



Smart Regulation 2015

**THE FUTURE REGULATION
OF SELF-CARE**

“ The future depends
on what we do in the present ”

Mahatma Gandhi

AESGP Vision

- Self-care is the first choice for informed and empowered consumers to treat illnesses and maintain health for themselves and their families. Through the wide availability of safe and effective non-prescription medicines, food supplements and self-care medical devices, people throughout the European Union can practise responsible self-care at the time they want, in the form they want and where they want.
- Self-care is recognised as a fundamental asset in maintaining and protecting the health and well-being of European consumers. All partners and stakeholders in the healthcare environment collaborate closely to support consumers to practice responsible self-care.
- The value of a vibrant and successful self-care industry is widely respected. It creates employment, welfare and well-being in Europe. State control of the industry takes place in areas related to consumer safety only.

To make this vision a reality there is a need for **making adjustments in the legal and regulatory environment** so that the future self-care market in the European Union is open and free: the market is open so that new products can be launched without untimely delays and free in the sense that the communication on self-care products is not unnecessarily restricted.

Making this a reality will require hard work and a strong political will in many areas to:

- Ensure the proper functioning of the 'single' market;
- Overcome the unnecessary regulatory delays experienced up to now in launching new products;
- Understand the particularities of non-prescription medicines with their well-known safety profile, which should be taken into account in the assessment process;
- Interpret medicines legislation in a way that it permits 'consumer-friendly' communication;
- Establish a risk-based approach in all measures designed to ensure drug safety.

Progress in these areas is possible by **applying the 'better regulation' approach to the area of non-prescription medicines** at both the political and the administrative level. This document highlights AESGP's proposals for 'smart regulation' for non-prescription medicines.

- **Advertising** to be **allowed for all non-prescription medicines**.
- **Package leaflets** to ensure **appropriate** comprehension and **use** of non-prescription medicines.
- **Labelling** requirements to **allow** the provision of all useful information such as **website addresses**, consumer-friendly wording **and an attractive layout**. Graphics and logos providing useful guidance to be permitted.
- **Trade names** and particularly umbrella brands to be recognised as

a **useful tool in guiding people** when using medicines and to be allowed **having a positive connotation**.

- **Ingredients switched** to non-prescription status to be **allowed to use the original trade name** of the prescription product in all EU Member States.
- **Good visibility of and access to self-medication products** in existing distribution channels to be ensured in all Member States.

- **Free pricing** for manufacturers of **non-prescription medicines** which are purchased by the citizens.



- All requirements to **take into account the safety profile of non-prescription medicines**. No obligation for manufacturers to carry out periodic safety update reports and literature search for well-established substances.
- **Pharmacovigilance data** for well-established substances to be **centralised** in one easily accessible system, thus avoiding multiple reporting requirements and systems.

- Enforcement of existing legislative provisions by the Member States resulting in **strict adherence to the timelines** in the assessment of self-medication dossiers.
- The national licensing procedure to be fully considered as one of the four procedures in the marketing authorisation system: budget, timing and priority setting should be in line with demand; the **national procedure not to be ranked lower than the other procedures**.
- The authorisation of a **non-prescription medicine with well-known substances** or combinations thereof granted by one Member State **to be automatically recognised** by other EU Member States without the need for further evaluation. EU Member States to obtain the legal competence to implement automatic mutual recognition of national marketing authorisations, e.g. through bilateral or multilateral agreements.
- The **mutual recognition** and **decentralised procedures** should

enable speedy market access for non-prescription medicines all over Europe.

After the finalisation of a procedure, national marketing authorisations to be granted in a timely manner.

- **All products** with a substance or combination of substances **not available** as such in the whole European Union as a non-prescription medicine should have the possibility to **access the centralised procedure**.
- **Minor product variations** to be put in place **without the need for prior approval or acknowledgement**. Authorities to be kept informed of such variations in an adequate manner. Major variations which need prior approval to be clearly defined.
- New means of product identification not to be mandatory for non-prescription medicines.
- Review of the current fee structure for the national and European marketing authorisation procedures so that the **fees become a true reflection of the work** reasonably expected to be carried out. Lowering in particular

of the fee for central applications covering non-prescription medicines with well-known substances.

- **New scientific data** resulting in, for example, new claims, dosages, indications or ingredients being authorised for non-prescription use **to be protected for three years**, in line with provisions currently in force in the United States and Japan.
- **Experts and staff** members of national authorities as well as of the EMEA to be sufficiently **familiar with issues specific to all non-prescription medicines** in order to ensure adequate evaluation of these products. All authorities to be open to dialogue with industry.
- **Monographs** adopted by the Committee on Herbal Medicinal Products (HMPC) at the EMEA to **grant** medicines with monographed plants **the right to obtain a marketing authorisation** provided the requirements concerning proof of quality are met. In case of reference to monographs, no need to provide literature references.

Why worry about the future when we are already so busy today?

There are many reasons. We live in time of great change. Over the next 10 years globalisation, technology and demographic shift have the potential to significantly alter the role that self-care plays within healthcare.

In 2007, AESGP initiated the project "Smart Regulation" to make sure that the European self-care industry can make the contributions which are expected by society. The proposals in this document should facilitate dialogue among stakeholders to understand what needs to be done to encourage innovation, improve public health and increase the competitiveness of non-prescription medicines.

Self-care:

The first choice in health care



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