Central Administration of Medical Devices

Notice to Applicant

Updating the categories of Medical Devices allowed for obtaining Annual Importation Plans

Year 2024

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An annual importation plan shall be issued for the following categories of medical devices:

1. **Registered medical devices for which a variation application has been submitted in the following cases:**

- Changing the name of the registration applicant while maintaining the same address and registration license number.
- Changing the address of the importing company while maintaining the registration license number.
- Adding/changing codes without a change in the design, the intended use of the device, or the class of use, following a notification from the Variations Department.
- Adding a country of origin / adding a manufacturing site for the same legal manufacturer.
- Changing the name of the foreign manufacturer while maintaining the same address.
- Changing the address of the legal manufacturer.
- Changing or adding a legal manufacturer (provided there is no change in the actual manufacturer)

The issuing of an annual importation plan is permitted for the following:

1. Any actual manufacturer listed in the registration license in the event of multiple actual manufacturers within the registration license.
2. A specific set of codes determined by the importation plan applicant, to the exclusion of other codes for which a registration license has been issued.
3. Any number of units/packs.
4. If there is more than one needle in the registration notification of a prefilled syringe, an application may be submitted to obtain an annual importation plan for one specific needle to the exclusion of others mentioned in the notification.

2. **Medical devices submitted for re-registration without change or addition to any of the device data mentioned in the expired registration license.**
3. **Medical devices previously registered and submitted for new registration due to a change in the composition statement only.**

In all the aforementioned cases, a one-year importation grace period shall be granted from the date of acceptance of the file by the General Administration for Medical Device Registration, in accordance with the regulatory guide for issuing importation approvals for medical devices of all types.

An annual importation approval is permitted to be issued, provided the following:

1. Verification from the General Administration for Medical Device Registration that the device has been granted the grace period.
2. Submission of a commitment from the importing company stating that the data recorded on the imported items matches the updated data.
3. The use of the annual importation plan is permitted throughout the validity period of the grace period granted by the General Administration for Registration. Upon the expiration of the grace period specified in the annual plan, the Consignment Release Unit shall verify the following:

	Category	Action Required for Verification
1	Registered medical devices for which a variation application has been submitted	Issuance of a letter by the Variations Department or a grace period extension letter
2	Medical devices submitted for re-registration.	Issuance of the re-registration License or extension letter.
3	Medical devices that were previously registered and are submitted for new registration.	Issuance of a new registration license or an extension letter.