

MVO PORTUGAL – Associação Portuguesa de Verificação de Medicamentos

Participation costs for 2019 Applicable to marketing authorization holders and parallel import authorization holders

The amount to be paid by each Authorization Holder is calculated in accordance with the following table:

Level	Criterion 1	Criterion 2	Amount
1	Up to 10 authorizations	Sales up to (and including) 1.000.000 EUR per year, per authorization	900 EUR + VAT per authorization
2	Up to 10 authorizations	Sales above 1.000.000 EUR per year, per authorization	9.000 EUR + VAT
3	More than 10 authorizations	n.a.	9.000 EUR + VAT

In addition to the information above:

- By "authorization" is meant the Marketing Authorization or Parallel Import Authorization granted by the authorities. For fee calculation purposes, a single authorization is given by the authorization number (*número de registo*) as per the information registered in the authorities;
- Only the authorizations with status "authorized" (*autorizado*) will be considered for fee calculation purposes;
- Only the authorizations whose products are marketed (*comercializado*) will be considered for fee calculation purposes;
- Only the products under the scope of the Delegated Regulation and national applicable legislation (if any) will be considered for fee calculation purposes;
- A single annual payment will apply, and no additional payments are planned for 2018;
- No other fees apply (i.e. entrance fee, etc).

In the case of cooperation agreement signed by a legal representative of the Authorization Holders, the annual fee shall be the sum of the application of the above formula to each of the represented Authorization Holders.

The first invoice will be issued in 2018, and in the following years the invoice will be issued in January.