Notice to applicants

Application of Article 54 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Notice to applicants dated 07/05/2026

Sommaire

General presentation

The purpose of this document is to provide information about the application of Article 54(1) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices, which allows any competent authority to authorise, by way of derogation, the placing on the market or putting into service in its territory, in the exclusive interest of patients or public health, of in vitro diagnostic medical devices for which the mandatory regulatory procedures prior to their placing on the market have not been complied with.
It is intended for patients, healthcare professionals and manufacturers and is an information document for all stakeholders concerned, as well as a tool intended to assist with the submission of applications and to clarify ANSM's decisions.
As a reminder, pursuant to the aforementioned Regulation (EU) 2017/746, only devices covered by the following may be placed on the market or put into service:

- an EU declaration of conformity attesting that they comply with the general safety and performance requirements applicable to them, and
- an EU certificate of conformity when they require the intervention of a notified body (NB).

Pursuant to part II of Article L.5221-3 of the French Public Health Code (Code de la Santé Publique – CSP), the derogation consists in ANSM authorising, by way of derogation, the placing on the market or putting into service of in vitro diagnostic medical devices for which conformity assessment procedures have not been applied, and provided that the interests of public health or patient safety or health have been established in the context of a duly justified application. It can be issued individually for a specific patient, or generally for a specific device. In the latter case, it is issued for a specific period and for a national territory only.

Applicable legislation:

- Article 54(1) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices provides that: "By way of derogation from Article 48, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.".
- Part II of Article L. 5221-3 of the French Public Health Code (CSP), as amended by Order No. 2022-1086 adapting French law to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, specifies that "pursuant to Article 54 of this Regulation, the National Agency for the Safety of Medicines and Health Products may, upon duly justified request, by way of derogation from the obligation of prior conformity assessment of each device provided for in Article 48 of Regulation (EU) 2017/746, authorise the placing on the market or the putting into service in France of a device which has not been subject to such an assessment, but whose use is in the interest of public health or in that of the safety or health of patients."

The use of the words "upon duly justified request" (in French: “sur demande dûment justifiée”) implies the transmission by the applicant of a certain number of elements and information motivating and justifying the request. This data will be evaluated by ANSM, and its conclusions will lead to a reasoned decision to grant or refuse this request.
With CE marking being the method used for placing on the market or the putting into service in vitro diagnostic medical devices under ordinary law, the implementation of this exceptional derogation procedure, despite the compassionate nature of the application and the potentially innovative nature of the device where applicable, is conditional upon the existence of analytical and clinical data, which provide guarantees for patient safety and demonstrate a benefit for the patient(s) in relation to the risks incurred.

ANSM considers that the derogation procedure can only be a temporary solution.
In this context and barring exceptions, the manufacturer's commitment to move "towards CE marking", and where appropriate to submit a performance study (PS) application, are important elements in the assessment of the application.

The derogation cannot be used to circumvent of the CE marking procedure, nor can it constitute a valid basis or be invoked in support of the conformity certification procedure. Furthermore, it cannot be used in the context of the development of in vitro diagnostic medical devices, since the regulatory and safety framework of performance study (PS) meets in particular the imperative of patient protection and reliable data collection, guaranteeing both optimal ethical and medical protection of people and the attainment of product performance and safety of use.

Therefore, the implementation in France of a performance study (PS) as provided for in the context of CE marking should be preferred over a request for derogation.

As a matter of principle, and in terms of safety, a manufacturer applying a derogation under the aforementioned Article 54 must be able to provide the data required to submit a PS application and to complete a statement pursuant section 4.1 of Annex XIV.

