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# AESGP Annual Meeting, Day 2: Communicating Risk, E-Commerce Boom, RWE And Sustainability

by Tom Gallen

Day two of the AESGP's 57th Annual Meeting featured discussions on communicating risk in times of uncertainty, how to foster a harmonized EU market for food supplements and the growth of the ePharmacy channel. The opportunities presented by real-world evidence were also debated, along with the challenges facing the self-care industry in the area of sustainability.

## Session 4 – Communicating Risk In Times Of Uncertainty

The COVID-19 pandemic has created an "unprecedented visibility of regulatory services" among the general public, according to the European Medicines Agency's executive director Emer Cooke. "People want to know what we're doing," she explained, especially when it came to authorizing vaccines and treatments for the coronavirus.

Opening the second day of AESGP's 57th Annual Meeting, Cooke said there was an "increasing appetite for instant information, which is difficult to manage when you're trying to have a sound scientific basis for what you communicate."

With this higher profile, in combination with the circulation of deliberate disinformation about medicines, EMA had to increase its outreach efforts to the public, Cooke said.

***AESGP Annual Meeting, Day 1: Life After COVID-19, The Value Of Self-Care And MDR Implementation***

The agency used social media to "explain

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science in more understandable terms," she noted, as well as stepping up press activity and inviting the public to open discussions with various stakeholders.

The EMA had to actively listen to questions and concerns so it could address them, Cooke said, helping to earn the public's trust and cement the agency as the "definitive source of information."

Echoing this message, Dr Gaya Gamhewage of the World Health Organization said her agency had "shifted from communication with a talking head to listening and engaging communities."

By Tom Gallen and David Ridley

27 May 2021

Opportunities, challenges and lessons learnt from the global COVID-19 pandemic was the theme of the AESGP's 57th Annual Meeting. Day one of the conference explored the future of consumer healthcare in a post-pandemic world, the growing role of self-care and the implementation of the new Medical Devices Regulation.

*Read the full article here*

Gamhewage – head of learning & capacity development for WHO's health emergencies program – detailed how lessons learnt during the Ebola outbreak in 2013 on the importance of risk communication had been applied during the COVID-19 pandemic.

The WHO had worked with 50 partners to analyse 1.2bn posts on social media and 61m questions asked by the public about the virus around the world, Gamhewage explained, and then used different outlets and tools to ensure accurate information cut through the noise.

It was important to remember that people were "not just empty vessels waiting for us to tell them information," she pointed out. Instead WHO and others had to empower the public by improving health literacy.

François Houÿez of EURORDIS – an alliance of rare disease patient organizations – explained how his group had worked to collect and filter information on COVID-19 to make it more easily digestible.

As the pandemic had generated many questions for people with rare diseases, Houÿez explained EURODIS had approached different stakeholders, including EMA and the pharma industry, to get accurate and relevant information it could share with patients. EURODIS then sifted though the responses and presented its findings in different ways on its website, including using data visualization.

Praising the EMA's approach, Houÿez noted that the agency's public debates had not only provided important information but also allowed patients to challenge experts and ask

questions.

Houÿez' key takeaway was that "less is more" when communicating during a pandemic, "to make sure the most important information will be found by the public."

Offering industry's perspective on pandemic communications, Reckitt's chief safety officer Simon Sinclair highlighted how his firm had been at the forefront of the battle against misinformation around a popular OTC treatment. (Also see "*EMA Quashes Claims That Ibuprofen Worsens Infection From Coronavirus*" - HBW Insight, 18 Mar, 2020.)

A tweet which linked ibuprofen to worsening COVID-19 symptoms had gone viral in the early days of the pandemic, Sinclair explained, leading Reckitt – owner of one of the biggest brands, Nurofen – to set up a crisis team to handle the response. (Also see "*EMA Quashes Claims That Ibuprofen Worsens Infection From Coronavirus*" - HBW Insight, 18 Mar, 2020.)

Mobilization in the company had been "rapid and substantial," he explained, however it was a huge job to reverse the damage done to trust in ibuprofen by the social media storm.

The social media "infodemic" had become "far more powerful than the traditional curated expert view," Sinclair noted. "So however much material we put out it's difficult to get that across."

"What we can do and have been doing as an industry is keep collaborating, keep generating the evidence to provide balance and keep voicing it in responsible way," Sinclair insisted.

Portugal's medicines regulator INFARMED was one of the stakeholders which had worked to disseminate factual information about ibuprofen during the pandemic, explained president Rui Santos Ivo.

The agency had partnered with a network of Portuguese pharmacies to counter disinformation about the popular NSAID, Ivo noted. This was part of a concerted effort by INFARMED to work with healthcare stakeholders, including healthcare professionals and the health ministry, to speak with one voice to the public so messaging around COVID-19 was clear, he noted.

