Agence nationale de sécurité du médicament et des produits de santé

Questions & Answers

Denotification or termination of notified bodies' (NB) activities

1. **For how long do CE mark certificates issued by a notified body (NB) that has lost its authorisation or stopped operating remain valid?**
2. **What are the terms and conditions that allow a manufacturer to continue marketing its medical device or *in-vitro* medical device (MD/IVMD)?**
3. **What information should be sent to ANSM?**
4. **Can the product continue to be marketed after this information has been sent to ANSM and up until the manufacturer has received a response from the agency?**
5. **Is ANSM automatically unopposed to the continued marketing of the MD/IVMD?**
6. **When should the application for continuing to market the device be submitted to ANSM?**
7. **Should the manufacturer wait for its certificates to expire before restarting the process with a new notified body?**
8. **Should MD/IVMDs marketed prior to the denotification date of the notified body be taken off the market?**
9. **If a MD/IVMD is placed in storage with a valid CE certificate prior to the denotification date, can it remain in storage?**
10. **Can MD/IVMDs with a CE certificate whose date of validity extends beyond the date of denotification continue to be kept on the market?**
11. **When switching to a new notified body, should MD/IVMDS already on the market be re-labelled with the new identification number of the notified body? What about MD/IVMDs in the distribution chain and placed in storage? Should engraved MDs be "counter-engraved"?**
12. **What is the potential impact of denotification on pending calls for tenders?**
13. **Should advertisements that included a notified body's identification number be re-produced?**
14. **Who at ANSM grants certificate extensions and in what format should an application be sent?**
15. **If ANSM is unopposed to the continued marketing of an MD/IVMD, does this decision apply to France or the entire European Union?**
16. **What sanctions do manufacturers face if they market a MD without a certificate or with an expired certificate?**
17. **If a notified body is denotified or stops operating, how does this affect the validity of CFSs (certificates for free sale)?**

Foreword:

ANSM reiterates that it is not the job of the competent health authorities to replace notified bodies (NB) and take on their activities by virtue of amended directives 90/385/EEC, 93/42/EEC and 98/79/EC; these activities constitute contractual relations between notified bodies and manufacturers and as such are governed by private law.

However, due to the lack of specific provisions in both French and European regulations regarding the future of CE certificates in the event a notified body is denotified (i.e. a competent authority has suspended or withdrawn the NB's authorisation) or stops operating, ANSM is implementing a procedure for manufacturers headquartered in France in the interest of public health. The aim of this procedure is to keep products on the market under certain conditions until they reach the end of their initial period of validity and in all instances within a maximum limit of 12 months following the denotification or effective end of activities of the notified body.

To this end, 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.

1. For how long do CE mark certificates issued by a notified body (NB) that has lost its authorisation or stopped operating remain valid?

Under certain conditions, CE compliance certificates issued by a notified body that has lost its authorisation or stopped operating remain valid until the end of their initial period of validity, and in all instances up to a maximum limit of 12 months (with a view to obtaining new certificates), following the notified body's denotification or effective end of activities (e.g. for SNCH, 12 months from 16 October 2016).

2. What are the terms and conditions that allow a manufacturer to continue marketing its medical device or *in-vitro* medical device (MD/IVMD)?

The manufacturer may continue to market its products as long as they are covered by a valid CE certificate at the time of the application and all information listed in Question 3 has been sent to ANSM as soon as possible (either before the date of denotification or after the end of activities, and preferably within one month) following the end of activities or denotification.

Moreover, if a manufacturer's certificates are no longer valid at the time of the application or if the final date of validity of these certificates falls before the date of denotification or the end of activities of the notified body, ANSM will object to the marketing of the MD/IVMD concerned.

3. What information should be sent to ANSM?

A formal application should be sent to ANSM; the Marking manager will then confirm receipt. The application should include the following documents:

- 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.

4. Can the product continue to be marketed after this information has been sent to ANSM and up until the manufacturer has received a response from the agency?

Yes. The product can continue to be marketed following the denotification or the end of operations of the notified body during ANSM's evaluation of the information sent to it and until ANSM sends the manufacturer a letter:

- indicating that it does not object to the product being put on the market pursuant to the terms and conditions set forth under question 1;
- declaring that the required conditions have not been met. In this instance, the certificates are no longer valid, and the products can no longer be marketed.

5. Is ANSM automatically unopposed to the continued marketing of the MD/IVMD?

ANSM's decision to not oppose the continued marketing of MD/IVMDs after a notified body's denotification or the end of operations is the result of the evaluation of the documents listed in question 3. These documents are sent by the manufacturer to demonstrate the continued safety of the relevant MD/IVMDs. ANSM may object to the marketing of a device if the agency has information that can call into question its compliance with regulations.

6. When should the application for continuing to market the device be submitted to ANSM?

Applications must be submitted to ANSM prior to the expiry date of the certificates and as soon as possible once the manufacturer knows that it will not have a CE certificate from a new notified body prior to the date of denotification or following denotification or the end of operations and preferably within one month following denotification or the end of operations.

