Generic medicines

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What are generic medicines?

A generic medicine:

- is created using the same drug substance as a medicine that has already been authorised (referred to as the reference, originator or proprietary medicine) for which the patent has expired and entered the public domain;
- must have the same qualitative and quantitative active substance composition, and the same pharmaceutical form as the proprietary medicine, and demonstrate that it has the same therapeutic efficacy (same bioavailability);
- is subject to the same prescription conditions as proprietary medicines.

Benefit of follow-up on the originator medicine

The life cycle of the proprietary medicine consists of two phases:

- a **10-year trial phase** to obtain an MA from a competent authority;
- followed by a **10-year use phase** post-marketing, after which the patent enters the public domain.

During the period of use, pharmacovigilance helps assess known adverse reactions, identify new ones, and thus improve safety.
Therefore, generic medicines are already well-known when released on the market.
A medicine for which the authorisation has been withdrawn for safety reasons cannot become a generic.
A generic medicine may only be marketed once the patient(s) protecting the originator medicine has expired.

Key points: active substance and excipients

The active ingredient or substance is the constituent of the medicine responsible for the therapeutic effect.

The qualitative and quantitative **active substance composition of a generic medicine is identical** to that of its originator medicine. The same applies for its pharmaceutical form (tablet, capsule, syrup, patch).

The term excipient refers to any substance other than the active substance contained in the medicine. It does not have any desired pharmacological activity. **All medicines – generic and proprietary – contain excipients.**

The generic medicine is not necessarily strictly identical to the original medicine: it **may** particularly **contain different excipients**.

A generic medicine may be of interest because it may not contain an excipient with known effects (e.g. allergic reaction, or particular intolerance syndrome) contained in the proprietary medicine.

Excipients with known effects are cited in the generic group registry to assist substitution.

Key messages

Generic medicines may contain different excipients from those of the proprietary medicine, and thus have a different appearance, colour, or taste.
These differences may be sought in the generic. A generic medicine may thus be of interest because it may not contain an excipient with known effects contained in the proprietary medicine (smaller tablet, strawberry flavour instead of banana, etc.).
The generic medicine is not necessarily strictly identical to the original medicine: more particularly, it may contain different excipients.

Substitution rules

For the prescribing doctor

Substitutions may be made between:

- a reference medicine and a generic medicine;
- a generic medicine and another generic;
- herbal medicines from the group in question.

The prescribed proprietary medicine may be substituted by a generic medicine containing one or more excipients with known effects not contained in the prescribed medicine if it is clear, after obtaining details, that the user is not at any risk of the onset of effects associated with these excipients.

- **Substitution of a proprietary medicine not containing any excipients with known effects** : it is recommended to choose a generic free from any excipients with known effects.
- **Substitution of a proprietary medicine containing one or more excipients with known effects** : it is recommended to choose a generic containing the same excipient(s) with known effects or a generic medicine partially or completely free from these excipients with known effects.

As of 1 January 2015, **all** prescribers (doctors, dental surgeons, midwives) regardless of where they practice (community, hospital, medical and social facilities) **are required to prescribe the international non-proprietary name** (INN), i.e. specifying the name of the active substance and not that of the medicine.

The non-proprietary prescription (Article R.5125-55 of the French Public Health Code) must contain at least:

- the active substance(s) designated by its/their non-proprietary name;
- the dosage of active substance(s);
- the pharmaceutical form and administration route.

Generic medicines are generally identified directly by the International Non-Proprietary Name (INN) followed by the name of the pharmaceutical company, the dosage, and the pharmaceutical form (tablet, capsule, oral solution, etc.).

As of 1 January 2020

The Social Security Budget Act for 2019 amended the conditions for substituting medicines by their generics and a medical justification is now **required if specifying "Do Not Substitute"** (Article 66, L. 5125-23 of the French Public Health Code).
Failing this justification, the French national health insurance system reimbursement shall be based on the most expensive generic medicine.

