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AESGP Regulatory Conference: EU Pharma Strategy, Med Devices Regs, European Green Deal And GCSF Sustainability Charter Launch

by Tom Gallen

HBW Insight reports on a packed agenda at the AESGP's Regulatory Conference on 25 November. Panels discuss the implications of raft of legislative changes for the European self-care industry, including the incoming EU Pharmaceutical Strategy, the new Medical Devices Regulations, and the inter-related European Green Deal, Farm to Fork and Chemicals Strategies. The conference also saw the launch of the GSCF's Charter for Environmentally Sustainable Self-Care.

Introduction

Welcoming attendees to the Association of the European Self-Care Industry, the AESGP's, virtual conference, titled "Regulatory agenda for self-care products: Towards an agile framework," president Birgit Schuhbauer noted how the event was taking place during the "most severe public health crisis in the century."

It was therefore crucial for policymakers, regulators and industry to learn from the COVID-19 pandemic, "and build health systems and regulatory frameworks to withstand the challenges of today and tomorrow," insisted Schuhbauer, who is also Johnson & Johnson Consumer Health's vice-president of self-care for EMEA.

Against the backdrop of the pandemic, industry was facing a "historic moment," she observed, with the introduction of the Pharmaceutical Strategy for Europe, European Green Deal and the new Medical Devices Regulation set to shape the regulation of self-care products for years to come.

"We need to work together to strive for better, more agile regulation," Schuhubaeur argued. "We cannot adopt a business as usual approach."

Industry had to continue to push to unlock the full potential of self-care, she noted, as underlined by a new AESGP study "*Self-Care in Europe: Economic and Social Impact on Individuals and Society*."

While publication was set for next year, Schuhbauer revealed that the study showed that resources freed up through adequate healthcare policies that support and encourage self-care can play a significant role in building more resilient health systems across Europe.

Session 1 – Pharmaceutical Strategy for Non-Prescription Medicines

AESGP director general Jurate Svarcaite kicked off the first session of the conference on the new Pharmaceutical Strategy for Europe by noting stakeholders had been presented with a "once in a lifetime opportunity" to contribute to the revision of the EU's pharmaceutical legislation.

For industry in particular, there was an opportunity to "gain further recognition of the importance of non-prescription medicines and broader self-care innovation," Svarcaite observed.

Andrzej Rys, director health systems, medical products and innovation at the European Commission's Directorate-General for Health and Food Safety, gave delegates an overview of the Pharmaceutical Strategy and how it aims to promote innovation and digitisation, while at the same time improving access to more affordable medicines.

Implementation of the strategy required a holistic and collaborative approach, Rys noted, with many consultations and studies to be carried out before the end of next year when the European Commission is scheduled to adopt its proposal.

"It's not a Commission or European Medicines Agency (EMA) strategy, it is a strategy in which every partner should participate," Rys explained.

"We would like to continue engagement with industry. At this moment of time all doors are open, we should put everything on the table and look at all options," he said, with the aim of creating a pharmaceutical system fit for the coming decades.

EMA executive director Emer Cooke noted how the agency was providing scientific and technical input to the implementation process of the strategy, and was looking at different options to tackle some of the issues that had been identified.

When it came to non-prescription medicines, EMA had identified some areas where there was room for improvement, Cooke revealed.

While the existing pharmaceutical legislation had been designed to facilitate switching, it had been underutilised, with only nine centralised reclassifications reviewed by EMA. This was "probably understandable," she admitted, due to the type of products that came under the scope of the centralised procedure.

One potential change to the switch process was better utilization of real-world evidence, Cooke suggested, with the opportunity to involve EMA's Data Analysis and Real World Interrogation Network (DARWIN EU).

Momir Radulovic, executive director of Slovenia's Agency for Medicinal Products and Medical Devices, grabbed delegates' attention with a suggestion that the Pharmaceutical Strategy could be an opportunity to harmonize packs of commonly used OTC medicines, such as paracetamol, across the EU.

