

SecurMed Micro-MAH Fee Waiver Scheme

Under the Northern Ireland Protocol, which came into effect from 1st January 2021, FMD (under Delegated Regulation 2016/161/EC) is still applicable in the United Kingdom in respect of Northern Ireland. This means that any MAH holding one or more marketing authorisations (MA) approving the marketing of a medicine in Northern Ireland (including UK-wide MAs) is obliged to register with and fund the UKNI MVO, SecurMed UK.

In 2021, SecurMed UK will not charge an Annual Operational Fees but a one-off MAH Set-up Fee of £1,000 applies to new registrations. The established Micro-MAH Fee Waiver scheme will be maintained.

To qualify as a Micro-MAH, an MAH with an MA valid in Northern Ireland 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 in the UK of GBP £632,000 or less.
- it has GBP £316,000 or less on its balance sheet.
- it employs 10 employees or less in the UK.

All MAHs, irrespective of the size of legal entity, are required to sign an MAH Agreement, 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 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 relevant fees.

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 MA; 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 a copy of the audited accounts and, where relevant, confirm to SecurMed UK in writing 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 addition, and where relevant, confirm to SecurMed in writing 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