Model Letter of Access: Active Pharmaceutical Ingredient Master File (APIMF)

Active pharmaceutical ingredient name: API name

APIMF holder’s name and address:

Active pharmaceutical ingredient manufacturing site(s):

APIMF version number:

Open part:

Closed part:

*(APIMF holder name)* hereby authorizes the relevant WHO staff members and external experts to refer to and review the above-mentioned APIMF (and subsequent versions) in support application(s) submitted by *(finished pharmaceutical product manufacturer’s name)* for the following products:

*(FPP product generic name), (strength) and (dosage form)* (WHO reference code if known)

The aforementioned active pharmaceutical ingredient master ﬁle holder is committed to ensuring batch-to-batch consistency and to informing *(FPP manufacturers name)* and WHO of any change in the Open or Restricted parts of the APIMF.

**Signed**

**Signature for the APIMF holder**

*(Date, name and address)*