"From a patient perspective It would be really good if paracetamol in Slovenia, Austria, Croatia or Italy is the same," Radulovic claimed. Harmonisation would make things easier for consumers, he argued, as they would recognise the package no matter which country they were in.

Patient information could be displayed in multiple languages, he suggested, pointing out that multi-lingual packs were already commonplace in smaller member states. Utlising Quick Response (QR) codes to bring up patient information on a smartphone was another possibility, given their widespread use by consumers for various purposes during the pandemic.

The session's final speaker was Bayer Consumer Health's regulatory affairs head, Christine Eising, who, as chair of AESGP's Regulatory Affairs Committee, presented the association's position on the Pharmaceutical Strategy.

While the current legal framework for pharmaceuticals was, overall, fit for purpose, Eising noted that issues did arise from divergent interpretation and disharmonised application.

Eising laid out the AESGP's views on how the new strategy should address a number of issues of key importance to the self-care sector, including electronic patient leaflets, supply chains, real-world evidence and switch.

On switch, Eising proposed that data protection should be increased from one to three years to encourage and reward innovation, as the current level was insufficient time for an applicant to recoup their investment in the reclassification procedure.

Furthermore, data protection should apply to all types of studies used to substantiate a switch, she argued, including clinical and real-world evidence.

Session 2 – Implementation of the Medical Devices Regulation

There was an unexpected maritime theme to the second session of the conference, with all four panelists, in one way or another, likening the new Medical Devices Regulation to a ship that had just left port.

Thomas Wejs Møller, director of the Danish Medicines Agency's medical devices section, was the first to employ the metaphor, describing how industry, notified bodies, competent authorities, and patients were all aboard the MDR ship, which had set sail around six months ago with the implementation of the legislation.

It had not been smooth sailing, Møller admitted, as not everything needed for the functioning of MDR was in place. “But it will be,” he insisted.

One of the challenges facing competent authorities when trying to implement MDR was limited resources, especially compared to their colleagues in the medicines sector. Møller said he had a message for politicians, “Competent authorities can’t take on anymore tasks without more resources.”

Presenting the view from inside the EU, Paul Piscoi, scientific policy officer at the European Commission’s Directorate-General for Health and Food Safety, gave an overview of the current work underway at the Commission in relation to the MDR.

Numerous guidance documents had been completed or were under consultation, Piscoi pointed out, from borderlines with medicinal products, to the Helsinki procedure under the MDR.

Rather than Møller’s ship, Piscoi likened the MDR to a submarine, as the Commission was currently “underwater” dealing with all of the work related to the regulation’s successful implementation.

Sabina L. Hoekstra-van den Bosch, vice president of EU notified bodies association TEAM NB, highlighted the strain MDR was placing on her members as manufacturers looked to ensure their products were compliant ahead of the 2024 deadline.

With the workloads of notified bodies increasing, Bosch warned that capacity needed to increase. Currently there were 24 designated notified bodies, with a further 30 still working towards designation.

Bosch extended Møller’s metaphor, describing the old Medical Devices Directive as a smaller ship compared to MDR, which “is still sailing but knows its time is limited.”

“This is a problem,” she explained, “as we want everyone onboard the new ship, but there are

several hurdles to overcome."

Given the workload of notified bodies with less than three years to the end of the MDR transition period, Bosch's message to manufacturers of self-care medical devices was, "please do not hesitate to get on board."

Michele Picchioni, regulatory affairs director at Johnson & Johnson Consumer Health, highlighted how certification for many self-care medical devices, particularly those that were substance based, was far from straight forward under MDR.

"The main concern from the sector is whether we will be on the ship or stuck on a rowing boat desperate to join," explained Picchioni, who chairs AESGP's medical devices committee.

Industry was facing a number of classification issues for substance-based devices under MDR, he pointed out, including workable definitions of pharmacological, immunological and metabolic (PIM). The current draft of the legislation did not ensure effective demarcation between such devices and medicinal products.

To address this issue, Picchioni suggested that the PIM definitions under MDD should be transferred to MDR for the time being to ensure effective application of the regulation and legal certainty for manufacturers.

