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

Including many big and small (e.g. generic) companies

- 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

Self-care medicines

- 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 harmonisating 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

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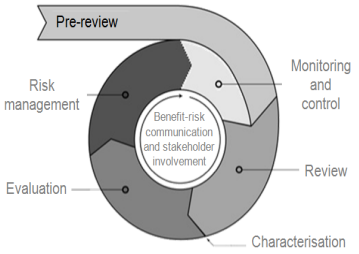
Brass model on benefit-risk assessment process for non-prescription medicines

Figure 1 Value-tree framework of benefits and risks for nonprescription drugs. The general framework is adapted from refs. 3,5, and 33. The center column identifies the major risk and benefit domains that should be considered for any nonprescription drug. The right-hand column is populated by product-specific attributes mapping to each domain. Each central domain may have attributes, ranging from none to several, that are of relevance for a specific product. See text for details.

Article by Brass et al, (2011) introduces a new benefit-risk evaluation model for non-prescription medicines

- Value tree tool
- Multiple criteria analysis

Maximise communication and transparency



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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