

12-Dec-2018

Dear Marketing Authorisation Holder or Parallel Distributor,

Following the announcements by SecurMed UK in May 2018, of the MAH Setup Fee and Annual MAH Operational Fee structure for the UK FMD implementation, SecurMed UK has received feedback on the fee levels directly from smaller companies and through their industry associations. After reviewing the feedback and consulting with UK competent authorities, the SecurMed UK Board of Directors has taken the decision to introduce an annual fee waiver scheme, in respect of the MAH Setup Fee and Annual MAH Operational Fee, for those MAH or Parallel Distributor legal entities that can demonstrate that they are a **micro MAH** in the relevant year.

How can a legal entity qualify as a micro MAH for the purposes of the fee waiver scheme?

To qualify as a **micro MAH**, an MAH or Parallel Distributor with one or more Marketing Authorisations applicable in the UK from 9th February 2019, is required to demonstrate to SecurMed UK that it is a 'micro-entity'. This means that an MAH or Parallel Distributor 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.

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

How can we demonstrate to SecurMed UK that our legal entity is a micro MAH?

SecurMed UK requires micro MAHs to provide:

- for those legal entities that have filed their first set of audited accounts with Companies House, please submit to SecurMed UK a copy of the audited accounts filed with Companies House for the relevant legal entity and, where relevant, confirm to SecurMed UK in writing (signed by a director of the relevant legal entity) that the relevant legal entity employs 10 employees or less; or
- for those legal entities that have yet to file their first set of audited accounts with 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, along with such other financial information as may be pertinent to enable SecurMed UK to assess the financial standing 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 employs 10 employees or less.
- for those legal entities residing outside the United Kingdom, they will need to submit their last set of published and audited annual accounts for the whole of their business. They can submit a letter

from their auditors on headed and addressed paper, stating the size / scale of the UK portion of their business and the fit with the micro MAH criteria.

The micro MAH fee waiver process

All MAH and Parallel Distributors are obliged under the Delegated Regulation 2016/161/EC to fund the UK Medicines Verification System from 9th February 2019. Therefore, notwithstanding the fee waiver scheme, all MAHs are required to complete the SecurMed UK Registration Form and sign a SecurMed UK MAH Agreement, irrespective of the size of legal entity, and submit these to SecurMed UK at mah@securmed.org.uk.

Where an MAH or Parallel Distributor can demonstrate to SecurMed UK that it is a micro MAH pursuant to the criteria noted above, SecurMed UK may issue a waiver agreement to the relevant micro MAH which, once signed, can waive the requirement for the relevant micro MAH to pay the MAH Setup Fee and Annual MAH Operational Fee for a period of one year from the date the waiver agreement becomes binding (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 UK. All waivers last for a period of one year, shall be agreed (or renewed) on a case-by-case basis.

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

Yours faithfully,



Jerome Bertin
General Manager

