

# EMEA Homeopathic Workshop

## Introduction of AESGP

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AESGP



Association of the European Self-Medication Industry  
7, avenue de Tervuren, 1040 Brussels, Belgium  
Tel: +32 2 735 51 30 ♦ Fax: +32 2 735 52 22

# AESGP: Who are we?

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- ❖ **AESGP represents the manufacturers of non-prescription medicines in Europe**
- ❖ **Founded in 1964**
- ❖ **Our offices are located in Brussels**
- ❖ **Membership in WSMI**

# AESGP Mission

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**To create a favourable  
climate for the growth  
of the self-care market**

# Homeopathic Medicines in Europe

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- ❖ **AESGP welcomes EMEA Homeopathic Workshop**
- ❖ **Harmonisation very important**
- ❖ **Interpretation of CD 2001/83/EC**
- ❖ **Existing products and national traditions**

# Homeopathic Medicines in Europe

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**Guidance documents prepared by HMPWG:**

- ❖ **CTD, Safe dilution**
- ❖ **Very useful to achieve harmonised assessment criteria**
- ❖ **Some open questions and need for improvement e. g. viral safety criteria**

# Homeopathic Medicines in Europe

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## Manufacturing methods:

- ❖ **Harmonisation of manufacturing methods difficult**
- ❖ **Very important for mutual recognition**
- ❖ **AESGP welcomes harmonisation, but national traditions and existing products must be respected**

# Homeopathic Medicines in Europe

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## Stability:

- ❖ **Pragmatic requirements for the submission of stability data (CPMP/QWP/122/02 rev. 1)**
- ❖ **Good approaches already made in Europe**
- ❖ **Guidance on a European level desirable**

# Homeopathic Medicines in Europe

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## GMP requirements for active substances:

- ❖ **Art. 46 of CD 2001/83/EC: "to use as starting materials only active substances which have been manufactured in accordance ... with GMP ..."**
- ❖ **For most of the starting materials used in homeopathic products, GMP conditions are not feasible**



# Homeopathic Medicines in Europe

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## GMP requirements for active substances (continued):

- ❖ **Solution proposed: Starting material itself is not a homeopathic active substance until having been processed in accordance with a homeopathic manufacturing procedure**
- ❖ **In line with the principles of homeopathy**
- ❖ **No need to extend the list of "Atypical Actives" by approx. 2000 positions**

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**Thank you!**