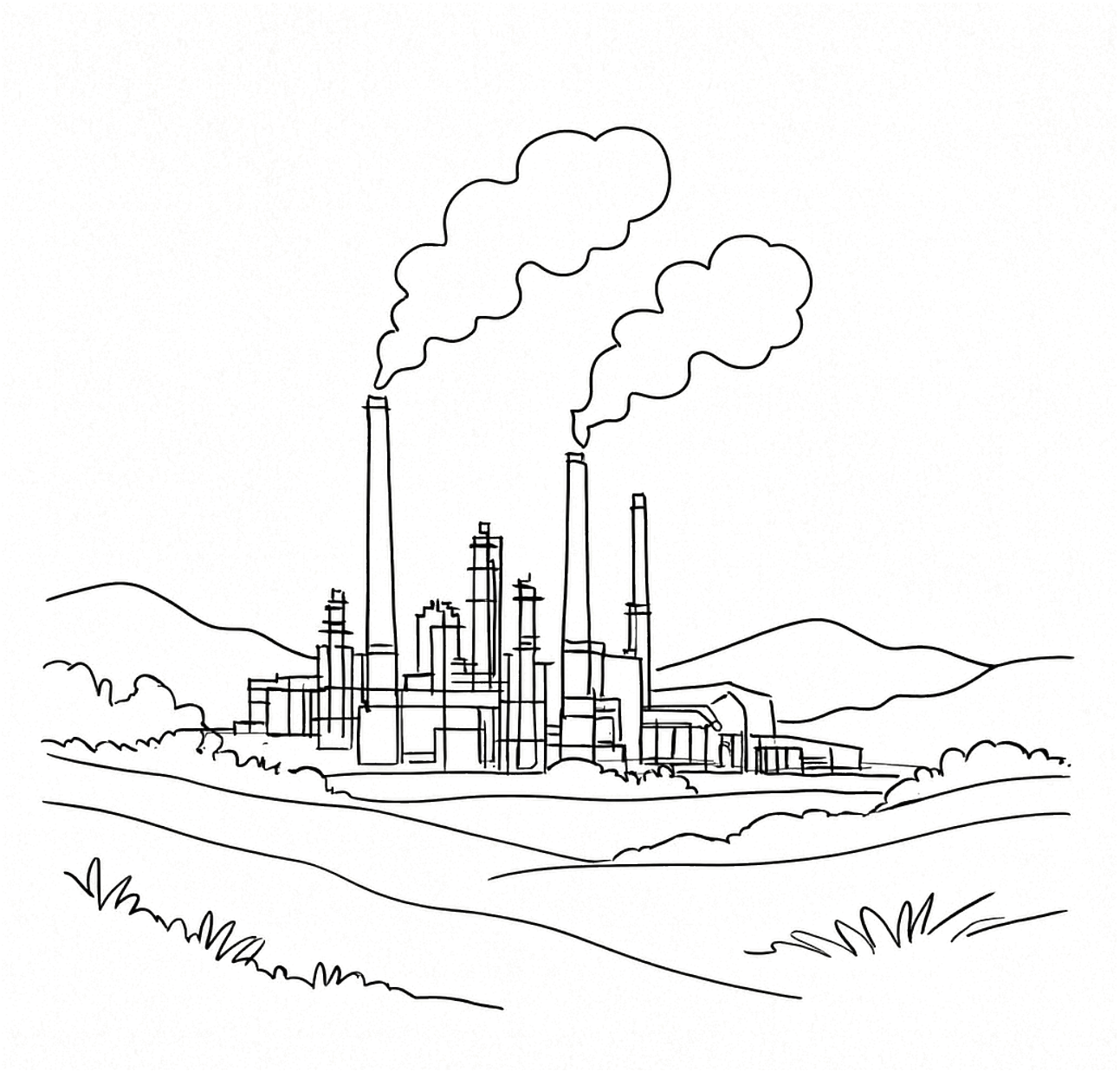
DECARBONIZING PHARMA

A CLIMATE-CONSCIOUS APPROACH TO PANDEMIC PREPAREDNESS



SALUD por DERECHO
Right to health foundation

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1 · CLIMATE CHANGE AND PANDEMIC PREVENTION

The relationship between human activity and the emergence, re-emergence and establishment of infectious diseases is widely studied. Land use, livestock patterns, chemical pollution, biodiversity decline, and climate change influence the way pathogens, vectors and hosts interact, altering transmission dynamics and ultimately increasing pandemic risk. It has been estimated that almost 6 out of 10 known human infectious diseases have worsened due to climate change (1-4).

