



FOCUS



When it comes to the Environment, Where Does the Pharma Industry Stand?

(Source: An article by Michael Earl for Pharma Manufacturing/PMLiVE)

Industry is taking environmental commitments more seriously, particularly after pivotal events, such as COP26 and the publication of the IPCC’s cautionary “now or never” report.

Pharma has made impressive strides in recent years. To give an overview of sustainable action across the broader pharmaceutical industry, Owen Mumford Pharmaceutical Services reviewed the current state of play among the top 25 companies reporting environmental, social and corporate governance (ESG) scores. The review identifies areas where companies have set concrete targets, as well as areas where more action is needed. As healthcare organizations set increasingly ambitious targets, suppliers are following suit. The following areas are where pharmaceutical companies are setting clear targets, helping to provide a framework for action across the industry.

Energy. Streamlining energy use is particularly attractive from a commercial point of view, helping to reduce operating costs. Comprehensive energy policies in the pharma sector often combine the use of renewable energy sources with self-generation and the reduction of energy requirements needed during the manufacturing process, which tends to be energy-intensive (since energy is needed for most processes – including but not limited to heating, cooling, humidification and air drying.)

To make significant progress in energy use, manufacturers must take a holistic view of their operations to accurately assess the energy consumption of these energy-intensive systems. Introducing digital tools and artificial intelligence (AI) can lead to even higher savings when constant monitoring of manufacturing conditions is incorporated into processes. By leveraging AI-generated data, manufacturers can continually improve energy management in their facilities.

Water. The pharma industry is a major consumer of water. Beyond cleaning, water may be needed as an excipient for the reconstitution of products or during synthesis. Approximately 50% of pharma companies have already set hard targets when it comes to water consumption. For instance, since manufacturing

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In Brief...

♦ **McKesson Canada** has opened a new 175,000 sq. ft. distribution center in Edmonton, Canada. “This is the main distribution center for pretty much all of western Canada, and it’s an important step forward as we are building a bigger pharmaceutical and life sciences industry in Alberta,” said Premier *Jason Kenney*. McKesson distributes to pharmacies and hospitals throughout Canada.

♦ **Pfizer** announced its new vaccine to prevent respiratory syncytial virus (RSV) has shown efficacy in adults 60 years and older with two or more symptoms of related lower respiratory tract infections, as well as patients with three or more symptoms. This puts Pfizer’s vaccine candidate in solid competition with GSK’s *GSK3844766A*, which has also shown exceptional results in patients 60 years and older. Pfizer has asserted that its candidate will offer wider protection than its competitors, due to its combination of prefusion (preF) vital proteins against both the A and B strains of RSV.

♦ The **International Sustainability Standards Board (ISSB)** received more than 1,300 comment letters on its two proposed sustainability disclosure standards. It received more than 600 responses to its draft *Climate Disclosure standard* and another 700 responses to its draft *General Requirements Disclosure standard*. Preliminary review of the feedback confirms responses from jurisdictions spanning six continents from stakeholder groups including academics, accountancy bodies, and audit firms, as well as public interest bodies, regulators and standard-setters.

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Walgreens Takes on the Clinical Trials Business

(Source: An article by Hannah Esper for Drug Store News)

Walgreens announced a plan this past June to launch its own clinical trials business with the overarching goal to redefine the patient experience, as well as increase patient access and retention in drug development research while tackling the challenge of diversity.

Ramita Tandon has assumed the role of chief clinical trials officer for Walgreens. She has been building and leading high-performing clinical trial businesses and teams at companies such as Trip Health and ICON. Through her 25-year career in healthcare, she has remained focused on finding innovative ways to partner with biopharmaceutical companies and amplify the patient voice so that trials operate more effectively.

Currently, clinical trials do not reflect the American population. Twenty percent of drugs have a variation in responses across ethnic groups, yet 75% of clinical trial participants are white, and only 11% are Hispanic and fewer than 10% are Black

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Environment (cont.)...

plants use different grades of water quality, purified water can be recovered and reused for another purpose where lesser quality is acceptable.

Multiple strategies can be employed to achieve 100% water “neutrality”, meaning the quantity of water “harvested” will be equal to fresh water consumption. One strategy is to “reduce, reuse and recycle” which results in less water consumption. Another strategy involves the capture of rainwater to be reused, resulting in further minimal external water use. Companies can also offset fresh water consumption by investing in projects for sustainable water management outside their own facilities.

