



AESGP Regulatory Conference

*Regulatory agenda for self-care products:
Towards an agile framework*

Online Conference | 25 November 2021



Objectives of the conference

Self-care products make an important contribution to the health and well-being of Europeans. Individuals want to take greater responsibility for their own health and wellbeing; this combined with learnings from the pandemic and demographic changes that are increasing pressure on healthcare system requires to advance responsible self-care in order to make European health systems future-proof.

The ability of people to safely and effectively care for themselves can be enhanced by improving the regulatory system governing self-care products. The **AESGP Conference “Regulatory agenda for self-care products – Towards an agile framework”** aims to bring together the self-care industry, legislators and regulators as well as other key stakeholders to discuss how to further improve the current framework for self-care products, notably non-prescription medicines, substance-based medical devices and food supplements.

Ultimately, the conference aims to deliver key, actionable insights into the latest regulatory, legislative and political developments. It will provide an outlook into a future regulatory landscape and its impact on the market.

Key topics

The following key topics will be discussed in 4 successive sessions:

- **The EU Pharmaceutical Strategy**, with a particular focus on non-prescription medicines;
- Ongoing challenges in the implementation of **the Medical Devices Regulation** six months after its date of application, focusing on substance-based medical devices;
- **The Self-Care Industry’s commitment to reducing its impact on the environment** whilst ensuring the availability of self-care products to individuals;
- **The risk assessment of food ingredients**;
- **The EU Chemicals Strategy** for Sustainability;
- **Perspectives on self-care** from various European stakeholders.

Distinguished speakers invited to be part of the session include representatives from the European Commission, the European Medicines Agency (EMA), European Food Safety Authority (EFSA); National Medicines Agencies, National Competent Authorities, Notified Bodies, Industry.



Thursday, 25 November 2021

08.45 - 09.00 **Opening & Welcome**

- **Birgit Schuhbauer**, AESGP President

09.00 - 10.45 **Session 1**

Pharmaceutical Strategy for Non-Prescription Medicines

The Pharmaceutical Strategy for Europe, the European Health Union and the European Health Data Space offer an opportunity for joint action at the EU level in response to public health needs. In this context, the revision of the EU pharmaceutical legislation is an opportunity to foster regulatory agility, modernisation of the regulatory processes through digitalisation, and to incentivise self-care innovation while keeping a patient/individual centric approach, as well as being science-based and risk-proportionate.

Panelists & Speakers include representatives from European Commission, European Medicines Agency (EMA), National Medicines Agency, European Parliament and Industry

Keywords: Pharmaceutical Strategy, Pharmaceutical Legislation, Non-Prescription Medicines, Resilience, change of legal status from Rx to OTC, Digital Transition, PiE, Patient Information

10.45 - 11.15 **Break**

11.15 - 12.45 **Session 2**

Implementation of the Medical Devices Regulation

Six months after the application date of the new Medical Devices Regulation in the EU, this session will discuss the status of the implementation process and related remaining challenges focusing on substance-based medical devices.

Panelists & Speakers include representatives from European Commission, National Competent Authorities, Notified Bodies and Industry

Keywords: Self-Care Medical Devices, Substance-Based Medical Devices, MDR Implementation, Notified Bodies, Borderline and Classification

12.45 - 13.45 **Break**



13.45 - 15.15 **Session 3**

Launch of the Global Environmental Sustainability Charter for the Self-Care Industry

Minimising the impact of self-care products on the environment while safeguarding access to effective treatment and well-being options for people across Europe is a critical issue for AESGP and its members. AESGP is proud to support GSCF's Environmental Sustainability Charter as part of its contribution to the European Green Agenda.

Panelists & Speakers include European Commission, Organisation for Economic Co-operation and Development (OECD), World Economic Forum (WEF) and Industry representatives

Keywords: Environment, Green Deal, Paris Agreement, PiE, Packaging, Carbon Emissions, Carbon Neutrality, Self-Care, Sustainability

15.15- 15.45 **Break**

15.45 - 17.15 **Session 4**

Food Risk Assessment: anticipated practical implications of the EU Chemicals Strategy for sustainability

The European Chemicals Strategy for Sustainability calls for simplification and strengthening of the legal framework and for reviewing how to better use the EU's agencies and scientific bodies to move towards 'one substance – one assessment'. The session will gather perspectives from various stakeholders on the current situation in the food risk assessment context and look at the proposed solutions to achieve the objectives while ensuring robust and state of the art science and regulatory predictability.

Panelists & Speakers include European Commission, European Food Safety Authority (EFSA), European Parliament and Industry representatives

Keywords: Substances in food, Food supplements, Risk Assessment, 'one substance – one assessment', Risk management, Regulatory Predictability, Public health, Sustainability

17.15 - 17.30 **Closing remarks**

Last updated on 13 October 2021

Practical Information

Registration Fee: 120 Euro (excl. VAT*)

The fee includes participation at the virtual AESGP Regulatory Conference.

** This event is subject to the Belgian 21% VAT rate.*

Registration Deadline and Cancellation Policy

Registrations can be made online on the [conference website](#).

Participants are encouraged to register by 18 November 2021.

Cancellations received before 18 November 2021 will be refunded less a handling charge of 50 Euro. After that date, the whole fee is withheld.

Registrations will close on 24 November 2021.



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