Moreover, if a manufacturer's certificates are no longer valid at the time of the application or if the final date of validity of these certificates falls before the date of denotification or the end of activities of the notified body, ANSM will object to the marketing of the MD/IVMD concerned (see question 16).

However, in such instances, if the MD/IVMD is essential to public health or if there is no other alternative, ANSM will specifically study the manufacturer's application on a case-by-case basis.
In this particular situation, it is the manufacturer's responsibility to provide evidence of the essential nature of the MD/IVMD.

7. Should the manufacturer wait for its certificates to expire before restarting the process with a new notified body?

As soon as a manufacturer is informed of a notified body's denotification or end of operations, the manufacturer should immediately start the process of selecting a new notified body in order to obtain new certificates. ANSM will ask the manufacturer to initiate the certification process with another notified body so as to continue marketing its products.

8. Should MD/IVMDs marketed prior to the denotification date of the notified body be taken off the market?

MD/IVMDs with a valid CE certificate and on the market before the date of denotification or the end of operations may continue to be marketed and distributed after this date in accordance with the terms and conditions set forth in question 2.

9. If a MD/IVMD is placed in storage with a valid CE certificate prior to the denotification date, can it remain in storage?

MD/IVMDs with a valid CE certificate and on the market before the date of denotification or the end of operations may continue to be stored after this date in accordance with the terms and conditions set forth in question 2.

10. Can MD/IVMDs with a CE certificate whose date of validity extends beyond the date of denotification continue to be kept on the market?

MD/IVMDs with a certificate whose validity extends beyond the date of denotification may continue to be marketed after this date under certain terms and conditions set forth in question 2 and until the end of their initial period of validity and in all instances up to a maximum of 12 months following the notified body's denotification or its effective end of operations.

11. When switching to a new notified body, should MD/IVMDS already on the market be re-labelled with the new identification number of the notified body? What about MD/IVMDs in the distribution chain and placed in storage? Should engraved MDs be "counter-engraved"?

This refers to changing to a new notified body:

MD/IVMDs already on the market and present in the distribution chain do not need to be re-labelled with a new notified body reference number as long as they comply with the terms and conditions set forth in question 2 and for a maximum period of 12 months after denotification or the effective end of operations of the notified body.
This same response also applies to MD/IVMDs in the distribution chain and those in storage.

No counter-engraving is necessary for medical devices already on the market as at the date of denotification.

12. What is the potential impact of denotification on pending calls for tenders?

Concerning pending calls for tender, whether in reference to those already at an advanced stage, or those still at the submission stage, it should be considered that, insofar as the certificate remains valid until the end of the initial period of validity, and in all instances up to the maximum limit of 12 months after the notified body's denotification or the effective end of operations, market procedures already initiated should remain unchallenged.
Upon receipt of ANSM's response, whether it is favourable or not, indicated in question 4, the manufacturer should inform the governing body.

13. Should advertisements that included a notified body's identification number be re-produced?

Concerning the identification number of a notified body (for instance one that has been recently denotified or whose operations have stopped) appearing in advertisements aimed at healthcare professionals, this number may remain in promotional documents insofar as a new notified body has not issued new certificates; in this case, the number of the new notified body should appear in promotional documents. This modification must have received, by virtue of the combined application of articles R. 5213-9, R.5213-5 and R.5213-2 of the French Public Health Code, a new authorisation from the general director of ANSM (for notified bodies subject to ANSM authorisation).

14. Who at ANSM grants certificate extensions and in what format should an application be sent?

The application and all supporting documents should be sent by email with the reference "Denotification/certificate application + Name of applicant" to the following addresses:

- For single use medical devices:
  dmtcos@ansm.sante.fr

- For collective use medical devices and *in vitro* diagnosis medical devices:
  dmdpt@ansm.sante.fr

15. If ANSM is unopposed to the continued marketing of an MD/IVMD, does this decision apply to France or the entire European Union?

If ANSM is unopposed to the continued marketing of the MD/IVMDs mentioned in question 2, this decision is valid for the entire European Union.

16. What sanctions do manufacturers face if they market a MD without a certificate or with an expired certificate?

Non-compliance with the terms and conditions set forth hereinabove is subject to administrative measures such as the withdrawal of a device from the market as well as financial and even criminal sanctions.

Consequently, article L.5461-9 3° of the French Public Health Code stipulates that the marketing and commissioning of a medical device without the prior delivery of the certificate mentioned in article L. 5211-3, or of a medical device that does not comply with the fundamental requirements indicated under the same article, or whose certificate of compliance is no longer valid, are subject to financial penalties.

Pursuant to article L.5471-1(III) of the French Public Health Code, the total amount of the sanction handed down may not exceed 30% of the turnover earned in the last financial year for the product or group of products concerned, up to a limit of one million euros, for a legal entity.

17. If a notified body is denotified or stops operating, how does this affect the validity of CFSs (certificates for free sale)?

CFSs remain valid and may be issued in line with the terms and conditions set forth in question 2.