Without a solution, self-care devices risked being left in vacuum between frameworks, he warned, classed as neither medical devices or medicines, and therefore with no route to market.

Session 3 – Launch of the Global Environmental Sustainability Charter for the Self-Care Industry

The session started with a video from the Global Self-Care Federation on the launch of its "*Charter for Environmentally Sustainable Self-Care*."

Presented by GSCF president and Bayer Consumer Health head Heiko Schipper, the video featured a range of industry stakeholders pledging their support and briefly outlining their own sustainability plans, including companies like Johnson & Johnson, GlaxoSmithKline, Bayer, Sanofi and Taisho Pharmeceutical and also GSCF member associations like the AESGP, the Japanese Self-Medication Industry association and the Latin American Association of Responsible Self-Care (ILAR).

The charter aims to reduce the impact of self-care products on the environment, GSCF director general Judy Stenmark explained, while ensuring better health outcomes, product safety and access to effective treatment options.

Representing the sustainability commitments of GSCF members, including consumer health manufacturers and associations, the charter focuses on three priority areas, she added, where the industry has the greatest impact and influence: plastics and packaging, pharmaceuticals in the environment and CO2 footprint.

AESGP director general Jurate Svarcaite also spoke to the charter, in her capacity as member of the GSCF sustainability working group. Industry is "ready to play our part," she insisted. "We are focusing on areas where we can deliver tangible, long-term results."

GSCF Launches Global Self-Care Industry Sustainability Charter

By David Ridley

25 Nov 2021
The Global Self-Care Federation (GSCF) launches today its "Charter for Environmentally Sustainable Self-Care," which it describes as the world's "first commitment from the consumer health industry to drive sustainable self-care."

Read the full article here

Given the ambitious sustainability strategies of many consumer healthcare companies, as shown by the GSCF video, Svarcaite noted that the aim of the charter is to maximize impact of individual actions by bringing companies together, using "peer pressure" to drive each other forward.

But she also wanted to make it clear that "no one should be left behind." Companies that are just starting their sustainability journey should also feel like they can make their own climate pledge, she said.

Svarcaite ended with a plea to participants: "We want to talk to you and see how you can feel comfortable to make a pledge no matter where you are on your sustainability journey."

Also representing the OTC industry, GSK Consumer Healthcare's global marketing chief, Tamara Rogers, said that the charter represented a "pretty unique" opportunity for manufacturers, who are usually competitors, to work together, within strict competition guidelines and the GSCF's code of practice, of course.

"The environment is something we shouldn't be competing on," she said. "We all have our own plans but when we bring the parts together that's when we really move the needle forward."

Away from industry, the conference heard from Rodolfo Lacy – director of the Environment Directorate of the Organisation for Economic Co-operation and Development (OECD) – who stressed the business opportunity that a transition to a green economy represents.

Green innovation could lead to an increase of up to 4% to a country's Gross Domestic Product (GDP), according to OECD estimates. Building back better, therefore, is not only compatible with business goals, but could in fact be a driver of economic growth, Lacy argued.

Ether way, he concluded, "we have to do it. We have to save the planet."

Head of the World Economic Forum's Retail, Consumer and Lifestyle Industries, Andrew Moose, also pointed to the importance of public-private partnerships in creating the forms of collaboration needed for radical climate action.

"We need to partner in ways we've never done before," he said. Meeting the goals of the Paris Agreement, as well as the new goals agreed at COP26, will require "deep commitment," he added, and a "mindset shift."

An example of such a partnership was then presented by the European Commission's Laure Baillargeon, policy officer at the Directorate-General for Internal Market, Industry, Entrepreneurship.

Baillargeon described how the EC's Circular Plastics Alliance had brought together a range of stakeholders to work towards the target of boosting the EU market for recycled plastics to 10m tonnes by 2025.

Drawing lessons from the initiative, she said that having stakeholders that covering the full plastics value chain, including 293 organizations representing industry, academia and public authorities, had been crucial in making progress towards this target, which required lot of cooperation.

Having a clear, measurable, quantitative target is also useful to organize the work because this made the discussion, as well as the formulation of sub-targets, "very concrete," she reflected.

