

Marketing Authorisation Holder [MAH]

A Marketing Authorisation Holder (MAH) is a company, firm or non-profit organisation that has been granted a marketing authorisation. The marketing authorisation allows the holder to market a specific medicinal product, in one or more EU member states. Once a medicinal product is marketed and in use by patients, the MAH continues to be responsible for monitoring safety (pharmacovigilance). Any suspected adverse reactions must be reported to the body which granted the marketing authorisation, in the form of a periodic safety update report (PSUR).