Marketing authorisation for medicines

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The granting of an MA is based on the review of the benefit-risk balance of the product, and more specifically on reviews of:

2. **evidence of its efficacy with regard to**:
   1. - the target indications, i.e. the disease(s) targeted by the medicine;
   2. - the patient profile for whom it is intended;
   3. - the recommended dosage (dose, treatment duration);
3. **foreseeable adverse reactions** associated with its use and their frequency, recorded during the non-clinical and clinical trials;
4. **the chemical, biological or microbiological quality of the medicine** (active substance and finished product), as well as the quality of the production processes.

In the countries of the European Union, **there are 4 procedures for obtaining** a marketing authorisation (MA). 3 European procedures and 1 national procedure.

Find out more about the 4 MA procedures +

On a European level

- **Centralised procedure :** this procedure applies to medicines intended for all Member States. The MA is granted by the European Commission and is valid for all Member States, but the pharmaceutical company may choose to market the medicine only in some of these countries.

  For some classes of medicines, this procedure is compulsory: this is the case for innovative therapies, medicines derived from biotechnologies, innovative medicines containing a new active substance and those used to treat certain diseases (HIV, cancer, neurodegenerative diseases, diabetes, auto-immune diseases, and viral diseases), as well as orphan medicines indicated in the treatment of rare diseases.

- **Decentralised procedure** : applies to medicinal products that are not yet authorised in the European Union and are destined for at least two Member States.
  In this case, the pharmaceutical company asks one of the Member States to act as the reference state. The reference state that it chooses must be a Member State where the medicine’s marketing authorisation is being sought.
  The MA granted by the reference state is valid in all the Member States concerned.

- **Mutual recognition procedure** : this procedure applies to medicines which have already been granted an MA in one of the Member States of the European Union according to a national procedure. The pharmaceutical company designates the new countries in which it wishes to market its medicine. The reference state, which granted the existing MA, coordinates the procedure.
  The MAs are granted by the competent authorities of the Member States concerned. The MA granted is valid in all the Member States concerned.

On a national level

- **National procedure** : this procedure applies to medicines for which marketing is only envisaged in a single Member State of the European Union. The MA is assessed and granted by this State's competent authority. It is only valid in this State.
  In France, ANSM thus issues MAs for medicines authorised under the national procedure and medicines authorised under European decentralised and mutual recognition procedures.

To be awarded an MA, a pharmaceutical company must submit a dossier to the competent authority (national or European); this dossier must contain :

- the data collected during:
  - preclinical trials, i.e. tests on animals, cells and tissues;
  - clinical trials, i.e. the first trials on humans;
- the data particularly pertaining to:
  - the chemical or microbiological quality of the finished product;
  - the production processes of the active substance and the finished product.

In the case of generic medicines, bioequivalence studies with the originator (or proprietary) medicine must be submitted in the MA application dossier.

The MA dossier will have the same format and the same content regardless of the procedure involved: at national, European, and even international levels, for example in Japan and in North America.

Registrations of herbal medicines and homeopathic medicines

In addition, ANSM also issues registration decisions: these are simplified authorisation procedures that may apply to certain herbal and homeopathic medicines in accordance with specific conditions.

What happens after the MA has been granted?

Once the MA has been awarded, the decision whether to market the medicine or not is solely within the remit of the pharmaceutical company. If the pharmaceutical company has not marketed the medicine within 3 years after the MA was awarded, the MA is deemed to be null and void.

The MA or registration is granted for an initial period of 5 years. It may then be renewed for an unlimited period, unless ANSM or the European Medicines Agency decides to proceed with one additional 5-year renewal for pharmacovigilance-related reasons.

Once the MA or registration has been granted, it may be amended at the pharmaceutical company's request (e.g. due to a change of composition, indication extension, etc.), or as instructed by the competent authorities (e.g. in order to introduce a new adverse reaction). Authorisations are required for implementation.

Systematic measures regulate the proper use of the medicine as soon as it is released to market. This includes the information contained in the Summary of Product Characteristics (SmPC) (for healthcare professionals) or in the package leaflet (for patients), the packaging of the medicine, as well as specific prescribing and dispensing conditions.

For some medicines particularly involving specific risks or specific conditions for use and surveillance, the prescription and dispensing conditions may be restricted. In this way, they may require prescription by a medical specialist, signature of a treatment consent form, or the running of preliminary tests, etc.

The conditions for marketing vaccines and blood-derived medicines are furthermore enhanced via a systematic release process of all batches by a national authority.

Prescribing and dispensing conditions in France

In France, medicines are classified in different lists according to their prescription and dispensing conditions.
Medicines belonging to Lists 1 and 2 are medicines available only on prescription, and therefore must be prescribed by a healthcare professional (doctor, midwife, dentist).
List I medicines (with a red box on the pack) can only be dispensed for the treatment duration specified on the prescription.
List II medicines (with a green box on the pack) may be dispensed multiple times from the same prescription for 12 months, unless specified otherwise by the prescriber.
Another list also covers narcotic drugs subject to stricter restrictions.