Session 4 – Food Supplements: Practical implications of the Farm to Fork Strategy and Chemical Strategy for Sustainability

AESGP deputy director general Maud Perrudin opened the fourth session of the day by pointing to the potential implications of the European Green Deal – which aims to reduce the region's greenhouse gas emission to net zero by 2050 – and related legislative changes for food supplements and other self-care products.

These developments have "clear cross sectoral dimensions," Perrudin noted, and reflect the core concerns of the AESGP, namely how the European self-care industry can "continue to deliver self-care solutions and products within the evolving regulatory landscape" while also meeting the region's ambitious sustainability agenda.

The panelists of this "exploratory session" were mostly concerned with outlining this evolving regulatory landscape as it relates to the wider food sector, rather than food supplements specifically.

European Commission policy officer Jonathan Briggs began by describing the EU Farm to Fork strategy, which is "at the heart of the European Green Deal," according to the EC website and aims to accelerate the transition to a sustainable food system that should, among other things, "ensure food security, nutrition and public health, making sure that everyone has access to sufficient, safe, nutritious, sustainable food."

Briggs is working specifically on the revision of EU rules concerning food contact materials (FCMs), for example materials used in food packaging and food processing equipment, in order to reduce the use of hazardous chemicals, support the use of innovative and sustainable packaging solutions using environmentally-friendly, re-usable and recyclable materials, and contribute to food waste reduction.

An "inception impact assessment" – which aimed to inform citizens and stakeholders about the EC's plans in order to allow them to provide feedback on the intended initiative – was completed earlier this year, he reported, followed by a period of policy development that will end with adoption of new legislation in Q2 2023.

European Chemical Industry Council director Miguel Angel Prieto Arranz then provided a summary of the EU's new Chemicals Strategy for Sustainability, which aims to "better protect citizens and the environment" and "boost innovation for safe and sustainable chemicals."

Actions planned by the EC as part of the chemicals strategy include banning the most harmful chemicals in consumer products – allowing their use only where essential – and establishing a simpler "one substance one assessment" (OSOA) process for the risk and hazard assessment of chemicals.

Linking the chemicals strategy to FCMs, Arranz pointed to a recent European Food Safety Authority pilot project on phthalates – a group of chemicals used to make plastics more durable that have been linked to a range of health risks, from asthma to autism – as an example of collaboration between different sectoral agencies, in this case, the EFSA and the European Chemicals Agency.

"Dialogue is needed," he urged in his conclusion. "Policies need to be better joined up."

In the final presentation, Manon Ombredane – a lawyer at Fieldfisher LLP – dug deeper into the Farm to Fork strategy, raising concerns about a lack of agreement as to what "sustainability" actually means.

“There is no universal definition of sustainability,” Ombredane pointed out. A recent fishing industry analysis uncovered 32 different definitions of this concept, she said, which is essential for providing legal certainty for such a wide-ranging piece of legislation like the proposed new food strategy.

“It’s not clear if the Farm to Fork framework will provide this definition,” she said. As a result, Ombredane warned that the concept could become a political “hot potato” for the sector.

Closing remarks

AESGP director general Svarcaite closed the conference by thanking attendees, the organizers and everyone contributing to the panels directly or via the questions on the webinar platform.

Svarcaite said that the objectives set out at the beginning of the day had been achieved, namely to identify and discuss the key regulatory policies and structural issues facing the European self-care industry.

Industry and regulators now had some “homework” to do, she said, in terms of following up on the “concrete actions and outcomes” that had come out of the many excellent sessions that can help the sector achieve significant progress in making sure that the region’s regulatory framework remains “fit for purpose” and continues to allow companies to deliver “safe and effective products to EU citizens.”

Svarcaite ended on a “cheery note,” pointing again to the “exciting journey” initiated by the launch of the GSCF charter, and to the possibility of an in-person 58th AESGP Annual Meeting next year – which will take place in Milan, Italy, from 7-9 June – after the “rollercoaster ride” of COVID-19 and the long break from face-to-face networking over the last 18 months.