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European Commission Lays Down ‘Zero Pollution’ Gauntlet To Consumer Health Industry

by David Ridley

Europe's consumer health industry is faced with proliferating regulations under the EU's Green Deal policy program. Proposed revisions to the Urban Wastewater Treatment Directive, for example, expect pharmaceutical and cosmetics manufacturers to pay for the removal of micro-pollutants that are mostly flushed into the wastewater system by consumers. While the European Commission says it is “sympathetic” to industry's concerns, such as those raised at the AESGP Annual Meeting and in recent publications, its director for zero pollution and green cities, Veronica Manfredi, stressed that “there are no excuses, there can be no business as usual” given the urgency of the situation.

There can be “no excuses, no business as usual” from the consumer health industry when it comes to achieving the EU’s zero pollution ambitions.

This was the uncompromising message from the European Commission, whose director for zero pollution and green cities, Veronica Manfredi, addressed the 59th AESGP Annual Meeting in Paris, France.

The Commission wants the EU’s pharmaceuticals and cosmetics industries to “assume responsibility” for the 92% of toxic pollutants in wastewater they contribute, and to accept the “polluter pays” principle at the heart of proposed new rules.

AESGP Annual Meeting: Sustainability Optional Now, But Not For Long, Warns Haleon

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"We think that it is only fair that when turning a profit on these products, you also participate in shouldering the cost to reduce pollution that result from them for as long as toxic free alternatives are being searched for," insisted Manfredi.

According to the revision of the 1991 Urban Wastewater Treatment Directive (UWWTD), published last October, pharmaceutical producers will in future make financial contributions to wastewater treatment companies based on the polluting potential of any marketed drugs whose compounds end up in the water system via consumer use, disposal and excretion.

By David Ridley

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European consumer health companies today have the luxury of voluntarily setting sustainability goals. But with regulations looming and pressure from retailers and consumers mounting, such requirements will soon be mandatory, Haleon's Joe Muscat warned at the recent AESGP Annual Meeting in Paris, France. To ride the climate wave, while achieving their objectives, OTC firms need to work together, he explained.

Read the full article here

Funding For Green Innovation

To soften the blow, Manfredi outlined a number of incentives to help industry design products and adapt production processes to reduce the pollution from consumer use, disposal and excretion – the three main ways that pharmaceuticals end up in the environment.

As part of the EU's Horizon research and development program, the Commission is investing €40m ($43m) in projects expected to pave the way for pharmaceuticals that are less toxic by design, or manufactured via cleaner and more resource efficient process, Manfredi pointed out. The Commission is also investing €20m in driving EU health and personal care systems towards enhanced sustainability, as well as €300m in a public-private partnership called Transforming Health and Care Systems, also focused on sustainable solutions.

"From the EU side we are trying our very best to provide clear direction and effective support through both legislation and investments," Manfredi concluded. "However, we also would like to challenge you today to show us what your innovations can do to reduce harmful impacts."

Needs To Be Fair

Responding to Manfredi's challenge, Reckitt's head of regulatory policy, advocacy and intelligence, Julie McManus, said that the European consumer health industry is "fully committed to the objectives of the green deal agenda and zero pollution goals."

Speaking on behalf of the AESGP, McManus said she agreed with the principle of "extended producer responsibility," but stressed the importance of applying it in a "fair and effective

manner."

In a recent joint statement, however, AESGP, alongside generic and branded medicines associations Medicines for Europe and EFPIA, called for the exemption of medicines for human use from extended producer responsibility measures under the proposed revision to UWWTD, "in light of their essential role in public health." (Also see "*European Pharma Pushes Back Against 'Discriminatory' New EU Drug Pollution Proposals*" - Generics Bulletin, 9 Nov, 2022.)

"The Commission's proposal to charge medicines in the Urban Wastewater Treatment Directive will ultimately jeopardize patient access to medicines," the joint statement reads. "Blanket levies on medicinal products based on patient excretion levels are unprecedented, disproportionate, unfair, and ineffective. This measure will be very detrimental to society if increased burdens on companies mean that many essential medicines are no longer viable and result in shortages."

Risk-Benefit, Not Just Hazards

McManus expanded on the AESGP's position during her panel contribution, pointing to arguments put forward in the association's recently published *position paper* on the revision of UWWTD.

For example, the AESGP disputes the EC's definition of a micro-pollutant as a "substance including its breakdown products, that is usually present in the environment and urban wastewaters in concentrations below milligrams per liter and which can be considered hazardous to human health or the environment" based on criteria set out in EU Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures.

Specifically, it questions the use of only "hazard" in selecting substances as micro-pollutants, rather than augmenting this with "easily implemented risk-based rules, which will account for degree of hazard and exposure potential."

