Forum: World Health Assembly

Issue: Measures to industrialise and integrate generic drugs for critical diseases through sustainable development

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Introduction

The pharmaceutical market is one the largest industries worldwide. In 2017, its estimated revenue across the world was 1143 billion US dollars. In recent years, this number has grown even larger. It is not a shock that this industry continues to thrive, considering that the largest driver of the industry's profit- pharmaceutical consumption- has also increased significantly. Between 2000 and 2015, the use of cholesterol reducing drugs increased by 400% and the use of antihypertensive drugs and diabetes medication each doubled, to give a few examples. One of the reasons for a larger frequency of critical diseases and other health issues becoming more prevalent is the continuing growth of an ageing population worldwide. Whilst there is no doubt that the profit provides long-lasting benefits economically, the environmental aspect of sustainability must be considered when discussing the industry's future with generic drugs.

A generic drug is a prescription medication that shares the same chemical components as a medication that was first covered by a chemical patent. Following the expiration of the patents on the original medications, generic medications may be sold. Generic drugs are often preferred over brand name drugs due to affordability. With the rise in ailments, the access to generic drugs, especially ones that do not require prescriptions (like over-the-counter drugs), has increased drug consumption notably.

The production, use and disposal of pharmaceutical products has significant impacts on the environment. Water system pollution, where drugs are discharged into the environment and end up in aquatic systems like lakes, oceans, rivers, and groundwater, is a prime example. The pollution produced as a result of pharmaceutical manufacturing has many consequences, such as aquatic ecosystem disruption, loss of biodiversity, antibiotic resistance and contamination of clean water sources. Whilst a handful of countries (such as Germany and Sweden) have recognized and began to work towards a more sustainable approach to the industrialization and integration of the production, use and disposal of drugs, many countries stances' remain neutral.

Definition of key terms

Generic drugs

A medication produced to be the same as a pre-existing brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Brand name drugs

A brand-name drug is a patented medicine originally discovered and developed by a pharmaceutical company.

Sustainability

Development that meets the needs of the present without compromising the ability of future generations to meet their own needs. Can refer to environmental, social or economical factors.

Patent

A type of intellectual property that gives the owner full rights over an invention

FDA

The United States Food and Drug Administration is a federal agency that ensures the safety and efficacy of products such as foods, medicines, cosmetics, etc in the US

Key issues

The pharmaceutical industry is a large contributor to pollution regarding the production, use and disposal of its products. Chemicals from pharmaceuticals can end up in the environment and cause adverse effects in many ways. Pharmaceutical manufacturing facilities frequently fail to filter out all of the chemicals used in the process of manufacturing drugs, which causes the chemicals to leak into nearby freshwater systems before finally reaching the sea, lakes, streams, and rivers. As a result of this, Many sources of water contain trace amounts of ingredients from medical products, such as birth control pills, antidepressants, painkillers, shampoos, antiepileptics and caffeine. Pharmaceutical factories are not the only way that these foreign chemicals end up in waterways, and can even find their way into water sources after being excreted from the body, seeing as only a small portion of the medications we consume get metabolised by our systems. The remainder can be expelled through sweat, but the majority is eliminated from the body by urine or faeces, which means the chemicals will eventually end up in the wastewater and the environment. Some medications can also be administered to the

skin as creams or lotions, and the medication's unabsorbed components will wash off the skin and end up in the environment.

A second effect of water pollution is the disruption of aquatic ecosystems. The chemicals found in pharmaceutical products impact the lives of aquatic organisms and can even reduce their populations significantly- a study has found that the fish population has depleted in a lake with high concentrations of contamination from birth control pills. Another impact is the increased chance of antibiotic resistance. Antimicrobial resistance, along with cases like multidrug resistance, has been attributed for years to careless antibiotic usage in both human medicine and agriculture. However, there is mounting evidence that illness can also be brought on by the pollution associated with medication production, as concluded by investigations conducted in 2016 and 2017 that examined the pollution caused by the manufacture of antibiotics in China and India.

An issue regarding the integration of generic drugs for critical diseases is the widespread mistrust of generic drugs compared to brand name drugs. FDA-approved generic medications function in the same way as brand-name medications and have the same clinical benefits and risks. A generic drug must be identical to a brand-name drug in terms of dose, safety, efficacy, strength, stability,

and quality, as well as in how it should be administered. The dangers and advantages of generic medications are identical to those of their brand-name equivalents. FDA employees keep a close eye on approved brand-name and generic medication goods to ensure that all components of the supply chain, including the active pharmaceutical ingredients, are safe. So, one would assume that generic drugs would be valued in the same way as brand name drugs in the eyes of patients. However, in a study conducted in 2007, when survey participants were asked if they “would rather take generics than branded medications", only 36.7% agreed, and 29.9% of survey takers stated that they agree with the statement: “branded drugs are more effective than generics". This image of generic drugs in the public’s eyes is an issue when it comes to integrating them for the treatment of smaller ailments, let alone critical diseases.

Major parties involved and their views

The EU

The EU Priority Substances Directive from the previous year emphasises the necessity of addressing the potentially dangerous effects of medications (3). The preamble to the legislation indicates that "the contamination of water and soil with pharmaceutical residues is an emerging environmental concern." The regulation states that the Commission should, by September 2017, propose measures on the

potential environmental effect of medicines after undertaking a research on the environmental hazards of medicines and developing a plan to address water contamination by pharmaceuticals. But because these actions would only be taken "where appropriate," they could only be taken at the national level. However, according to some analysts, the legislation's language is so ambiguous that the Commission can decide not to take any legislative action.