Derogation decisions taken by the ANSM are binding:

- the manufacturer is responsible for providing the information that guarantee, in particular, the safety of use of its in vitro diagnostic medical device and the benefit to the patient(s). The manufacturer remains ultimately responsible for the device that is the subject of the request. For more information, please consult the derogation application procedures.
- The practitioner, prescriber and/or user remains responsible for the choice of the therapeutic strategy or for the decision to use a non-CE-marked device, for the use of that device, and for the obligation to provide patients with clear and exhaustive information enabling them to give their free and informed consent. The granting of a derogation also assigns a role and obligations to healthcare organisations, in particular with regard to the adoption of appropriate information, monitoring and traceability procedures for in vitro diagnostic medical devices not covered by CE marking. **(See *the focus on healthcare professionals on page 10, and healthcare establishments on page 11).***

Key points to remember

The standard procedure for placing in vitro diagnostic medical devices on the market or putting them into service is CE marking. It guarantees the application and compliance with strictly defined technical and regulatory requirements.
Therefore, a derogation for placing on the market or putting into service an in vitro diagnostic medical device pursuant to Article 54(1) of Regulation (EU) 2017/746, remains an exceptional measure which cannot, under any circumstances, permanently replace the procedures applicable to conformity assessment (as defined in Article 48 of said Regulation) or the procedures for placing a product on the market or putting it into service (according to Article 5 of said Regulation), or circumvent the regulations on performance studies (which provide a safe framework for patients and healthcare professionals).

I. Requests for derogation

Simplified procedure – Global application:
https://www.demarches-simplifiees.fr/commencer/ansm-demande-de-derogation-globale-relative-aux-dispositifs-medicaux

Simplified procedure – Individual application:
https://www.demarches-simplifiees.fr/commencer/ansm-demande-de-derogation-individuelle-relative-aux-dispositifs-medicaux

Please note: apart from the patient identification in point 4 of the form, which must be provided solely by the initial of the patient's last name, the initial of the patient's first name, and their year of birth, any document mentioning this patient (such as the prescription) must be anonymized.
Similarly, any date concerning the patient, appearing in the elements or documents submitted, must be limited to the year.

Applications must be reasoned, substantiated and anticipated, so as to enable an assessment of the safety data and the expected benefits for the patient(s) in relation to the risks associated with non-compliance with applicable procedures, and must form part of a regulatory process for access to the market through CE marking. In this context, the prior implementation of a performance study should be considered as a guarantee of optimal regulatory, ethical and medical protection of persons, but also of the performance and safety of use of the products.
Derogations are granted by ANSM on an exceptional basis, in light of the information provided by the applicant pursuant to this notice, and of the interests and safety of the patient(s).

The following types of derogations are granted:

- Global: issued for unidentified patients, but for a precisely targeted scope (duration, device references, specific conditions, etc.),
- Individual: issued to one identified patient(s).

ANSM may monitor the application of the exemption and the conditions under which it is granted, and may subsequently withdraw or suspend it.

Criteria required to assess the application

Global derogation

- Justification of the patient's need/interest (characteristics, context and medical condition).
- Inability to include patients in a performance study.
- Absence of a suitable and/or available alternative CE-marked in vitro diagnostic medical device for the indication, or proof of the inability to use it.
- Reasons for the absence of CE marking and information on the device's status with regard to CE marking procedures: previous CE marking obtained, timeline if CE marking is in progress or planned…
- Safety and performance data: summary of analytical and clinical performance data and performance study data, standards where applicable.
- Information on the characteristics of the in vitro diagnostic medical device (principle of the method, principle of interpretation of results, stability data, storage conditions, etc.),
- Qualitative and quantitative assessment of derogation already granted, where applicable.
- Declaration of conformity to general safety and performance requirements, with the exception of the aspects covered by the derogation, and attestation that all precautions have been taken to protect the health and safety of patients.

Individual derogation

- Justification of the patient's need/interest (characteristics, patient's last name initial, first name initial and year of birth; context and medical condition; degree of urgency; life expectancy if applicable…).
- Inability to include the patient in a performance study.
- Absence of a suitable and/or available alternative CE-marked in vitro diagnostic medical device for the appropriate indication, or proof of the inability to use it.
- Reasons for the absence of CE marking and information on the device's status with regard to CE marking procedures: previous CE marking obtained, timeline if CE marking is in progress or planned…
- Safety and performance data: summary of analytical and clinical performance data and performance study data, standards where applicable.
- Information on the characteristics of the in vitro diagnostic medical device (principle of the method, principle of interpretation of results, stability data, storage conditions, etc.),
- Declaration of conformity to general safety and performance requirements, with the exception of the aspects covered by the derogation, and attestation that all precautions have been taken to protect the health and safety of the patient(s).

