

# HBEL: PDE/ ADE Monographs

Represents a **substance-specific dose** that is **unlikely to cause an adverse effect** if an individual is exposed at or below this dose **every day for a lifetime**.



Developed  
by an  
expert



Implementation deadlines:

- Human medicines June 2016
- Veterinary medicines June 2017



Compliant with the last  
EMA Q&A of 2018



WHO Annex 2 on HBELs  
Technical Report Series, No.1033

More than **1,500 PDEs**  
developed monographs

## Active Substances

- From chemical synthesis
- Or biological
- Or plant origin

## Chemicals

- Cleaning agents
- Degradation products
- Excipients
- Growth media
- Common and biological reagents
- Solvents

## Homeopathic products

- Plants
- Minerals
- Animals