Furthermore, coordinating its activities with the EMA and the European Commission had been really important, Ivo said, establishing good practices that would remain in place after the pandemic.

## Session 5.1 – (e)-Internal Market Of Food Supplements: How To Foster Harmonized Implementation?

The AESGP's deputy director general Maud Perrudin opened the fifth session, which ran in parallel with session 5.2 (see below), by noting the "significant growth" of the European food

supplements sector during the pandemic.

There has been an "increasing recognition" of role of self-care in preventing illness, rather than just treating it with OTC medicines, she noted. However, given the complexity of EU food supplements regulation, its lack of harmonization within the region, and the growth of e-commerce, it was crucial that industry ensured that consumers can trust in products.

The European Commission's Eric Marin – deputy head of the DG Sante Food Hygiene and Fraud Unit – presented the results of a year-long investigation into online platforms illegally advertising food supplements with health claims related to COVID-19.

As reported by HBW Insight, the Commission's e-Commerce Action Plan identified 510 national and 79 cross-border cases of illegal supplement advertising between 20 April and 6 October. (Also see "*'No Miracle Cures For COVID-19' Warns German Food Safety Authority*" - HBW Insight, 8 Dec, 2020.)

In Germany alone, the country's Federal Office for Consumer Protection and Food Safety's (BVL's) "G@ZIELT" initiative identified 60 websites offering illegal supplements claiming to cure COVID-19 or making unauthorized health claims for supplement products – reported also during the session by G@ZIELT head Dennis Raschke.

What was new at the session was a slide from Marin on the types of problems identified by the Commission. At the top of the list, with 105 occurrences, was the presence of unauthorized novel food ingredients in supplements – such as cannabidiol (CBD) – followed by other unauthorized and dangerous substances, such as 2,4-Dinitrophenol DNP, a potentially dangerous substance sold illegally as a weight loss aid.

Raschke's BVL colleague Evelyn Breitweg-Lehmann also spoke about a lack of harmonization with regards to botanicals – plants, plant extracts and fungi – in food supplements, which, if not regulated effectively, could present a potential health risk when taken by consumers. (Also see "*Resolving Botanicals Deadlock 'Not A Priority' For European Commission*" - HBW Insight, 2 Dec, 2020.)

Breitweg-Lehmann outlined a German initiative that, in collaboration with experts from Austria and Switzerland, classified 870 plant and 280 fungi ingredients.

While not legally binding, the classification, if shared and used by other authorities, could be a step towards bringing systematization and efficiency to an EU market that Breitweg-Lehmann noted was not yet harmonized, with neither positive nor negative lists, and in many cases, food substances that were not specified properly and were lacking conditions of use.

Harmonization was also discussed by the chair of the European Council working party on foodstuffs, Ana Batalha, who reported on an intensive period of reflection within the Council under the Portuguese presidency on the status of food supplements regulation in the region.

Mapping the many problems faced by the sector working within a now 20-year-old EU Directive (2002/46/EC) on Food Supplements, Batalha presented possible ways forward, which she hoped the Commission would incorporate into their own work.

An intriguing suggestion was the proposal to have a centralized approval mechanism for food supplement marketing authorizations, potentially granting manufacturers access to all 27 EU Member States simultaneously.

## Session 5.2 – ePharmacy: What Has Changed During COVID-19 And What Is Here To Stay

COVID-19 has helped to speed up the adoption of ePharmacy by European consumers, according to Jyoti Shah, IQVIA Consumer Health's director, global insights.

In four key European markets – Germany, France, Poland, and Czech Republic – the online share of consumer heath sales grew double digits in 2020, Shah reported. In Poland and Czech Republic this built on strong growth the previous year, she pointed out, highlighting the willingness of consumers to use the channel for OTC purchases.

Certain consumer health categories lent themselves to ePharmacy more than others, Shah explained, with prevention, wellness and lifestyle products enjoying the highest online penetration. Consumers were turning to these categories as COVID-19 had made them more aware of the need to manage their long-term health.

Going forward, Shah said we were likely to see "a more proactive and connected consumer is who is more informed and demanding." (Also see "*Post-COVID Consumers Want Digitally Enabled, Personalized And Continuous Self-Care*" - HBW Insight, 25 May, 2021.)

With consumers taking a more active role in their health, Eddy Gilissen, IQVIA's senior director, supplier alliances EMEA, explained that their OTC purchases would take place in both the online and offline world.

"The consumer going forward will inform himself online and offline and buy on both," Gilissen said. The challenge for manufacturers, he observed, was how to create the "online merging offline" (OMO) experience for the consumer. "You need to understand what the strengths of your products are and the profile of your consumer, and ask yourself how you can reach them."

