

## Marketing Authorisation Application

updated: January 2015

1. **Name and address of the applicant and of the manufacturer**
  - a) Applicant Please indicate E-mail address!
  - b) Manufacturer
2. **Place of manufacture**
3. **Name of the product**

Short version of the name: ...  
(IMPORTANT: The name of the product and the short version of the name must be identical in all documents.)
4. **Components of the product by type and quantity, common or chemical name**
5. **Manufacturing procedure**
6. **Field of application**
7. **Pharmaceutical form**
8. **Shelf-life**
9. **Precautions and safety measures with regard to**
  - a) Health risks for humans and animals
  - b) Storage conditions
  - c) Waste disposal
10. **Test methods applied by the manufacturer (sensitivity, specificity)**
11. **Results of validation tests including test period**
12. **Summary of product characteristics (see information sheet "Summary of Product Characteristics"), sample of container and outer package of the product, instructions for use (see information sheet "Labelling requirements")**
13. **Manufacturing authorisation**
14. **Samples of the product**