

Single License Policy Implementation - FAQs

Category	Question	Answer
Policy Overview and Timeline	What is the new "Single License for Each Establishment Role" policy and when will it be implemented?	The new policy, directed by the Minister of Health's General Order No. 1 of 2024, mandates that each establishment role requires a separate license. This policy will come into effect on July 1, 2024.
Policy Overview and Timeline	What is the timeline for implementing the new Single License policy?	Key dates are: <ul style="list-style-type: none"> - February 16, 2024: New license applications limited to one role per application - July 1, 2024: Full implementation begins; renewal applications for licenses with multiple roles no longer allowed - July 1, 2024 to end of 2027: Period for affected establishments to apply for refunds of excess fees paid
Policy Overview and Timeline	What is the significance of the date February 16, 2024, in relation to the new Single License policy?	February 16, 2024, marks the date from which MDA established that new license applications could only be filed for one role per application. This was an initial step in transitioning to the full implementation of the Single License policy on July 1, 2024.
License Types and Permitted Activities	What are the permitted activities for different types of licenses under the new policy?	The permitted activities are: <ul style="list-style-type: none"> - Manufacturer License: Manufacturing and distribution of medical devices (only for devices manufactured by them) - Authorized Representative (AR) License: Registering medical devices - Authorized Importer License: Importing registered medical devices - Distributor License: Distributing registered medical devices
License Types and Permitted Activities	How does the new policy affect manufacturers?	Manufacturers with a Manufacturer License can engage in manufacturing medical devices and distributing only the devices they manufacture. Their license fee remains unchanged at RM 4000 for new applications and RM 2000 for renewals.

Category	Question	Answer
Impact on Existing Licenses	How will the new policy affect existing licenses that combine multiple roles?	Starting July 1, 2024, establishments with licenses that currently combine multiple roles will no longer be allowed to renew these combined licenses. Instead, they will need to apply for separate licenses for each role they wish to maintain.
Impact on Existing Licenses	How does the new policy affect establishments that currently hold a license as an Authorized Representative (AR) and also perform importing and distribution activities?	After July 1, 2024, establishments that previously held a single license as an AR while also conducting importing and distribution activities will need to obtain separate licenses for importing and distribution if they intend to continue these activities.
Application and Renewal Process	How should establishments handle the renewal process if their current multi-role license expires after July 1, 2024?	<p>They should:</p> <ol style="list-style-type: none"> 1. File a renewal application for the existing license, keeping only one role 2. Update the Google Form to indicate the Submission ID and the role being maintained 3. Apply for new licenses for the additional roles that were previously combined 4. Update the Google Form again to indicate the Submission IDs for the new license applications 5. Complete the Refund Request Form for fee refunds
Fees and Refunds	How have the license fees changed with the implementation of the Single License policy?	<p>License fees have been adjusted to reflect the new policy. For example:</p> <ul style="list-style-type: none"> - Single role licenses remain the same for both new and renewal applications - Combined roles now require separate applications/fees: <ul style="list-style-type: none"> - AR + Distributor: New license fee increased from RM 4000 to RM 6000 (RM 4000 + RM 2000) - AR + Importer + Distributor: New license fee increased from RM 4000 to RM 8000 (RM 4000 + RM 2000 + RM 2000) <p>(Technically, The fee structure hasn't changed per se as it closely reflects the fee prescribed in the Medical Device Regulation 2012 Schedule Fifth)</p>
Fees and Refunds	What is the process for requesting a refund for excess fees paid due to	To request a refund:

Category	Question	Answer
	the new Single License policy?	<ol style="list-style-type: none"> 1. Complete the Google Form "Permohonan Pulangan Balik Hasil (Refund - Single License)" at https://forms.gle/fp5pDtL8Uu1h6Pau7 2. Provide all necessary information in the form 3. MDA will review the application history to determine eligibility 4. If approved, the MDA finance unit will refund the excess fees to the specified bank account
Fees and Refunds	How long will the refund eligibility period last for establishments affected by the new Single License policy?	The refund eligibility period for establishments affected by the new Single License policy will last from July 1, 2024, until the end of 2027.
Compliance and Transition	What happens if an establishment haven't separate their multi-role license by July 1, 2024?	They will have to separate the license that corresponds to the activities that they intend to conduct during renewal (Authorized representative, importer, distributor)
Compliance and Transition	Is there a grace period for establishments to comply with the new Single License policy after July 1, 2024?	The single authorization, the single license policy will be fully implemented starting from 1 July 2024, and it will continue until the end of 2027 (until all of the establishments have converted their multiple role licenses into single role licenses)
Additional Information	What should establishments do if they have questions or need clarification about the new Single License policy?	They can forward their inquiry with regard to the single license policy to the License Unit official email address. (license-unit@mda.gov.my)
Forms and Documentation	What Google Forms are mentioned in the document, and what are their purposes?	<p>Two Google Forms are mentioned:</p> <ol style="list-style-type: none"> 1. "Borang Kemaskini Peranan Establismen" (Establishment Role Update Form): <ul style="list-style-type: none"> - Purpose: To update establishment role information - Link: https://forms.gle/5386BaPF3WjD7txe7 2. "Permohonan Pulangan Balik Hasil (Refund - Single License)" (Refund Request Form): <ul style="list-style-type: none"> - Purpose: To request refunds for excess fees paid - Link: https://forms.gle/fp5pDtL8Uu1h6Pau7

