

Sustainability—The Many Facets of Action

The Pharmaceutical and Biotech Industry Already Contributes Significantly to Reduce Its Environmental Footprint. Nevertheless, Even More Can Be Done.

Climate change, energy crisis, the call for a more environmentally compatible production method and socially responsible action do not stop at the pharmaceutical and biotech industries. Sustainability is becoming a central competitive and reputation factor and carries a high economic value. This need not be to the industry's disadvantage. It helps companies to make processes more efficient, reduces energy consumption and keeps costs in check. But is the pharmaceutical industry already doing enough in this regard?

It's just a small word, but simultaneously a big term: hard to grasp, a bit fuzzy, ambiguous, yet on everyone's lips and increasingly important: sustainability. Some call it a megatrend.

Sustainability is so elusive because it includes several dimensions such as fair trade, social commitment, prudent use of resources, natural ingredients, animal welfare, environmentally friendly packaging or regional production. Also, governance, compliance and integrity are an important part of sustainability. Last but not

least compliance issues such as product quality, transparency in collaboration with healthcare professionals as well as patients, and anti-corruption remain important.

As with nearly every industry, pharmaceutical and biotech companies cannot avoid dealing with the contents and implications of this term. The European Federation of Pharmaceutical Industries and Associations (EFPIA) admits that there are many risks associated in the whole life cycle of a medicinal product that

impact the environment negatively. Further understanding of these impacts and the interface between society, health and the environment is the key to guaranteeing that the pharmaceutical industry can form and execute actions.

For its part, the consulting firm PWC emphasizes the need to set the right priorities when it comes to sustainability. Even though many health-care companies have committed to stricter climate protection targets, the industries still emit significant amounts of greenhouse gases. Adjusting production and supply chains would not only benefit the environment, but also add value.

Importance of Social Criteria

In addition to environmental aspects, social criteria also play an important role, i.e., above all access to medicines for humans and animals for food security. According to PWC this topic is receiving a lot of atten-

tion, but there remains substantial untapped potential. Decision-makers need to develop a focus on the issues that fit their strategy, using all available levers—from research and development to pricing strategies and capacity building. The focus here in the future will be particularly on developing countries with immature agriculture and healthcare systems.

Digital Integrity

PWC also highlights the importance of digital aspects when it comes to sustainability: The industry is currently undergoing a transformation from traditional value chains to a patient-centric business model. Data plays a central role in this. For this model to be sustainable and for patients to trust companies, a high level of data protection must be ensured, argues the consulting company. High ethical standards and consistent implementation are therefore necessary to successfully shape the digitalization of pharmaceutical and life science companies.

What Pharma Is Already Doing

A closer look shows that the health-care industry is already making a lot of efforts in terms of sustainability. Although research driven pharmaceutical companies do not typically belong to high energy consuming companies, they are at the forefront of numerous ground-breaking initiatives to help reduce CO_2 emissions, according to EFPIA.

The German Association of Research-based Pharmaceutical Companies (Vfa) points out that pharmaceutical manufacturers are committed to the guiding principle of sustainability. Thanks to their "long-standing and international commitment to the environment," they are well positioned to meet the challenges of the future.

And Bengt Mattson, chair of the Interassociation Industry Pharmaceuticals in the Environment Task Force, says in a blog for EFPIA the





industry has already taken "strides forward in minimizing its emissions and driving environmental sustainability. Every stakeholder concerned must play its fair part and the industry has taken a leading role in this respect."

Target: CO₂-Neutral

In fact, many companies want to become CO2-neutral in the coming years, or at least significantly reduce their CO2 emissions. Roche has set itself the strategic goal of halving its environmental footprint between 2020 and 2029. On the way there, CO_2 emissions per employee are to be reduced globally by 40% by 2025. Boehringer Ingelheim aims to become climate-neutral in its operations by 2030. And Novartis wants to achieve CO₂ neutrality in its own operations by 2025 and complete CO_2 neutrality by 2030. Siegfried has set itself the goal to reduce its CO₂ footprint by 50% by 2030. In addition, the CDMO will introduce long-term activities conforming to the so-called net-zero target 2050 to limit global warming to 1.5 °C via the reduction of greenhouse gas emissions.

