

# Authorisation procedure for herbal medicinal products (human medicinal products)

**Ordinary authorisation /  
New active substance**  
Art. 11 TPA

**Medicinal products and  
procedures authorised  
in foreign countries**  
Art. 13 TPA

**Simplified authorisation procedure**  
Art. 14 TPA

**Authorisation on the basis  
of a notification**  
Art. 15 TPA

**Co-marketing  
medicinal products**  
Art. 34 ff. TPLO

**Simplified  
authorisation procedure**  
Art. 14 para. 1 let. a TPA  
(known active substance)  
Art. 14 para. 1 let. a<sup>bis-quater</sup> TPA

**Herbal medicinal products**  
Art. 14 para. 1 let. c<sup>bis</sup> TPA  
and Art. 8 – 11 KPTPO

**Notification procedure  
for teas**  
Art. 15 para. 1 let. b TPA  
Art. 12 KPTPO

**Herbal medicinal product  
with known active substance**  
  
(Medicinal product with a  
plant-based active substance  
that is/was contained in a Swiss  
comparator product)

**Herbal medicinal product  
with well established use**  
  
(Herbal medicinal product  
with an active substance  
with 10 years of med. use in  
the EU/EFTA)

**Herbal medicinal product  
with traditional use**  
  
(Herbal medicinal product with  
30 years of med. use, of which  
15 years in the EU/EFTA)

**Green:** Special simplified authorisation procedure for **herbal medicinal products** described in more detail in the **Guidance document Authorisation of herbal medicinal products HMV4** or the **Guidance document Authorisation of individual teas, cough and throat lozenges and pastilles in the notification procedure HMV4**.

**Grey:** General authorisation procedure