AESGP views

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Who is AESGP?

- AESGP represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices
- Offices in Brussels since 1990
- 24 national member organisations
- 25 member companies / organisations including primarily the main international companies operating in the area of self-care
- Membership in the World Self-Medication Industry (WSMI)
Self-care medicines

- Non-prescription medicines contain older substances with a well-known safety profile, authorised for indications proper to self-care.
- Marketing authorisations for non-prescription medicines may be obtained by using the general marketing authorisation procedures, e.g. the generic approach.

In general non-prescription medicines are nationally authorised –

one central marketing authorisation with OTC status granted in 2009: Pantoprazole to be used for the short-term treatment of the symptoms of acid reflux in adults like heartburn.
Self-care medicines

European Assessment Report for PANTOLOC Control (pantoprazole 20 mg)

Eligibility to the centralized procedure under Article 3(2)(b) of Regulation (EC) No 726/2004 was based on demonstration of interest of patients at Community level considering the possibility to obtain a pan-European nonprescription status. This took into account that the need for an optimal self-treatment of heartburn is universal and that it is in patients’ interest across the community to allow access to a harmonised nonprescription pantoprazole product. In addition, it would give Community-wide access and consumer protection, based on harmonised labelling and avoid diverted markets.

Self-care medicines

Centrally authorised medicines and change from RX to OTC:

- alli (60 mg orlistat) for weight loss in adults who are overweight (2009)
- emergency contraceptive ellaOne (2014)
Non-prescription medicines: a new priority of the EU Medicines Agencies Network

**EU Medicines Agencies Network strategy 2020**
- key role in improving patient access to well-established medicines including [...] non-prescription medicines

**HMA multi-annual work plan**
- will explore other ways to reach agreements between Member states regarding non-prescription products, to facilitate a greater number of product switches.

**CMDh strategy to 2020**
- There should be easier access to OTC-products and there is a need to explore (further) possibilities for MRP/DCP procedures for OTC products (especially in procedures where legal status is different in MSs involved).

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**Regulatory convergence & non-prescription medicines**

- International Council on Harmonisation (ICH) Pharmacopoeial Discussion Group (PDG) aim at harmonising the technical requirements

- IGDRP aims at greater alignment of regulatory approaches and technical requirements for generic medicines

- Legal status (prescription or non-prescription) is a national prerogative but definition of supply without prescription is similar in Europe, US, Japan, etc.

- Common methodical approach to achieve convergence in legal status, e.g. by use of Brass model
Brass model on benefit-risk assessment process for non-prescription medicines

Article by Brass et al, (2011) introduces a new benefit-risk evaluation model for non-prescription medicines
- Value tree tool
- Multiple criteria analysis

Herbal medicinal products

- Basic technical requirements harmonised by ICH also apply to herbal medicines
- More and more dedicated regulatory fora exist, potentially leading to regulatory convergence
  - Complementary/ herbal medicines workshop in the margins of the International Coalition of Medicines Regulatory Agencies (ICMRA)
  - WHO International Regulatory Cooperation for Herbal Medicines (IRCH)

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Conclusion

- We live in a global village
- Patient empowerment is a reality worldwide
- AESGP fully supports all efforts to improve international cooperation
- Global companies: quality, safe and efficient non-prescription medicines (including herbals) to be increasingly made available to the patient/consumer world-wide
- Perspective: Convergence on legal status, for the benefit of both companies and patients/consumers worldwide