Investment was required in a range of areas, Gilissen explained, including convenience, price,

speed, personalization, and essentially becoming a partner in the management of the consumer's well-being.

For manufacturers looking to increase their online penetration, Tobias Brodtkorb, managing partner at SEMPORA Consulting, highlighted the need to work with the biggest ePharmacy players.

In Germany, it was essential to partner with Zur Rose's DocMorris and Shop Apotheke, he noted, as they controlled 80% of the online market. However, Amazon was also an important and growing player, with 50% of e-pharmacies selling through its online marketplace.

The e-commerce giant was already in discussions with a lot of industry players, Brodtkorb noted, and could potentially acquire one of the big e-pharmacy operators and dominate the market.

"The market entry of Amazon would be game changer," he said, pointing to research which revealed 42% of the firm's 20m registered users in Germany would prefer to buy OTCs on its platform rather than through an e-pharmacy.

Offering a manufacturer's perspective, Sophie Even, Procter & Gamble's sales VP, Europe personal health care & pharmacy sales forces, said the growing e-pharmacy channel was not only about selling products but was also a useful tool for information and services about self-care.

While 60% of European consumers would start their shopping journey with e-pharmacy, less than a third would complete the purchase, Even pointed out. "E-pharmacy is used not only to buy, but to get information [about products], and if that information not available consumers will go elsewhere. So as a manufacturer we have to make sure relevant content is both online and offline to close the purchase."

While online was growing, the bulk of sales would continue to take place in bricks-and-mortar pharmacies, Even said. Therefore, P&G's strategy was to partner with pharmacy retailers to build capabilities to address new shopper needs and habits. A key focus, Even noted, was having consistency online and offline across all media touch-points for P&G's brands.

Echoing the need for a strategy that combined online and offline, Paul Martingell, Sanofi Consumer Healthcare's region president for Europe & Eurasia, emphasized how the pandemic had renewed the important role of the pharmacist in healthcare.

For Martingell, e-pharmacy represented an opportunity for the pharmacist to continue to be an accessible source of trusted and reliable information.

Pharmacists played a fundamental role in self-care, especially in certain categories, he explained,

and they could create trust and ensure proper use of medicines. E-pharmacy could help strengthen that personal face-to-face support by utilizing data, Martingell suggested.

## Session 6.1 – RWE/RWD In The Self-Care Space: What Is Stopping Us Using More Of It?

"The time of real-world evidence (RWE) and big data is now," insisted Peter Arlett, head of data analytics and methods taskforce at EMA, as he opened the session.

With the benefits of RWE "manifold," there were "lots of opportunities for the self-care industry," Arlett argued.

Observational studies of medicines in the real world offered an alternative to clinical trials to collect data, Arlett said. "You can get useful information on how medicines are used, but you need some good methodology work to demonstrate the value of collecting data direct from patients." Observational data was already being used by EMA to authorize prescription medicines, he pointed out.

Arlett cautioned however that it was "very easy to do bad studies." "You will need good methodologists or you will perpetuate the narrative that they aren't generating good evidence."

Giving an industry perspective, Bayer Consumer Health's Emese Csőke – who is also AESGP's lead expert on RWE and real-world data (RWD) – said the association's efforts to advance RWE for self-care were progressing well. In the coming weeks AESGP hoped to have a manuscript accepted for publication in a scientific journal on the topic of the value of RWE in OTC, Csőke revealed.

Up until now there had been little focus on the potential role of RWE in the OTC market, she pointed out. Of the numerous scientific publications on RWE only 0.22% included key words relevant to the consumer health industry.

Csőke contended that RWE in an OTC setting enabled an understanding of how drugs worked outside controlled settings, which could help to fill data gaps.

While still relatively rare, there were some notable examples of RWE in action in the consumer health industry, she noted, including a large three-month open label study of orlistat without healthcare oversight. This had demonstrated the product, Alli, could be used appropriately without supervision over the long-term, helping to support its switch from Rx-to-OTC status.

Exploring further how RWE might be generated, Bayer Consumer Health's director of clinical development, Andreas Ehret, said primary data collection sources could include retrospective and prospective observational studies, as well as wearables and mobile health apps.

Secondary data sources could include publicly available information such as social media in combination with AI and machine learning. Data was also available from sources such as electronic health records, he noted, but this rarely covered self-care products.

While the data sources existed, the only real guidance on RWE was for the prescription sector, Ehret pointed out. Therefore to increase adoption for OTC products RWE needed to be defined for self-care, he argued, to satisfy the needs of both industry and regulators.

This was a challenge, Ehret admitted, but with a fit for purpose framework, RWE was a tool which could generate valuable scientific evidence in a fast and cost-effective way.

