

## De-notification or termination of notified bodies' activities

**Marketing authorisation for medical devices is regulated by the establishment of valid certificates and regular monitoring by notified bodies. For several months now, many of these organisations have ceased operations either voluntarily or following a denotification decision issued by the competent authorities. In this context, the French National Agency for the Safety of Medicines and Health Products (ANSM), as the French competent authority for market surveillance, hereby indicates the procedures put in place for medical device manufacturers.**

### Background

For several months now, several notified bodies have ceased their operations, either voluntarily or following a denotification decision made by their competent authority.

The French National Agency for the Safety of Medicines and Health Products (ANSM) reiterates that medical devices may only receive marketing authorisation with a valid certificate and under regular device surveillance by a notified body.

ANSM therefore asks affected manufacturers to contact a new notified body as soon as possible in order to obtain new certificates as quickly as possible.

There is currently no European regulation that includes specific provisions concerning the consequences of a notified body's denotification on manufacturers who used its services.

In this context, guidelines for managing situations created by NB denotifications were unanimously agreed upon at the European Meeting of Competent Authorities (EMCA) on 19 October 2016. These guidelines were in perfect keeping with ANSM's position.

### Procedures put in place by ANSM for manufacturers affected by the denotification of a notified body

ANSM has decided that, for a manufacturer with valid CE certificates at the time of its application with a date of validity subsequent to that of the de-notification of the notified body, the marketing of the concerned MD/IVMDs (medical devices and *in-vitro* medical devices) can continue until the end of the initial period of validity of the certificates and in all instances within a maximum limit of 12 months following denotification or the effective end of activities of the notified body (NB) provided that the following has been submitted to and favourably evaluated by:

- A list of the references for all MD/IVMDs affected by the denotification decision or the end of operations; it should also specify the sales volume and the European Union member states in which they are being marketed and/or distributed;
- A copy of the most current version of the CE compliance certificates identifying the MD/IVMDs covered by these certificates;
- A statement issued by the manufacturer certifying that its products continue to comply with fundamental requirements;
- Identification of the new notified body, evidence that the certification process has been initiated, and the anticipated date that it will be finalised.

Finally, as soon as possible, the audit report drafted by the new notified body should also be sent to ANSM as well as the new certificate.

For a manufacturer who has expired certificates at the time of the application period, or if the validity date does not fall after the date of the notified bodies' de-notification, ANSM shall not grant an extension for the marketing of the medical devices concerned.

However, if a medical device is essential or has no existing alternative, ANSM will examine the manufacturer's application on an individual basis. In this particular situation, it is the manufacturer's responsibility to provide evidence of the essential nature of the medical device.