Practical details of the application and required documents

- The application is submitted to the ANSM using the simplified procedure form (in French: “démarche numérique”), completed by the manufacturer, or where applicable by its authorized representative. It may be submitted via a consultant, in which case a copy of the application is systematically sent to the manufacturer; it cannot be submitted directly to ANSM by a healthcare professional.
- It must be fully completed.
- The documents identified by an asterisk in the form are mandatory (blocking) and must be provided by the manufacturer, possibly via the applicant.
- The derogation is granted to the manufacturer; the letter is sent to the manufacturer and a copy is sent to other potentially concerned persons (applicant, prescriber and/or user, director of the health establishment).

The application includes 3 items:

- the description of the device,
- the justification/description of non-compliance with applicable regulatory procedures,
- the interest in relation to public health or to the health or safety of patients.

II. Focus for healthcare professionals

Although the derogation is granted to the manufacturer as the person responsible for placing on the market or putting into service the devices, and therefore in the best position to transmit the required analytical and/or clinical data, the role and responsibilities of healthcare professionals in the derogation procedure should be emphasized. One the one hand, they relate to the information that may be provided in support of the application, and on the other hand, they concern their professional obligation to provide clear and exhaustive information to the patient(s).

Role and responsibilities regarding the manufacturer's application for a derogation

The justification of the public health interest and the benefit likely to be provided to the patient(s) by the device that is the subject of the application for a derogation, as required by Article 54(1) of Regulation (EU) 2017/746, implies, in addition to the safety data under the manufacturer's responsibility, the transmission of information relating to medical practice, including justification for the choice to use a non-CE marked in vitro diagnostic medical device, considering the alternatives and the specific characteristics of each situation: emergency, patient's condition, etc.

By their nature, these elements are provided and justified by prescribers and/or users, who therefore assume responsibility for these points, as well as for any resulting medical procedures should the derogation be granted. In this regard, the complexity and specificity of certain medical situations may lead ANSM to request the prescriber or user concerned an undertaking attesting to their knowledge of the assessment carried out by ANSM and their responsibility.

Similarly, they remain involved in monitoring and the consequences of actions carried out following the use of in vitro diagnostic medical device(s) "under derogation", as well as with regard to the reactovigilance obligations.

Role and responsibilities with regard to patients

The French Public Health Code (CSP) stipulates that all the patients are entitled to clear and exhaustive information about their state of health and the care they receive (Article L.1111-2), and that they are responsible for giving their free and informed consent (Article L.1111-4).
Insofar as these provisions are applicable within the framework of medical practice, or even the "one-on-one doctor/patient encounter", this obligation is incumbent upon prescribers and/or users, who are also required to compile and retain the documents needed to prove their total compliance.

III. Points brought specifically to the attention of healthcare facilities in which in vitro diagnostic medical devices subject to derogation are made available and used

As a healthcare facility in which a non-CE-marked in vitro diagnostic medical device is likely to be used, the facility is responsible for:

- firstly, demanding and to allocating the resources required to ensure compliance with transparency requirements and the obligation to inform all parties involved (directors, heads of department, etc.) about the circulation and use of these in vitro diagnostic devices, from their entry into the facility to their use;
- secondly, implementing appropriate procedures for monitoring these in vitro diagnostic medical devices, to enable the tracking of their circulation within the facility, in the interest of patients.
- lastly, notifying ANSM and the manufacturer of any incident or risk of incident involving with this non-CE-marked in vitro diagnostic medical device.

143/147, boulevard Anatole France
F-93285 Saint-Denis Cedex
Tél. : +33 (0) 1 55 87 30 00

ansm.sante.fr • **@ansm**