Moreover, industry experts emphasize that innovative technologies are key to their success in environmental sustainability. Such technologies enable high output in next-generation facilities with a smaller physical footprint, smaller carbon footprint, and less water usage.

Less Wastewater, Less Waste

In this context the German Vfa points out, that the consumption of energy and raw materials has already been declining significantly for years; less wastewater and waste are being produced, and greenhouse gas emissions are also falling. The industry is therefore not only meeting the increasing requirements of environmental legislation. In many cases, the companies are even going above and beyond the prescribed level to protect the environment, climate and natural resources.

This also applies to the European pharma and biotech scene. According to information from EFPIA, the members of the association take responsibility for reducing environmental risks from manufacturing emissions, through implementation of risk-based containment procedures in their manufacturing Effluent Man-

agement Programs. They also pursue extended producer responsibility (EPR) programs for waste pharmaceuticals and support the meds disposal campaign and other take-back schemes.

Beyond this, even small steps can have a big effect. Many companies offer bike-to-share stations to their employees, use green electricity from biomass power plants, build solar panels on its plant roofs, operate beehives on their premises, or offer only food that comes from the region in the plant cafeteria.

For Siegfried for example, sustainability has been one of the company's five core values since 2019. In 2021 the Swiss CDMO called into life the Corporate Sustainability Board, an interdisciplinary body that coordinates and pools its sustainability activities. These efforts are being recognized by external parties and independent institutions. In addition to certifications such as the ISS ESG Rating and the MSCI ESG Rating, Siegfried has also been included in the Dow Jones Sustainability Index Europe in 2021.

More Can Be Done

Nevertheless, more can be done. EFPIA believes, a cooperative approach with broader stakeholders to be the way that will allow to expand the common knowledge and comprehension of the industry on how to proactively handle any potential risks imposed by the existence of Pharmaceuticals in the Environment (PiE). Consequently, EFPIA along with AESGP and Medicines for Europe have established the Eco-Pharmaco-Stewardship (EPS) framework with the focus on PiE and is executed across the industry and with broader stakeholders in the healthcare and environmental sector.

As part of the pharmaceutical legislative review, the Commission will adopt legislation looking at strengthening the environmental risk assessment for medicines. Minimizing the impact of pharmaceuticals on the environment, the extended Environmental Risk Assessment (eERA) concept was proposed by the pharmaceutical industry to address the challenges and strengthen the Environmental Risk Assessment process in the EU.

As pointed out in a blog on the EF-PIA website, ERA should be reviewed and, if necessary, updated throughout a product's lifecycle to reflect the latest information on the medicine's potential impact on the environment, while avoiding duplications of submissions for off-patent drugs. However, the focus should be on the active pharmaceutical ingredients (APIs) entering the environment and not on each single product, as a single API can be used in multiple products. Regulatory, academic and industry resources and associated environmental mitigation strategies should be prioritized on those APIs that pose a potential risk to the environment.

German Supply Chain Act Heats Tempers

In parallel, the framework conditions are also being adjusted, for instance in Germany. The new Supply Chain Sourcing Obligations Act (LkSG), which came into force at the beginning of 2023, heated tempers in the run-up.

Supporters see the regulation primarily as a necessary instrument to push companies toward more sustainable practices; others argue that the legislation will not bring any noticeable changes in society. The LkSG focuses on the social aspects of sustainability, such as human rights, child labor, working conditions or fair pay, and only marginally addresses specific environmental issues.

Especially for highly regulated industries like the pharmaceutical industry, it can be assumed that they know better how to deal with administrative efforts, since topics like the traceability of each batch already have to be ensured today. Thus, it can be expected that the documentation processes are well established and can be applied or adapted. Riskbased assessments are also known and proven in the pharmaceutical industry from approvals, validations and qualifications.

Communication is Key

In addition to all active measures in sustainability, another aspect also plays an important role: communication. "Sustainability doesn't work without transparency," says Robert Paffen, Partner at PWC Germany. "The last decade has seen a steady increase in public demand for transparency for pharmaceutical and life science companies on their environmental, social and governance performance, including their contributions to the local economy." According to the proverb: Do good and talk about it.

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