

Frequently Asked Questions (FAQ) for: Singapore Health Product Access and Regulation E-System (SHARE) – Post-Industry Briefing

System Access and User Management

1. How do I access the SHARE system?

Access to SHARE requires Corppass authentication. The process involves two key steps:

- (i) Your company's Corppass Administrator must first add "HSA E-Services: Singapore Health Product Access and Regulation E-System (SHARE)" to your entity's e-Services through the Corppass portal.
- (ii) After adding the e-Service, the Administrator needs to grant you access rights to use SHARE.

For more information about Corppass and managing e-Services, visit <https://ask.gov.sg/corppass/>

We recommend completing this setup now to ensure a smooth transition. From 14 July 2025, you will be able to log into SHARE and access Medical Devices related applications via <https://share.hsa.gov.sg/>.

2. How can foreign staff access the system?

Foreign staff can access SHARE through a Singpass Foreign user Account (SFA). For detailed information about setting up and managing SFA accounts, please refer to the official guide at: <https://ask.gov.sg/corppass/questions/cm1q0y3qy0045wdnwhfznmw8a?from=search>

3. Will existing MEDICS access credentials be automatically transferred to SHARE? What steps are required for system access?

No, MEDICS access credentials will not be transferred to SHARE.

SHARE and MEDICS operate as separate systems with distinct access management protocols. Access to SHARE requires specific CorpPass authentication. Your company's CorpPass Administrator must explicitly grant access to "HSA E-Services: Singapore Health Product Access and Regulation E-System (SHARE)" through the CorpPass portal.

To ensure a smooth transition, we strongly recommend completing this setup prior to the system launch. From July 14, 2025, authorised users can access Medical Devices related applications through SHARE at <https://share.hsa.gov.sg>.

4. What are the user roles and access permissions available within SHARE, and how are they managed?

All users granted access by their CorpPass administrator will have full access rights within SHARE, including the ability to draft and submit applications.

5. Can multiple users from the same company access and work in SHARE simultaneously? How is concurrent access managed?

Yes, SHARE supports concurrent access by multiple users from the same company.

6. How does SHARE facilitate third-party entities to submit responses to Input Request?

When an application's Input Request requires third-party input, the primary applicant can designate specific queries for third-party response. The steps to request for third party access to Input Request Queries is as follows:

- (i) Request for Third Party access in SHARE under the Input Request
- (ii) Key in the email address of the Third Party counterpart for authorisation by HSA
- (iii) Provide the Third Party counterpart with the Third Party Access Link (<https://share.hsa.gov.sg/medics/thirdparty/login>) and the Application Number.

When the Third Party counterpart accesses the access link, they will be required to key in their authorised email address and application number. An One-Time-Password (OTP) will be emailed to the provided email address to authenticate the access.

7. What access rights will Third Parties have after being granted access to Input Request?

Third parties will only have access to their designated queries. They will be able to respond to the queries and attach supporting documentation.

They will no longer have access to the queries after they have successfully submitted the response.

8. Who can view responses and documents provided by Third Parties?

Responses and documents uploaded by Third Parties will be visible only to HSA officers and not to the primary applicant, ensuring appropriate information segregation.

File Management and System Capabilities

9. What file types are supported for upload in SHARE?

SHARE accepts a wide range of file formats:

- PDF files (.pdf)
- Microsoft Office files (.docx, .pptx, .xlsx)
- Image files (.bmp, .gif, .jpeg, .jpg, .png, .tif, .tiff)
- Video files (.avi, .mpeg, .mpg)
- OpenOffice files (.ods)
- Other formats (.csv, .rtf, .txt)

10. What are the file size limits for uploading documents?

Each upload has a maximum size limit of 5GB.

If you have multiple files that exceed this limit when compressed, you can upload them as individual files instead of a single zipped file. Each individual file upload also maintains the 5GB size limit. This flexibility allows you to submit large documentation sets while staying within the system's parameters.

11. What is the acceptable dossier format for product registration?

Currently, SHARE accepts the ASEAN Common Submission Dossier Template (CSDT) format. We are working to incorporate the IMDRF Table of Contents (ToC) format in future updates.

12. How does SHARE manage document organisation and accessibility during Input Request responses?

SHARE implements a structured folder system for document management during Input Request responses. Applicants can upload supporting documents within predefined folder structures and reference specific documents when addressing queries.

