

...about licensed, off-label, and unlicensed use

The **marketing authorisation (MA) system** is the European licensing mechanism for medicines, ensuring their safety, quality, and efficacy.

MAs may be granted via several routes: the **centralised** procedure is valid in all EU states simultaneously and is mandatory for certain classes of medicines; the **decentralised** procedure applies to medicines not covered by the centralised procedure, allowing simultaneous authorisation in several EU countries; a **national MA** is one granted in a single member state; and finally, the **mutual recognition** procedure is used where a medicine obtains the MA in one member state and other states then recognise its validity.

MAs are granted for a period of up to five years and must then be renewed, reflecting any new knowledge of the product, including issues relating to safety.

Licensed use refers to use of a medicine within the terms of its MA. This means that the medicine is being used for a licensed indication, at the correct dose, in a patient matching the criteria for use in that country.

Off-label use is said to occur when a medicine with a valid MA is used outside the terms of the license. This might include use for an indication, at a dose, or in a patient not specifically covered by the MA. Informed consent for off-label use should be obtained and documented.

Unlicensed use differs from off-label use in that the medicine in question does not have a valid MA in the country in which it is being used. (The medicine may be licensed elsewhere, or it may be a product yet to be licensed anywhere.) Again, informed consent should be obtained and documented.