Germany

Germany recognizes that the pharmaceutical industry's practices are not sustainable and is currently conducting research into the environmental impacts of the production, use and disposal of drugs. Germany has conducted a large portion of the most recent studies in Europe on the risks that various medications, especially APIs, pose to the environment. The German Environment Ministry (BUMB) has encouraged the country's environment agency (UBA) to research or support studies on topics such the contamination of soil and sludge by medicines through emissions from manufacturing processes, sewage, and waste-water treatment facilities.

Sweden

Sweden has taken action within the nation to reduce the ecological footprint of the industrialization of drugs. For instance, the Swedish government has set goals for a toxin-free environment by the year 2020. According to Jerker Forssel, deputy head of the chemicals division of Sweden's environment ministry, "Concentrations of non-naturally occurring substances will be close to zero and their impacts on human health and on ecosystems will be negligible… The pharmaceutical authorities should be in a better position to make a first scientific estimation of risks, particularly with regard to degradability, bioaccumulation and long-term environmental effects." Forssel made this statement at a conference in Geneva. Sweden is now hopeful that regulatory actions will be made at the EU, particularly so that hazards may be addressed as much as feasible at source.

Barbados

The Prime Minister of Barbados has previously spoken out about the effect of pharmaceutical waste on the environment. In a recent UN Environment Assembly in Nairobi in 2022, the Prime Minister stated “The connections between antimicrobial resistance, environmental health and the climate crisis are becoming increasingly stark…We must act now to protect the environment, and people everywhere, from the damaging effects of antimicrobial pollution.”.

Kenya

In 2022, Kenya hosted a UN Assembly regarding the impact of antibiotic drug waste on the environment held in Nairobi. In the conference, action like developing and implementing regulations, standard operating procedures, better control and supervision over the pharmaceutical industry, etc was discussed.

Previous attempts to solve the issue

The issue of sustainability in the pharmaceutical industry has been a concern in the market for several decades, although few have compromised profit for sustainability. Some pharmaceutical companies themselves have attempted to make their ecological footprint lighter:

Novo Nordisk is an outstanding example of how medications may be produced in a sustainable manner. This Swedish giant has created a framework whereby its diabetes products, like injection pens and medications, are made with sustainable materials, with no production waste, and with post-use recycling and repurposing in mind. These products are also made to last the entire expected lifetime of the product. AstraZeneca, a UK-Swedish pharmaceutical company, is one of the few in this field to make significant investments in reducing emissions while prioritizing fair healthcare access, environmental preservation, and open, ethical business

practices in its sustainability program. The international group CDP has given it a double-A certification for its environmental responsibilities for four straight years. With an expenditure of $1 billion, the Ambition Zero Carbon program seeks to forward the date of zero carbon emissions by ten years.

With a current level of 73%, not far off from its 2025 objective of 90%, Sanofi, a French pharmaceutical company, has achieved a significant milestone in its effort to recycle, reuse, or recover the waste produced during drug development. Compared to 2005 levels, the Japanese business Takeda has reduced carbon emissions by more than a third. By eliminating all greenhouse gas emissions from its factories by 2040 and assisting suppliers in doing the same, it hopes to become carbon neutral. Bayer's current primary focus is on environmentally friendly packaging. By 2050, this corporation aims to have zero greenhouse gas emissions. By the end of the current decade, all over-the-counter medicines from its consumer health division will be packaged in green materials in an effort to cut carbon emissions. This entails spending 100 million euros, or 2% of this division's sales. For its brand packaging, it has a more ambitious goal of using solely sustainably produced paper and at least 50% recycled material by 2050.

Timeline of relevant events

1962- FDA authority given, manufacturers now required to prove that generic drugs are safe and as effective as brand name alternatives

1966- The National Academy of Science (NAS) starts to classify all drugs approved prior to FDA authority as effective, ineffective of needing further study in order to ensure the safety of generic drugs

1992- The Generic Drug Enforcement Act requires manufacturers to provide more detailed information regarding the bioequivalence of generic drugs

2007- Percentage of prescriptions filled with generic drugs rises to 63% in the United States

Possible solutions

Preventing pharmaceutical contamination at its source- stopping the contaminants from entering water sources- is the simplest, most affordable, and most efficient course of action. Public education about how to properly dispose of narcotics should be funded. People would then understand how to dispose of unwanted or expired medication safely and without adding to pharmaceutical pollution.

Initiatives to reduce the existing negative environmental consequences of medications can be developed as a result of increased awareness.

Another possible solution is that restrictions and legislation could be implemented. In hospitals, nursing homes, and other healthcare facilities, widespread medication flushing might be lessened if stricter controls were in place. The health department of a country or state, or a national organisation that deals with health issues, might enact stricter rules. The institutions would make sure that they could return the pharmaceuticals if they were out-of-date and would forbid themselves from disposing of the medications without following the correct procedures. Restrictions and rules are likely to be put into place if more research backed up the negative impacts of pharmaceuticals on the environment- If a serious long-term danger to public health or the ecosystem is detected, more active steps can be made to control the condition as needed. To evaluate the possible impacts of pharmaceutical pollution on people, more study is urgently needed. It will also cover the most effective ways to remove the chemicals at treatment facilities in a way that is safe for humans and the environment as a whole.

Limiting bulk purchasing of medication is another option. The majority of people buy them in large quantities since doing so results in discounts that lower the price

per unit. But it results in a situation where there are big bottles of unopened medications that are ultimately disposed of improperly, ending up in the environment. By restricting bulk purchasing, less pharmaceutical pollution will result from only the necessary quantity being delivered.

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