricing Resubmission	<b>SGD5,450 including GST</b>

<sup>2</sup> There is an upcoming fee revision in 2024 for review and critique of submission for full and expedited evaluation. The revised fees will be updated in the document when ready. The current fees for review and critique of submission for full and expedited evaluation shown here are the respective existing fees (since 2021) with 9% GST with effect from 1 Jan 2024.

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11. 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. No additional administration or review fees for ACE staff or MOH committees involved in the evaluation process will be charged to companies.

12. The fee for S/N 3 takes into account the time spent by ACE personnel to review the company submissions and prepare the necessary reports for consideration.

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

## **REFUNDS**

### Submission for Full and Expedited Evaluations

14. Refunds will not be provided once the submission has been sent to the ERC for critique. Refunds will only be given for reasons that are acceptable to ACE, as described in paragraphs 15-17. 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.

15. If a company provides an evidence submission to ACE but then subsequently withdraws it (e.g. if the product fails to achieve regulatory approval by the Health Sciences Authority (HSA), or the company no longer intends to make the product commercially available in Singapore), ACE will not provide any refund to the company **if the submission has already been sent to the ERC** for critique.

16. If ACE identifies that an evidence submission is not fit for purpose (e.g., significant information is missing or economic model is non-functioning) before it is sent to the ERC for critique, the submission will be rejected and the payment will be refunded unless the company requests to provide a revised evidence submission. In this instance, all existing timelines for the evaluation will no longer apply and the topic will be rescheduled once the company confirms revised submission timelines.

17. If a company initially pays the fee for a full evaluation but provides a submission for an expedited evaluation instead, ACE will refund the difference in fee if the ERC has not begun its critique of the submission yet, 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 the 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 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. For any queries regarding payment, please contact Ms Leck Hui at [leck\\_hui@moh.gov.sg](mailto:leck_hui@moh.gov.sg). All other enquiries relating to company evidence submissions should be directed to [ace\\_submissions@moh.gov.sg](mailto:ace_submissions@moh.gov.sg)