McManus used everyday examples to illustrate AESGP's position: "Each element, each chemical has inherent hazards," she pointed out. "Even water and oxygen have inherent hazards. If you drink too much, if you absorb too much oxygen, if you can't swim and you go in water – it is about mitigating the risks."

Take lightning, she continued. "If you are inside, and you also have electric charge absorbers even better, then you are protected. You've mitigated the risks. If you decide to stand under a tree when you're outside, then you've doubled your chances of getting hit. The lightning can hit the tree that can fall on you, or you can get hit directly. That was a bad decision. It's really about understanding the nature around you and mitigating risk."

Evidence Questioned

McManus also questioned the evidence behind the Commission's application of the "polluter pays" principle solely to the pharmaceutical and cosmetic industries. "You can generate lots of data but is it good data? That's what we want decisions to be based on."

In its position paper, AESGP argues that the Commission's impact assessment "fails to recognize several evidence-based studies led by independent organizations, academia, regulators, and the pharmaceutical industry, suggesting that only 10% of the active pharmaceutical ingredients (APIs) could pose a potential risk to the environment and that most medicines (more than 80%) indicated a low environmental risk."

Other sources of micro-pollutants such as metals, metal oxides, non-metals, forms of carbon, and other industrial chemicals (as registered under the EU's REACH legislation) from other industries that can also be found in many widely used consumer goods were also not addressed in the EC's assessment, it adds.

"We want the new legislation to be effective, right?" McManus continued. "To be effective actually means that when an investment is made at the treatment plants, they are addressing the micro-pollutants in the water that truly have an adverse effect on the environment."

"We need to be able to establish that there is an adverse effect, what is causing this and actually see results from this," she added. "It's so important to get it right."

Self-Care Jeopardized?

Finally, McManus pointed to the enormous contribution that the self-care industry already makes to the sustainability of European health care systems, which may be jeopardized by the EC's extended producer responsibility proposals.

As noted by the Global Self-Care Federation's Economic & Social Value of Self-Care report, the consumer health industry currently helps save individuals a total of 11bn hours per year and raises their productivity at work to the tune of 41bn extra days-worth of labor every year.

Expanding, rather than restricting, access to self-care products could increase this to 18bn hours saved and 72bn extra workdays by 2030, the GSCF argues. (Also see "*Self-Care Saving Taxpayers $120bn Per Year, Could Increase To $180bn By 2030*" - HBW Insight, 14 Jul, 2022.)

"We must maintain access to non-prescription medicines," McManus insisted, "because I don't think our healthcare systems can manage the additional referrals and appointments."

EC Digs In

Manfredi, however, was not impressed. "Are we in a mood of resistance?" she asked, pointing specifically to McManus's skepticism with regards to the EC's interpretation of "micro-

pollutants" and evidence for pharmaceutical and cosmetic industry responsibility.

"All the facts and the data that we have on water quality are well established, well known and are publicly available," Manfredi stated. "We have identified those substances that are causing the bigger challenges. They are polyfluoroalkyl substances (PFAS), they are pesticides, they are pharmaceuticals."

"We are basing this on data from member states and the water treatment sector. Clearly 92% of the overall toxic load comes from pharmaceuticals and cosmetics. This is not a finger pointing, this is a fact," she said.

However, this did not mean that these sectors would be the only ones that would contribute to the introduction of quaternary wastewater treatment – the stage of water purification that deals with parts per million to parts per billion levels of contamination.

The aim with the proposals is to establish a "minimum basis" for extended producer responsibility across the region, Manfredi explained. While the pollutants identified as coming from pharmaceuticals and cosmetics represents a "minimum common denominator," national authorities may also bring other sectors into the extended producer responsibility principle "if it is justified by their own data."

What matters at this stage, Manfredi said, is to "recognize this principle of assuming responsibility."

Sympathy, Up To A Point

Manfredi said she "sympathized enormously" with the pharmaceutical sector, being as it is at the center of a whole raft of legislative changes under the EU Green Deal.

"I do realize that the number of transformative changes that we are bringing forward is difficult to digest," she acknowledged. "But I also want to stress that you should not look at the European Commission, at member states, as wanting to knock you down and straitjacket you."

"The progressive, fair, and inclusive supportive approach is equally there all the time," she added. "However, it's true that we are saying we need to move and that there is not much time left to move, so there is this urgency mixed with support."

"I don't think that industry, and regulators – we can put everyone in the same basket – can say that we're doing enough or that enough has been done," Manfredi concluded. "Because there are no excuses, there can be no business as usual. That's the only point where we disagree."