Frequently Asked Questions

General FAQs

Q: Will HSA allow retrospective changes for the previous completed applications as they may not be in line with new requirements?

A: For approved applications
Company can incorporate these updates together with upcoming labelling revisions or changes for the registered devices and submit change notification.

For pending/new apps
Companies are encouraged to align with the new requirements for all pending and new applications for contact lens registration. However, if for some cases the company requires additional time, they can inform HSA on the proposed timeline in which the changes can be made for our consideration.

Q: With these changes to grouping criteria when implemented, the information to be reflected on Free Sale Certificate may differ. As company uses Singapore FSC for registration in other countries (e.g. China), approvals may be affected in other countries.

A: Company can write in to HSA on the issue faced with FSC so that HSA is aware of the issues faced on the ground. HSA will review the feedback received.

Q: When must the labelling change be done for registered contact lens?

A: Currently, HSA has not finalised the time line for already registered contact lens applications, however applicants are encouraged to submit the change for the already registered applications to align with the new requirements during the next labelling revision for the registered devices.

Electronic IFU (E-IFU)

Q: Should company inform HSA if the approved labels are to be supplied in soft copy?

A: There is currently no timeline on when company has to inform HSA.

But companies are advised to bundle the changes and inform HSA on the mode of supply of the IFU during the change notification application.

Q: Is eIFU allowed for other medical devices, such as contact lens solutions?

A: No. eIFUs are not allowed for any other non-professional use medical devices other than contact lenses.

The rationale for allowing eIFU for contact lenses is due to the small packaging size of the lenses. As such, it may not be easy to include the hard copy IFU into the packaging.

Q: Is over label allowed to include the weblink?

A: It will be allowed if the overlabel is to include the weblink only. Overlabel shall not include any other information and should not hide/cover any other information that exists on the approved labels for the device.

Q: Are replacement schedule, wearing schedule and intended use to be on all forms of labels?

A: The essential information can be included in label or IFU or a combination of both.

Contact Details of Registrant

Q: Does the company need to submit the change in the contact information on MEDICS and CRIS separately?

A: Yes.