What MDEL holders need to know about annual licence review for 2022

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About the annual licence review

To continue doing business, holders of an active medical device establishment licence (MDEL) must apply to have their licence reviewed every year before April 1. This requirement is in section 46.1 of the *Medical Devices Regulations* (MDR).

Licence holders with a suspended MDEL do not need to apply.

An annual licence review (ALR) ensures that MDEL holders are:

- complying with the regulatory requirements
- keeping their licence information up-to-date with Health Canada

Health Canada encourages you to submit your application early, any time after December 16, 2021, once you have received your ALR package. It's important to do so especially if:

- you are making amendments within your ALR application (for example, list of manufacturers, change in activity or class of device)
- you have multiple sites, manufacturers or suppliers (for example, more than 20) listed on your application

You must email your completed ALR application package as soon as possible and before April 1 of each year. We are not able to process any mailed-in application forms at this time. Email your package to mdel.application.leim@hc-sc-gc.ca.

As part of your application, a senior official must attest to having certain required procedures in place. This is in accordance with subsections 45(g, h and i) of the MDR. Health Canada posts the names of officials (refer to a previous MDEL bulletin about this) to ensure public accountability of an MDEL holder's activities.

A new fillable ALR summary report is now available in your ALR package. We encourage you to make your revisions and sign the form electronically before submitting it back to mdel.application.leim@hc-sc.gc.ca.

Fees

If you receive your new MDEL before April 1, 2022, you will also need to submit an ALR package before this date. You must also pay the applicable fees when you do so. This is in accordance with section 46.1(1) of the MDR.

We will issue an invoice after we receive and screen your ALR application for completeness. If you do not pay your invoice, we will not process your MDEL application and your MDEL will be cancelled.

A flat fee is charged for an ALR. The current fee for an MDEL is $4,581. If you qualify as a small business, you are eligible for a 25% reduction in the fee. The current fee payable for a registered small business is $3,435.75.

A small business is defined as:

- any business, including its affiliates, that has fewer than 100 employees **or**
- has between $30,000 and $5 million (CAD) in annual gross revenues

Applicants must be registered as a small business with Health Canada **before** they submit their ALR application. The registration must be completed through the Drug and Medical Device Small Business Application portal.

Please note that a company's small business status expires 1 year after registration. If you have previously registered as a small business with us and you still meet the definition, you will need to ensure the status is renewed **before** you submit your ALR application. If your unique identifier has changed since your previous registration, you will also need to register again.

If you no longer hold small business status **before** submitting your 2022 ALR application, we will issue an invoice for the full fee. Once issued, the invoice for the full fee amount will **not** be re-visited. It will remain payable regardless of any future changes to your small business status. Please note that the small business registration process can take up to 2 weeks.

For information on how to apply for or renew your small business status, visit the following webpage:

- Small business mitigation for drugs and medical devices: How to apply for or renew small business status

For questions about your small business status, please email the Small Business Office at sbo-bpe@hc-sc.gc.ca.

Timelines

We process ALR applications in the order we receive them. Our service standard is 120 calendar days to review and process a complete and paid application. For more information on the completeness of an application, please refer to the MDEL application instructions.

As a courtesy, we send out an ALR application package to all active MDEL holders starting in December every year. If you do not receive your ALR package by mid-January, email us at mdel.questions.leim@hc-sc.gc.ca.

If you do not wish to continue doing business after April 1, 2022, please indicate this on your ALR package and we will cancel your licence.

If we do not receive your application before April 1, 2022, we will cancel your licence.

Addressing ALR deficiencies

If your ALR application has deficiencies, you will be contacted to correct them. If we do not receive your response to the deficiency notice within the given timeframe or the information is incomplete, we will reject your application and cancel your MDEL. A deficient application does not meet the requirements stated under section 46.1(1) of the MDR.

If your licence is cancelled, you will no longer be authorized to manufacture, distribute or import your medical device. To resume any licensable activities, you will need to apply for a new MDEL. However, the fees related to processing the ALR application will still be due.

Contact us

For questions about an MDEL and the application process, contact the Medical Device Establishment Licensing Unit by email: mdel.questions.leim@hc-sc.gc.ca.

For questions about invoicing and fees for an MDEL, contact the Cost Recovery Invoicing Unit by email: criu-ufrc@hc-sc.gc.ca.

Related links

- Medical device establishment licence (MDEL) application: Instructions (FRM-0292)
- Annual review documents (information)
- Guidance on medical device establishment licensing (GUI-0016) - Summary
- Guidance: Fees for the review of medical device establishment licence applications
- How to pay your establishment licence fees
- Small business mitigation for drugs and medical devices: How to apply for small business status

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