Doctors may specify that a medicine is non-substitutable in three scenarios described in the Order of 12 November 2019 :

- prescription for children under 6 years of age, when no generic medicine has a suitable dosage form and the reference medicine available allows this administration;
- prescription for a patient presenting with a proven formal contraindication to an excipient with known effects contained in all generic medicines available, and absent from the reference medicine;

- prescription of medicines with a narrow therapeutic index (where the patient is stabilised with a medicine with a narrow therapeutic index). The Order of 12 November 2019 sets out the list of active substances in question. This list is liable to change with the arrival of new generics for the originator medicines in question.

In order to identify scenarios in which non-substitution applies, the prescriber must mark a three-letter code on the prescription next to the phrase “Do Not Substitute”:

- **EFG**: no generic with a suitable dosage form for the child’s age (under 6 years) is available.
- **CIF**: the patient is allergic to an excipient with known effects (formal contraindication), which is absent from the proprietary medicines and present in all generics. This scenario is rare (around a dozen proprietary medicines), as generics generally have the same excipients as the proprietary medicine, or their formulation is free from excipients with known effects.
- **MTE**: the narrow therapeutic index medicine is listed in the Order of 12 November 2019.

For pharmacists dispensing treatments

Since 1999, pharmacists have been authorised to make substitutions according to the precise rules set out by the legislator:

- the substitute product dispensed must belong to the same generic group as the product prescribed;
- the doctor must not have specified non-substitution by marking “Do Not Substitute” on the prescription;
- the substitution must not incur an additional expense for the French national health insurance system.

The pharmacist must note the name of the substituted medicine on the prescription to reduce the risk of confusion for the patient.

If the patient refuses to accept the dispensing of the generic medicine:

- the patient must pay the pharmacy the full price of the medicine dispensed (the co-payment option is not available for this prescribed medicine);
- the French national health insurance system reimburses the patient based on the price of the most expensive generic medicine.

In the event of a national supply shortage of generics for a given medicine (which is nonetheless rare), pharmacists may of course dispense the non-generic medicine, and patients will be reimbursed based on the price of that medicine.

Pharmacists may opt not to make a substitution even if the prescriber has not marked “Do Not Substitute”, if they believe that the change may affect the quality of care provided to the patient for medicines with a narrow therapeutic index or in the case of known stock shortages.

+ The French Ministry of Solidarity and Health launches the implementation of the reform on cover for medicines for which generics are available (07/01/2020) - Ministry website

+ View the public medicines database

+ Generic medicines for use by healthcare professionals - French Ministry of Health and Social Affairs website

Download the ANSM report - Les médicaments génériques, des médicaments à part entière [Generic medicines – medicines in their own right] (14/12/2012)

Registry of generics

This **tool is used by community pharmacists as a basis for dispensing** substitutable generic medicines and herbal medicines.

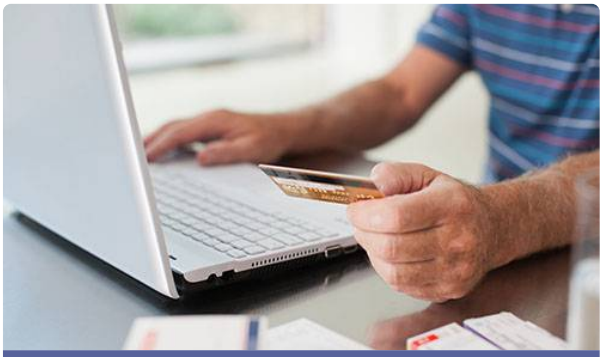
The medicines included in the registry are classified by groups. Each group includes the reference medicine and its generics. Pharmacists are only authorised to substitute medicines listed in the same group with each other.

The registry is used along with the public medicines database. This database provides access to all information intended for professionals (SmPC) and users (package leaflet) pertaining to marketed products.

Generic medicines - French Ministry of Health and Social Affairs website

FAQ on generic medicines - French Ministry of Health and Social Affairs website

The online sale of medicines is regulated.
To find out more, refer to the file on “Online sale of medicines”.



Vente en ligne de médicaments