Central Administration of Medical devices

Notice to Applicant

Updating the Applicable Procedures for Issuing Annual Plans for Registered Medical Devices and submitting a Request for Change/Re-Registration/ New Registration

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Category	Procedures Followed	
1. Medical devices that: • Were previously registered. • Have been considered as a new registration by the General Administration for Registration. • Have obtained a preliminary acceptance number.	Annual importation plans are permitted for medical devices previously registered and considered as new registrations by the General Administration for Registration in the following cases: • Change in raw materials and/or any other variation. • Change of registration applicant name only, or change of registration applicant name with other variations included in the variations list, in addition to the termination of the contract with the previous agent. **In the event of submitting an application to issue an importation plan with new data to the Registration Department, the application must refer to one of the following cases only:** • Transfer of manufacturing site / adding a country of origin / adding a manufacturing site for the same legal manufacturer (in case of adding a non-reference country of origin, a free sale certificate from a reference country must be submitted). • Changing the name of the foreign manufacturer while maintaining the same	The applicant is committed to submitting an application for a new importation plan immediately upon the issuance of the new notification.

	address. Changing or adding the legal manufacturer, provided there is no change in the actual manufacturer. The company must provide all new certificates covering this data, in addition to a letter issued by the registration applicant explaining the difference between the data in the registration file and the data mentioned in the old registration notification. A commitment from the applicant must be submitted to notify the Importation Plans Unit immediately upon issuance of the new registration notification. The issuance of an annual importation plan is **NOT** permitted for medical devices submitted to the Registration Department as a new registration, re-registration, or for variations in the following cases: 1. Adding or changing codes other than those mentioned in the [expired] notification. 2. Adding a non-reference country of origin that was not listed in the [expired] notification, unless presented to the Specialized Scientific Committee through the General Administration for Registration.	

2. Medical devices that: Are submitted for re-registration. And have obtained a preliminary acceptance number. In the following cases: A. No change in the data of the expired notification compared to the data mentioned in the re-registration file. B. A change in the re-registration file data compared to the expired notification.	The issuance of an annual importation plan is permitted in the following cases: * In the absence of a change in the expired notification data compared to the data mentioned in the re-registration file, the annual plan is permitted to be issued based on the data mentioned in the expired notification. * In the event of a change in the re-registration file data compared to the data mentioned in the expired notification, the plan is permitted to be issued based on the new data in the re-registration file, which includes the following cases: Request to transfer manufacturing site / add a country of origin / add a manufacturing site for the same legal manufacturer (in case of adding a non-reference country of origin, a free sale certificate from a reference country must be submitted). Changing the name of the foreign manufacturer while maintaining the same address. Changing the address of the legal manufacturer. Changing or adding the legal manufacturer, provided there is no change in the actual manufacturer. The company is committed to providing all new certificates that cover this data, in addition to a letter from the registration applicant explaining the discrepancy between the data in the re-registration file and	The applicant is committed to submitting an application for a new importation plan immediately upon the issuance of the new notification. An undertaking from the registration applicant must be provided to notify the Importation Plans Unit immediately upon the issuance of the new notification.

	the data listed in the expired registration notification. A commitment from the applicant must be submitted to notify the Importation Plans Unit immediately upon issuance of the new registration notification. The issuance of an annual importation plan is **NOT** permitted for medical devices submitted to the Registration Department as a new registration, re-registration, or for variations in the following cases: 1. Adding or changing codes other than those mentioned in the [expired] notification. 2. Adding a non-reference country of origin that was not listed in the [expired] notification, unless presented to the Specialized Scientific Committee through the General Administration for Registration.	
3. Registered medical devices for which a variation application has been submitted and which have obtained a preliminary acceptance number in the following cases: * Changing the name of the registration applicant. * Changing the address of the importing company. * Adding / canceling / changing codes.	The importation plan is permitted to be issued based on the data mentioned in the variations file and the renewed certificates, and shall expire upon the end of the one-year grace period granted by the Registration Department. The issuance of an annual importation plan is **NOT** permitted for medical devices submitted to the Registration Department as a new	The applicant is committed to submitting a request for amendment to the importation plan immediately upon obtaining the variations letter.

* Adding a country of origin / adding a manufacturing site for the same legal manufacturer / transfer of manufacturing site. * Changing the name of the foreign manufacturer while maintaining the same address. * Changing the address of the legal manufacturer. * Changing or adding the legal manufacturer, provided there is no change in the actual manufacturer. * Change of classification (Up and Down Classification).	registration, re-registration, or for variations in the following cases: 1-Adding or changing codes other than those mentioned in the [expired] notification 2-Adding a non-reference country of origin that was not listed in the [expired] notification, unless presented to the Specialized Scientific Committee through the General Administration for Registration. In all variation cases, the device is granted an importation grace period for one year from the date of file acceptance by the Medical Device Variations Department, provided the following: * Verification from the General Administration for Medical Device Registration that the device has been granted the grace period. * The importation plan shall remain valid until the end of the grace period granted by the General Administration for Registration. * a commitment from the importing company that the data recorded on the imported items matches the updated data. * After the expiration of the grace period mentioned in the plan, the Consignment Release Unit shall follow up on the matter.	

	A commitment from the registration applicant must be submitted to notify the Importation Plans Unit immediately upon the issuance of the variations letter.	
4. In the event of applying for an importation plan pursuant to a letter issued by the Licensing Department stating that the supplier is being added to the registration license in the Register of Medical Device Importers: * A grace period of one month from the date of the letter. * Or a case of no objection to accepting a non-legalized contract (grace period of 6 months from the date of the letter).	The importation plan is issued conditional upon the grace period granted by the Licensing Department. The company must apply for a variation request to the Importation Plans Unit immediately upon obtaining the registration license to which the supplier has been added with a valid and legalized contract and payment of the prescribed service fee for the amendment.	The applicant is committed to submitting a request for variation request to the importation plan immediately upon bringing the renewed registration license.
5. Medical devices submitted to the General Administration for Registration (Variations - Re-registration - New Registration) and which have obtained a preliminary acceptance number and have a one-year grace period to allow device circulation, starting from the date of file acceptance.	* An importation plan is permitted to be issued after the company obtains a 6-month extension of the registration grace period for the device, following the expiration of the original grace period (one year) granted to complete the registration procedures (Variations - Re-registration - New Registration). * Importation is permitted during the validity of the importation plan or the granted grace period, whichever is closer, with follow-up through the Consignment Release Unit.	The applicant is committed to requesting a new importation plan immediately upon obtaining the new notification or variations letter.

6. In the case of expired CE certificates and the issuance of a grace period extension letter from the European laboratory, where discrepancies appear regarding the device and/or its data compared to the expired certificates and notification.	An importation plan is permitted to be issued provided that the following documents are submitted: 1. An official letter from the foreign manufacturer confirming that MDR certificates have not been issued to date, and that the shipments to be supplied will bear the original data mentioned in the registration notification and the expired CE certificates. 2. A commitment from the importer that, in the event MDR certificates are issued, the Importation Plans Unit will be notified immediately.	The applicant is committed to submitting an application for a new importation plan immediately upon obtaining the variations letter.