

## ATC code applications

ATC = Anatomical Therapeutic Classification

An Anatomical Therapeutic Classification (ATC) code is a set of 6 letters and numbers issued by the World Health Organisation (WHO) that identifies and classifies an active substance according to its therapeutic use.

Prior to submitting an MAA, an ATC code application should be submitted. The procedure is straightforward, and there is no fee, however there are some key considerations.

### **Timing**

In order to limit the number of ATC codes granted to active substances that are not subsequently marketed, an ATC code application should be submitted only when the submission date of the MAA is known, taking into account that the WHO ATC code committee meet twice yearly, in March and October. Premature applications will be rejected by WHO.

Generally, submission of an application two meetings prior to the intended MAA submission date is likely to be accepted.

The deadlines for submission are published on the WHO website, and are approximately 2 months before each meeting.

### **Documentation**

The application documents are an application form (completed online), a justification document.

The justification document should include:

- Chemical structure and relationship to similar drugs
- Pharmacology and mechanism of action and relationships to similar drugs
- Main indication as shown in the product information in major countries where it is licensed or submitted for licensing
- Other indications which are licensed or for which licensing is proposed in the future
- Proposed ATC classification with justification based on the evidence submitted
- Status concerning marketing authorisation
- Information about therapeutic use, if available

Whilst not required for an ATC code application, it is advisable to have a draft SmPC in place at the point at which the ATC code application is submitted to ensure the intended indication is precisely described and harmonised throughout company documentation moving forward.

### **Procedure**

The application is submitted online by attaching the justification document to the online application form.

Confirmation of receipt will then be issued by WHO (by e-mail only) and within 6-8 weeks, a draft ATC code is usually assigned.

The draft ATC code is then approved at the next working group meeting and published on the website, together with a deadline for receipt of objections. Any objections received are discussed at the next Working Group meeting at which point either the draft ATC code is made final, or in the event of objections being upheld, a new ATC code is published and a deadline for new objections set.

If the drug substance is difficult to classify, the draft code may be discussed at the Working group meeting before being issued to the applicant.

Once the ATC code is considered final, it is published on the WHO website and publication and the applicant notified by e-mail.

### **Insights**

- The application should be submitted two Working Group meetings before the planned MAA submission date, although it is possible to submit an MAA whilst the ATC code application is under review.
- Whilst this is a relatively straightforward process, the justification document should be well written because there is no opportunity for clarification or presentation of additional information.