

SecurMed Micro-MAH Fee Waiver Scheme

Under Delegated Regulation 2016/161/EC all MAHs and Parallel Distributors (an MAH) active in the UK market are obliged to fund the UK Medicines Verification System. SecurMed published its funding model in April 2018 and has published thereafter annually the fees payable to SecurMed UK via our website at www.securmed.org.uk. The Micro MAH Fee Waiver scheme was published on 1st June 2018.

To qualify as a *micro MAH*, an MAH or Parallel Distributor with one or more Marketing Authorisations applicable in the UK, is required to demonstrate to SecurMed UK that at least TWO of the following criteria apply to it as a legal entity:

- it has a turnover of GBP £632,000 or less.
- it has GBP £316,000 or less on its balance sheet.
- it employs 10 employees or less.

All MAHs are required to complete the SecurMed Registration Form and sign an MAH Agreement, irrespective of the size of legal entity, and submit these to SecurMed, prior to consideration being given to any micro-MAH fee waiver application.

Where an MAH can demonstrate to SecurMed that it meets the criteria for a micro MAH, SecurMed may grant a fee waiver agreement which, once signed, waives the requirement for the MAH to pay the MAH Setup Fee and Annual MAH Operational Fee for a period of one calendar year from the date the waiver agreement becomes binding (the *waiver period*). This means the legal entity does not have to pay any fees to SecurMed during the waiver period.

The waiver agreement will automatically expire at the end of the waiver period, from which point the relevant legal entity shall be responsible for paying the MAH Setup Fee and Annual MAH Operational Fee to SecurMed. All waivers shall be agreed (or renewed) on a case-by-case basis by submission of updated information.

Please also note the following: (i) an MAH status as a micro MAH will be assessed in relation to the size of the relevant MAH legal entity, and is not assessed per Market Authorisation; and (ii) turnover is assessed by reference to business turnover of the MAH legal entity in the UK.

Please provide the following information:

- for those UK legal entities that have filed audited accounts with UK Companies House, please submit to SecurMed UK a copy of the audited accounts and, where relevant if not documented on the audited accounts, confirm to SecurMed UK in writing (signed by a director of the relevant legal entity) that the relevant legal entity has 10 employees or less; or

- for those UK legal entities that have not filed any accounts with UK Companies House, please submit a copy of the business projections for the relevant legal entity for the next 12 months, in a form that has been adopted and signed by the directors of the relevant legal entity. In addition, and where relevant, confirm to SecurMed UK in writing (signed by a director of the relevant legal entity) that the relevant legal entity has 10 employees or less.
- for those legal entities residing outside the United Kingdom, please submit the last set of published annual accounts or submit a letter from their auditors on headed and addressed paper, stating the size / scale of the UK portion of the business and the fit with the micro MAH criteria.

To apply for the fee waiver scheme please submit your request to accounts@securmed.org.uk