13. How will historical documentation be accessible in SHARE?

All historical documentation will be migrated to SHARE and remain accessible. Companies can access past submissions, supporting documents, and regulatory correspondence through their dashboard.

Application Management

14. Can I update applicant information during application processing?

Yes, you can update the applicant contact information without requiring an Input Request (IR). This includes adding email addresses under the notification email section to ensure multiple team members receive application updates.

15. What is the character limit for the form fields?

The character limits have been expanded for frequently utilised fields, including:

- (i) Intended Use: 5000 characters
- (ii) Input Request Response: 5000 characters

16. How can I search for applications?

Applications are organised into three categories: active, draft, and closed. They are displayed in a card format showing key information such as application type and product name. You can use the browser's search function (Ctrl+F) to locate specific applications.

17. Can I save applications as draft and access them again later?

SHARE allows users to save draft applications for future completion. However, draft applications will be automatically deleted after 180 days of inactivity.

18. How does SHARE handle extension requests for Input Requests, and what is the process for submission?

Applicants can submit extension requests directly through the system, and email notifications will be sent regarding the approval status.

19. How can contact information be updated after submission?

The “Address Book” feature allows companies to update their company contact information at any time. Additionally, notification email addresses for individual applications can be modified until the application is closed.

System Features and Limitations

20. Can we export lists of queries in input requests?

While the system is designed to export queries in Word document format, this functionality may be limited during the initial launch. We will provide updates regarding any temporary limitations.

21. Is it possible to export lists of licences and products?

Currently, this feature is not available but is under active development. In the meantime, you can search for licence and product information within the system. Licence information includes licence number, type, expiry date, and status. Product information includes product number, name, owner, device risk classification, expiry date, and status.

Data Migration and Transition

22. What information will be migrated from MEDICS to SHARE, and how will existing applications be handled?

All closed applications and those under evaluation will be migrated to SHARE. However, draft applications will not be transferred. Companies should ensure all critical draft applications are submitted in MEDICS before the cutover period. Historical data, including past applications and supporting documentation, will be accessible in SHARE to maintain continuity of records.

23. How will applications with pending Input Requests be managed during the system cutover period?

All Input Requests must be addressed by 4 July 2025, 5:00 PM. Any unanswered Input Requests will be administratively closed by HSA officers. Following the system cutover, these Input Requests will be reissued through SHARE to ensure continuity of application processing. Reissued Input Requests that were originally due during the cut-over period will be given additional days to respond on SHARE with no impact on the application's extension pool.

24. How will licence renewals and product retentions be handled during the cutover period?

Companies with renewal or retention due during the cutover period are strongly advised to submit their manual renewal and retention before 27 June 2025. This proactive approach will ensure continuous regulatory compliance and prevent any potential disruptions to business operations.

For companies with GIRO arrangement, auto-retention and auto-renewal that falls within the cut-over period will be automatically generated in SHARE after migration. If you do not intend to maintain the listing or licence, please submit a cancellation in MEDICS before 27 June 2025.

25. How will SHARE handle urgent submissions during the cutover period?

For urgent submissions during the cutover period, please submit a formal written request to HSA for our review.

26. Will existing company information and GIRO arrangements be transferred to SHARE?

Yes, all company information and GIRO arrangements will be automatically migrated to SHARE. GIRO processing is managed through a separate system and will continue uninterrupted.

Medical Devices Specific Queries

27. How does SHARE manage Class A product notifications and what submission options are available?

SHARE allows for individual submissions and bulk uploads via Excel format. Class A products in a single product notification application would have to be submitted under a single Importer's licence or Manufacturer's licence. You will have to submit a separate application if you wish to notify Class A products under a different licence.

28. How are product modifications and UDI updates handled in SHARE?

For Class A devices, modifications are submitted through amendments, while Class B, C, and D devices require change notifications.

29. How will existing SMDR listings and Class A databases be managed in SHARE?

All existing SMDR listings and Class A database information will be migrated to SHARE while maintaining public accessibility.

Miscellaneous

30. What resources will be available to support the transition to SHARE?

Comprehensive user manuals will be made available on the HSA website concurrent with the system launch on 14 July 2025.

31. Will post-market processes such as adverse event reporting be integrated into SHARE?

The integration of post-market processes into SHARE is in the pipeline. We will update you when the functionalities have been ported over.