Waste. While 28% of pharma companies have set targets to reduce their waste emissions by at least 25%, their approaches can differ. Some companies try to avoid landfill use, while others pursue a zero-waste strategy. There is a commercial incentive for waste reduction. In the U.K., it is estimated that companies typically spend 4-5% of turnover on waste – not only due to disposal, but also through inefficient use of raw materials, unnecessary use of energy and water, or waste treatment. This figure can be as high as 10%. This can include medicines that do not get used before expiration dates due to overproduction, or incorrect disposal of solvents. Solvents make up a significant share of waste from the chemical industry, and companies may not be doing enough to improve disposal efficiency. Other measures to sustainably dispose of waste while reducing cost include separating pharmaceutical solids from packaging, so that non-hazardous materials can be recycled or diverted into general waste, or reselling waste products that have intrinsic value elsewhere.

Emissions. It is estimated that the pharmaceutical industry directly generates about 52 megatonnes of CO₂ equivalent per year – 55% higher than emissions from the auto industry, according to one study. This excludes indirect energy-related emissions in the entire supply chain during transportation or distribution. Almost 70% of pharma companies have set specific targets around air emissions. It is critical that companies take a holistic view of processes to reduce overall emissions.

In addition to carbon emissions, pharma companies are also assessing the release of gaseous pollutants, such as acid gases, basic gases, dust and aerosols, pharmaceutical ‘actives’ and volatile organic compounds.

While companies are taking positive steps to reduce their carbon footprint, bigger steps are needed to make bigger improvements, including reduction in pharmaceutical pollution in water supplies. Another area lacking is the streamlining of packaging. The overall view of sustainability progress is positive, but action in the field must be ongoing. Seventy-six percent of all pharma companies have policy on packaging but this is not translating into definitive action. It may be the industry has yet to reassess criteria to include environmental considerations.

The biggest differentiator between top companies and those just starting the environmental journey appears to be willingness to take on the challenge, rather than budget or location. A next step for the industry is to narrow the gap and achieve greater consistency. Standardization across the industry will help facilitate this. One way of addressing this is ESG certifications currently under development by organizations such as ISSB, SASB/ VRF, GRI, EcoVadis and others.

Walgreens (cont.)...

and Asian, according to the U.S. Food and Drug Administration.

During an interview with Drug Store News, Tandon emphasized her belief that everyone should be educated, empowered, and provided the opportunity to access innovative and cutting-edge therapies that improve their health. However, today’s current clinical trial infrastructure and patient demographics are in crisis. Her mission at Walgreens is to redefine the patient experience by making participation in these trials more accessible, convenient, and equitable for the diverse communities that Walgreens and these clinical trials serve.

Tandon embraces the fact that clinical trials are not only a research path, but a way to get patients in underserved communities into the overall healthcare system. To achieve that goal, Walgreens has created the ideal blend of technology, personal connection and flexible care capabilities required to transform clinical trial delivery, with patient security and privacy at the forefront. With more than half of Walgreens stores located in socially vulnerable areas, she acknowledges Walgreens’ intrinsic responsibility to address clinical trial disparities in these communities.

Tandon believes that Walgreens’ new clinical trial offering could forge the missing bond between public and clinical research needed to inspire trust and improve patient outcomes. Given the presence Walgreens has across the nation and combined with their enterprise-wide data and health solutions, Tandon hopes to unlock a combination of in-person, virtual and hybrid clinical trial models at scale to meet patients wherever they are located. This will in turn boost patient enrollment, engagement and retention needed for these clinical trials to be successful and effective.

Also the journey isn’t complete for Walgreens simply because a trial has ended. Tandon’s goals are to take trial participants, even after they’ve finished their obligations to a clinical trial and continue their care coordination as part of Walgreens’ commitment for “last-mile” enablement for the patient.

In Brief (cont.)...

- ◆ A new state-supported program aims to provide funding for R&D programs at Japanese bioventures. Eight venture capitalists will fund one-third of the total, and the Japanese government will provide the remaining funding. Japan opened applications from domestic bioventure companies under a national funding program with a total budget of US\$366 million. The initiative, supported by the **Strategic Center of Biomedical Advanced Research & Development for Preparedness and Response** will assist in the R&D and commercialization of projects that contribute to new vaccines/therapeutics for infectious diseases.

- ◆ **Moderna** took the next step in the development of COVID-19 vaccines with the approval of its bivalent vaccine that can produce a broader immune response to SARS-CoV-2 variants. The U.K.’s **Medicines and Healthcare Products Regulatory Agency (MHRA)** has granted a conditional authorization to *SpikeVax Bivalent Original/Omicron* for use as a booster dose in individuals 18 years or older. In each dose, 50% of the vaccine targets the original virus strain from 2020 and the other 50% targets Omicron. The U.S. FDA has approved use of the new Moderna booster along with Pfizer’s bivalent booster.

(Sources: Drug Store News, FiercePharma, Scrip Intelligence and World Pharma News)