



## **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**

- **Video launch « The social and economic value of self-care » (2021)**
- **Birgit Schuhbauer**, AESGP President & Vice President Self Care EMEA Region and Developed Market Cluster, Johnson & Johnson Consumer Health Europe

**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.

**Moderated by Jurate Svarcaite**, Director General, Association of the European Self-Care Industry (AESGP)

- **Andrzej Rys**, Director Health Systems, Medical Products and Innovation, Directorate-General for Health and Food Safety, European Commission
- **Emer Cooke**, Executive Director, European Medicines Agency (EMA)
- **Momir Radulović**, Executive Director, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
- **Christine Eising**, Head RA EMEA Consumer Health, Bayer Consumer Care AG

**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.

**Moderated by Oliver Hartmann**, Legal and Regulatory Affairs Manager, Association of the European Self-Care Industry (AESGP)

- **Paul Piscoi**, Scientific Policy Officer, Unit B6 Medical Devices Health Technology Assessment, Directorate-General for Health and Food Safety, European Commission
- **Thomas Wejs Møller**, Director of the Medical Devices Section in the Danish Medicines Agency, Chair of the CAMD Executive Group
- **Sabina L. Hoekstra-van den Bosch**, TÜV SÜD, Vice-President of Team NB
- **Mike Picchioni**, Chair of the AESGP Medical Devices Committee, Johnson & Johnson Consumer Health Europe

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

12.45 - 13.45

Lunch 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 safe and effective treatment and well-being options for people is a critical issue for the global self-care industry. AESGP is proud to support the launch of the first global environmentally sustainable charter for the consumer health industry as part of its contribution to the European Green Agenda.

**Moderated by Shiulie Ghosh**, TV Presenter & Moderator



- **Judy Stenmark**, Director General, GSCF
- **Rodolfo Lacy**, Director, Environment Directorate, Organisation for Economic Co-operation and Development (OECD)
- **Jurate Svarcaite**, Director General, Association of the European Self-Care Industry (AESGP)
- **Andrew Moose**, Head of Retail, Consumer Goods & Lifestyle, World Economic Forum (WEF)
- **Laure Baillargeon**, Policy Officer, Chemicals and Plastics, European Commission
- **Tamara Rogers**, Global Chief Marketing Officer, GSK Consumer Healthcare
- **Dr Tumi Semete-Makokotlela**, CEO, SAPHRA (pre-recorded video)
- **Alexander Mangwiro**, Programme Officer, Focal point to the Africa Region, UNEP (pre-recorded video)

**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 supplements: Practical implications of the Farm to Fork Strategy and Chemical Strategy for Sustainability**

The Farm to Fork Strategy and the Chemical Strategy for Sustainability are key Commission policies under the EU Green Deal with practical implications for food supplements and their packaging. Concretely, the implementation of these policies includes the ongoing revision of the Food Contact Material legislation as well as a forthcoming proposal for a legislative framework for sustainable food systems. The session will gather perspectives from various stakeholders on the solutions currently explored and piloted to ensure food safety while increasing sustainability.

**Moderated by Maud Perrudin**, Deputy Director General, Association of the European Self-Care Industry (AESGP)



- **Jonathan Briggs**, Legal Officer, Food processing technologies and novel foods, Directorate-General for Health and Food Safety, European Commission
- **Miguel Angel Prieto Arranz**, Director Specialty Chemicals, European Chemical Industry Council (CEFIC)
- **Manon Ombredane**, Lawyer, Fieldfisher (Belgium) LLP

**Keywords:** Substances in food, Food supplements, Risk Assessment, Hazard Assessment, Food Contact Materials, Sustainability, Public health, Environmental Footprint

**17.15 - 17.30**

### **Closing remarks**

- **Jurate Svarcaite**, Director General, Association of the European Self-Care Industry (AESGP)

*Last updated on 24 November 2021*

The conference will be live streamed on a dedicated event platform hosted by EventMobi: <https://eventmobi.com/regconf21/>.

Recordings of the sessions, as well as speakers' presentations, will be available on the platform after the event.

To get access to the event platform, interested participants need to have registered beforehand through the AESGP dedicated event website: <https://aesgp.eu/events/aesgp-regulatory-conference>.

**Already registered but have trouble accessing the event platform?  
Contact us on [info@aesgp.eu](mailto:info@aesgp.eu)!**

# 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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