IQVIA Consumer Health's senior director, global R&D services, Volker Spitzer, drilled down further into the potential applications of RWE in self-care, arguing that it offered firms the potential to interact directly with a consumer using one of their products.

By utilizing digital health tools such as wearables, consumer health players could get real time data "in continuous way like never before," Spitzer noted, allowing them to learn much more about consumers' activity than could be gained through a questionnaire.

This device data could then be translated using algorithms into "digital biomarkers," he explained, to allow firms to understand consumer behavior and experience. For example, it could measure how a consumer's mobility was supported by a pain product, Spitzer suggested, which would help to develop new claims.

An example of RWE in action was offered by Johnson & Johnson's Julie Sutherland who presented insights into the firm's Nicorette QuickMist smoking cessation product, which launched in the UK in late 2020. (Also see "*J&J Leverages Power Of Digital Personalization With Nicorette UK Extension*" - HBW Insight, 26 Nov, 2020.)

Describing QuickMist as the "world's first connected OTC medicine," Sutherland explained how usage was recorded by a linked mobile app. This helped consumers track their progress towards a quit goal, she said, and to better understand their patterns of behavior.

"From J&J's perspective, the app gives us a huge amount of data," Sutherland said, "helping us develop a deeper understanding of quitting smoking, and consumers' daily patterns and behaviors more so than in past."

There were limitations, Sutherland admitted, as all data was anonymized. "Ideally we would like to track someone's individual quit journey," she noted. Also, there were sometimes difficulties interpreting the data as J&J was unable to go back and verify it with the user.

“There are complexities to navigate with RWE,” Sutherland concluded, “but the benefits to the industry are huge.”

## Session 6.2 – Circular Economy And Sustainability: What Is The Role Of Our Industry?

Sustainability is an area that has become more important to the consumer health industry since the pandemic, and Organisation for Economic Co-operation and Development (OECD) environmental economist Frithjof Laubinger kicked off this final session by describing the impact of pharmaceutical waste on the environment.

Up to half of prescription medicines are currently wasted, Laubinger explained, with a significant share of pharmaceuticals, liquids and creams flushed down the toilet, ending up in freshwater systems.

The good news for the self-care industry is that preventing diseases from occurring in the first place is the best way to way to reduce the number of pharmaceuticals in the environment.

Packaging has also been top of mind for environmentally conscious consumer health firms, a topic that Francesca Stevens – managing director of the European Organization for Packaging and the Environment (EUROPEN) – spoke about next.

Well-designed packaging should be fit for the product it is protecting, should minimize economic and environmental impacts and use only as much of the right kind of material as necessary, Stevens recommended. As with waste, the best way of reducing industry’s negative impact on the environment is to reduce the amount of material used in the first place, which is where packaging design comes into play.

When waste does end up in our water systems, there needs to be methods of removing organic compounds, which is where Linda Kren’s work comes in.

Head of Environment and Responsible Care at Scienceindustries – the Swiss business association of the chemical, pharma and life sciences industries – Kren described a successful collaboration between industry and researchers in Switzerland looking at industrial discharge, which used a multi-stakeholder approach to drive awareness of the problem of water contamination and innovation with regards to addressing this problem in the future.

Johnson & Johnson’s Jody Lodge next outlined his firm’s journey in eliminating CO2 emissions at its plant in Helsinborg, Sweden, which Lodge manages and is where all the world’s Nicorette smoking-cessation products are made.

Energy efficiency measures, strategic partnerships with green energy suppliers and a gradual

transition from natural to biogas heating sources enabled the site to achieve carbon neutrality in 2018, becoming "a role model for sustainability" within both the company and the consumer health industry.

Lodge said that site's contribution to J&J's ambitious climate goals provided employees with a "tremendous sense of pride," and he hoped that other industry representatives at the conference were as "inspired by this story as I am." (Also see "*'It's A Win-Win Situation' – Nicorette At The Vanguard Of J&J's Global Sustainability Efforts*" - HBW Insight, 23 Feb, 2021.)

## Closing Remarks

AESGP director general Jurate Švarcaite closed the 57th Annual Meeting with a brief summary of the two days' sessions, concluding that "it has never been a better time for self-care industry."

There was no going back to the way of working before COVID, she insisted, with the "new normal" requiring collaboration, partnership and the skills to be able to adapt to rapid change.

"We hope that we can co-create the future together, that we can partner with the regulators, pharmacists and other healthcare professionals, and put people at the heart of what we do when we re-imagine and recreate our health systems and come out of what has been a devastating public health emergency," she said.

Švarcaite ended by inviting delegates to the upcoming AESGP Regulatory Conference in Lisbon, Portugal on 25 November, which she hoped would be face-to-face, rather than online, as well as to the 58th Annual Meeting next year in Milan, Italy, from 7-9 June 2021.