22 November 2012
EMA/393905/2006 Rev. 2

# Questions and answers on generic medicines

## What is a generic medicine?

A generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised (the 'reference medicine').

A generic medicine contains the same active substance(s) as the reference medicine, and it is used at the same dose(s) to treat the same disease(s) as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine.

## What does a generic medicine contain?

A generic medicine contains the same quantity of active substance(s) as the reference medicine. The inactive ingredients, or 'excipients', may differ between the generic medicine and its reference.

The active substance of a medicine is what gives it its therapeutic effect. A generic manufacturer may choose to use a different form of the active substance, for example the manufacturer can decide to use a 'hydrochloride' salt of the active substance because this form is more stable. However, this can only be done as long as it does not affect the medicine's activity.

## When can a generic medicine be developed?

A company can only develop a generic medicine for marketing once the period of 'exclusivity' on the reference medicine has expired. This period of exclusivity is given by law to the company that developed the innovative medicine on which the generic medicine is based. The innovator company benefits from data and market exclusivity under pharmaceutical legislation (typically 10 years from the date of first authorisation).

Innovator companies can use patent law to obtain further protection for an innovative medicine. This protection applies to new uses of the medicine, such as new indications. While this 'use patent' protection is in place, a generic medicine cannot be marketed for the protected indication, even if the period of exclusivity on the reference medicine has expired. Until the expiry of the use patent, generic medicines can only be marketed for indications that are not patented.

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Generic manufacturers can also choose to develop a generic medicine that is based on a reference medicine, but is presented as a different strength or with a different route of administration to the reference medicine. They may also decide to develop a medicine with a slightly different indication, such as a limited indication that will allow the medicine to be used without a prescription. This type of generic medicine is called a '**hybrid**' medicine, because its authorisation relies in part on the results of tests trials on the reference medicine and in part on new data.

## How are generic medicines manufactured?

Generic medicines are manufactured according to the same quality standards as all other medicines. As for other medicines, regulatory authorities perform periodic inspections of the manufacturing site(s), to ensure that good manufacturing practices are in place.

## How are generic medicines authorised?

As for all medicines, generic medicines must obtain a marketing authorisation before they can be marketed. Marketing authorisations are granted after a regulatory authority, such as the European Medicines Agency, has conducted a scientific evaluation of the medicine's efficacy (how well it works as measured in clinical studies), safety and quality.

## How are generic medicines evaluated?

As the reference medicine will have been authorised for several years, information is already available on the efficacy and safety of the active substance(s) it contains. The pharmaceutical legislation defines the tests that must be carried out to demonstrate that the generic medicine is comparable to the reference medicine so that it can receive a marketing authorisation.

Specifically, a company producing a generic medicine needs to provide information on the quality of the medicine. In most cases, it will also need to supply data from a bioequivalence study to show that the generic medicine produces the same levels of the active substance in the body (whether human or animal) as the reference medicine.

Bioequivalence studies are only needed for medicines that are absorbed by the body before being released into the bloodstream, such as medicines that are taken by mouth. Generic medicines that are administered directly into the bloodstream, such as those given directly into a vein by injection or infusion (drip), do not need to be tested for bioequivalence against the reference medicine.

If a generic medicine contains a different salt of the active substance to the salt used in the reference medicine, regulatory authorities will consider whether additional tests are needed for the medicine to be granted a marketing authorisation. If the medicine is a hybrid, additional tests may be required, such as the results of clinical trials that test the efficacy of the medicine.

Once the generic medicine is authorised, the same information will appear in the 'product information' of the generic medicine (the summary of product characteristics, the labelling and the package leaflet) as in the product information of the reference medicine. The only differences relate to any differences in excipients and any patented indications. If precautions are necessary because of an excipient, they will be described both on the label and in the package leaflet of the generic medicine. If the reference medicine is benefiting from patent protection for some indications, these cannot appear in the product information of the generic medicine.

## How is the safety of generic medicines monitored?

As for all medicines, the safety of generic medicines continues to be monitored after authorisation. Each company is required to set up systems to monitor the safety of all medicines that it markets. Regulatory authorities may also perform an inspection of these monitoring systems. If specific safety precautions have to be considered when taking the reference medicine, the same precautions will generally also be required for the generic medicine.