Category	Question	Answer
Forms and Documentation	What is the purpose of Appendix 1 in the document?	Appendix 1 provides scenarios to help establishments understand the implementation of the single license policy. It covers three key scenarios: 1. New license applications 2. License renewal applications before July 1, 2024 3. Permitted activities after July 1, 2024
Forms and Documentation	What information does Appendix 2 provide?	Appendix 2 outlines the procedure for license applications for establishments that want to renew licenses with grouped roles starting July 1, 2024. It provides a step-by-step guide for the renewal process under the new policy.
Forms and Documentation	What information is contained in Appendix 3?	Appendix 3 provides a comparison of license fees before and after the implementation of the Single License policy. It shows how fees have changed for various combinations of roles.
Application and Renewal Process	How does the new policy affect new license applications filed from February 16, 2024?	For new license applications filed from February 16, 2024, establishments can only choose one role per application. They are no longer allowed to combine multiple roles in a single new license application.
Application and Renewal Process	Can establishments still file renewal applications for licenses with multiple roles before July 1, 2024?	Yes, establishments can file renewal applications as usual, including for licenses that combine multiple roles, before July 1, 2024.
Fees and Refunds	Are there any changes to the fees for single-role licenses?	No, the fees for single-role licenses (e.g., Manufacturer, AR, Distributor, or Importer alone) remain unchanged for both new and renewal applications.
Fees and Refunds	When did the new fee structure for new license applications come into effect?	The fee structure hasn't changed per se as it closely reflects the fee prescribed in the Medical Device Regulation 2012 Schedule Fifth).
Compliance and Transition	How will the new policy affect the license renewal cycle for establishments	Existing establishments that hold multiple role licenses will be required to separate these licenses into individual role licenses during their renewal applications.

Category	Question	Answer
	currently holding multi-role licenses?	They will still be allowed to have multiple roles in one existing license until this time comes.
Specific Scenarios	How does the new policy affect establishments that currently hold a license as an Authorized Representative (AR) but also perform importing and distribution activities?	After July 1, 2024, establishments that previously held a single license as an Authorized Representative (AR) while also conducting importing and distribution activities will need to obtain separate licenses as an importer and distributor in addition to their AR license if they intend to continue these activities.
MDA's Role and Processes	How will MDA handle the evaluation and approval process for new license applications under the single license policy?	MDA will: <ol style="list-style-type: none"> 1. Evaluate the application. 2. Return the application to the applicant if any documents or information are needed. 3. Approve the new license application for the chosen role if the application is complete. 4. Require the establishment to pay the license fee according to the rates specified in Schedule 5 of the Medical Device Regulations 2012. 5. Check the eligibility of the applications to see if they are eligible for a refund.
MDA's Role and Processes	How will MDA determine refund eligibility?	MDA will review the application history to determine which establishments are eligible for refunds. This review will be based on the information provided in the Google Forms and the establishment's application history in the system.
Legal Basis	What is the legal basis for the implementation of the Single License policy?	The policy is based on the Minister of Health's General Order No. 1 of 2024, which directs the implementation of the single license policy for each establishment role.
Fees and Refunds	How do the renewal fees change under the new policy for establishments with multiple roles?	Renewal fees have also been adjusted. For example: <ul style="list-style-type: none"> - AR + Distributor: Renewal fee increased from RM 2000 to RM 3000 (RM 2000 + RM 1000) - AR + Distributor + Importer: Renewal fee increased from RM 2000 to RM 4000 (RM 2000 + RM 1000 + RM 1000)

Category	Question	Answer
		(The fee structure hasn't changed per se as it closely reflects the fee prescribed in the Medical Device Regulation 2012 Schedule Fifth)
Compliance and Transition	What about establishments that have renewed their licenses before July 1, 2024? Do they need to immediately separate their licenses?	<p>For any establishments that have renewed their licenses before July 1, 2024:</p> <ol style="list-style-type: none"> 1.They can continue using their combined license without needing to separate it into single licenses until their next renewal period. 2.When the time comes for their next license renewal, that's when they will need to apply for single licenses for each role. 3.However, if the establishment wishes to apply for single licenses earlier (before their next renewal period), they are still allowed to do so.
License Types and Permitted Activities	What about the role of manufacturers who produce their own products? Do they need separate licenses to import and distribute these products?	<p>For manufacturers who produce their own products:</p> <ol style="list-style-type: none"> 1. They are allowed to import and distribute the products they manufacture themselves using only one license, which is the Manufacturer License. 2. This Manufacturer License permits them to: <ul style="list-style-type: none"> o Manufacture their medical devices o Import materials or components needed for manufacturing their products o Distribute the medical devices they produce themselves 3. Manufacturers do not need additional licenses as importers or distributors for their own products. 4. However, if a manufacturer wishes to import or distribute products made by other manufacturers, they would need appropriate additional licenses (Importer License or Distributor License).
Application Process Details	How long does it take to remove roles after	The process of removing roles will take 3-5 working days after the role update form is completed.

Category	Question	Answer
	filling in the role update form?	
Application Process Details	When can a new application be submitted for roles that have been removed?	<p>There are two scenarios:</p> <ol style="list-style-type: none"> 1. If the update form is filled in after the renewal application has been submitted: <ul style="list-style-type: none"> ○ The new application can only be made after the renewal application process is completed. 2. If the update form is completed before submitting the renewal application: <ul style="list-style-type: none"> ○ The new application can be submitted concurrently with the renewal application – after the role stated in renewal application has been updated in the Medcast system .