Marketing Authorisation [MA]

Marketing authorisation (MA) refers to the approval for a medicine to be marketed.

A system of marketing authorisation was put in place to protect public health. Marketing authorisations are granted only when a competent authority (or 'regulatory authority') has conducted a scientific evaluation, and is satisfied that a medicine is sufficiently safe and effective, and of high enough quality.

Different procedures exist to obtain a MA. The EMA (the 'Agency') is responsible for the 'centralised procedure'. A single application is submitted to the EMA for evaluation by the Agency's Scientific committees. If the assessment is positive, a single marketing authorisation is issued by the European Commission. The Marketing Authorisation Holder can then legally begin to market the medicine in all EEA (European Economic Area) countries (EU *member states* and the three *EEA* EFTA States (Iceland, Liechtenstein, and Norway).

National Competent' Authorities (NCAs) are responsible for evaluation of marketing authorisation applications and granting MAs for medicines that fall outside the scope of the centralised procedure. Companies can apply for authorisation of these medicines in several countries simultaneously, using the 'decentralised procedure'. Or, once a medicine is authorised in one EU member state, a company can apply for this authorisation to be recognised in other EU countries (the 'mutual recognition procedure'). These procedures result in national MAs for each member state involved.