Overseeing early access to healthcare products

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In order to offer patients rapid access to innovations representing major therapeutic progress or addressing an unmet medical need, various procedures allow us to oversee and support the safe provision of innovative products. **The reform on special access to medicines that came into force on 1 July 2021 has simplified the process, by setting up 2 schemes replacing the 6 previous ones**.

+ Read the news relating to the reform of exceptional access to medicines (01/07/2021)

Scientific opinions

As an expert agency, ANSM may issue scientific opinions, at the request of pharmaceutical companies or medical device manufacturers. These opinions are based on the specific characteristics of the product under development, as well as the latest knowledge in terms of diseases, target populations, and existing treatments. By shedding light on the general product development strategy, particularly in terms of the clinical trials to be conducted, these opinions help guide innovations in compliance with the regulatory framework.

Compassionate access and early access authorisations

Where a medicine has not been granted a marketing authorisation (MA) in France, in some special cases, ANSM may authorise the use of this medicine if it deems the presumed benefit to be greater than the risk. This special access procedure is only applicable if no appropriate alternative treatment is available.

Authorisations may be for compassionate access (AAC) or early access (AAP)

Compassionate access authorisations are granted by ANSM, at the request of a doctor or healthcare institution for a named patient. They apply to medicines not intended to be marketed for the indication in question, and which are not currently under development or the subject of an MA application. These authorisations are valid for a renewable period of 1 year.
Early access authorisations are granted by the French National Health Authority (HAS), at the request of a pharmaceutical company. In this case, the medicine may be prescribed for a patient cohort treated and monitored according to criteria set out in a data collection (RD) and therapeutic use protocol (PUT).

If the early access authorisation application is submitted before the MA application, it can only be granted after assessment and approval by ANSM. If the early access authorisation application is submitted after the MA is granted, HAS acts directly in the assessment and decision-making role.

Compassionate prescription framework

Where a medicinal product has already been granted a marketing authorisation for one or more given indications, but is used for other indications in practice, ANSM may grant a compassionate prescription framework (CPC) for a renewable period of 3 years.

A CPC may only be granted on the condition that the therapeutic need is hitherto unmet by any other treatment, and that the scientific data indicate a favourable benefit-risk balance for the patients concerned.

+ Apply for compassionate access authorisation
+ Apply for early access authorisation

+ View the repository of special access medicines

Exemption for medical devices

An exemption scheme is in place for medical devices, authorising use in special cases in the absence of CE marking; a device that has not undergone the CE marking procedure may only be marketed under this scheme under special circumstances and in patients' interests.

+ Apply for exemption for a non-CE-marked medical device

Innovation and Referral Service

We set up the Innovation and Referral Service in 2020 to facilitate discussions with innovation stakeholders (industry, academic sector, start-ups) leading a healthcare product development project. It consists of an electronic exchange platform that allows users to submit requests for opinions or meetings on scientific, technical or regulatory issues in a harmonised framework adhering to ethical requirements.

Support for a medical device or in vitro diagnostic medical device development project

ANSM improves and facilitates support for project leaders' innovation or development pipelines. It helps improve the understanding and clarity of the regulatory framework applicable to MDs and IVDMDs and related processes, and, ultimately, supports the development of products meeting quality and patient safety requirements.

Within this framework, ANSM's role is to:

- provide an opinion on the qualification and classification of MDs;
- provide a scientific opinion on applicable requirements and clinical research;
- intervene in the context of the preliminary clinical investigation or performance study submission process.

Go to the Innovation Service