This relationship between human, animal and environmental health must be considered, in order to ensure an appropriate pandemic preparedness and response. One Health approaches1 take into account these dependencies, highlighting the need for multisectoral coordination mechanisms (1), to facilitate the understanding of disease emergence and spread, as well as policy development and implementation processes (2).

BOX 1 · Examples of the connection between anthropogenic activities and outbreaks of infectious diseases with epidemic potential.

- Rodent-borne diseases: The 1990s hantavirus outbreak in the U.S. was linked to a 10-fold increase in deer mouse populations, driven by short-term climate fluctuations that boosted food supply and reduced predators.
- Wildlife migration and disease spillover: Over the past 100 years, climate change has pushed black flying foxes in Australia 100 km south, contributing to Hendra virus outbreaks in horses and subsequent human infections.
- Vector-borne diseases on the rise: Mosquitoes, ticks, and fleas, which transmit malaria, dengue, West Nile virus, and Lyme disease, are highly sensitive to changing rainfall, temperature, and extreme weather events(3).

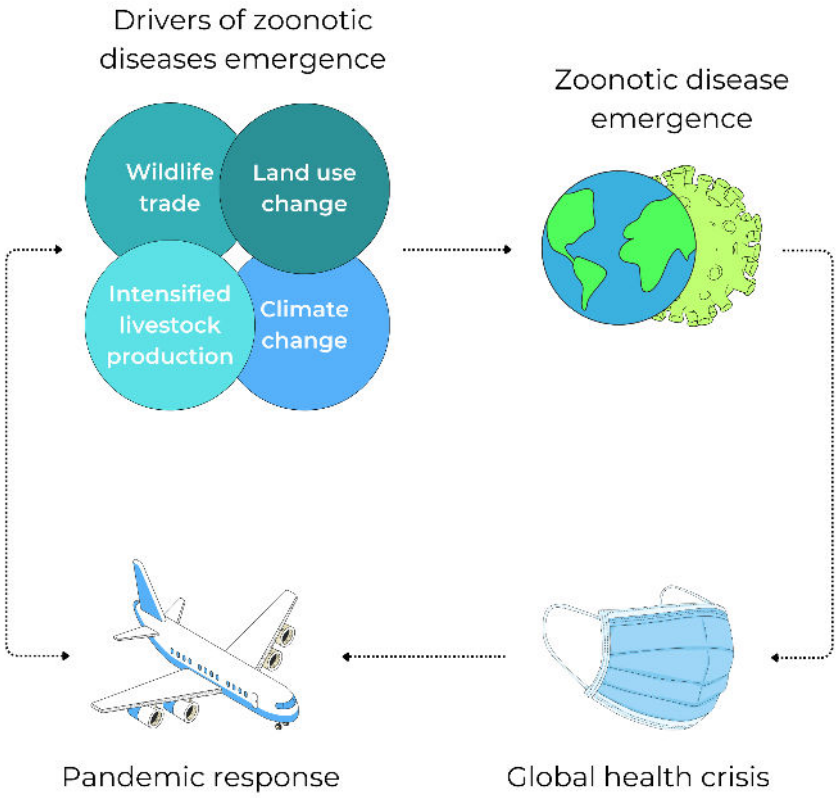
The environmental health aspect of One Health has gained more attention in recent years due to the increasing evidence of climate change's direct effect on human health (4,5). However, the impact of pharmaceutical research, development and production activities as a pandemic threat multiplier remains neglected (6). For instance, whereas the negotiations of the pandemic treaty have addressed the need to ensure a One Health approach, the text does not address the environmental impact of the pandemic preparedness and response cycle.

In addition to the policy focus in the last few decades to make pharmaceutical affordable and accessible pharmaceutical products that meet global health needs, we must now add decarbonization and nature positivity2 (7) as new objectives. (8).

In the case of pandemics and infectious disease outbreaks, mitigating the environmental footprint of the pharmaceutical industry is necessary for three reasons. Firstly, it ensures the sustainability of pharmaceutical supply chains, making it less exposed to extreme weather events. Secondly, mitigation efforts reduce the impact of climate change on the emergence of new zoonosis. And thirdly, pandemics increase the environmental impact of the industry, as supply chains stretch to meet demand. By increasing mitigation efforts, we collectively break a cycle of increased pandemic risk driven by the increased environmental impact of pandemic response.

This document aims to summarize some of the evidence available on the environmental impact of pharmaceutical research, development and production activities, in the context of current efforts to improve global pandemic preparedness and response. Section two summarizes the evidence found on the environmental burden of the pharmaceutical sector. Section three gives an account of the environmental impact of three groups of medical countermeasures during COVID-19: vaccines, monoclonal antibodies and medicinal oxygen, diagnostics and personal protective equipment. Finally, section four provides some next steps and areas for future advocacy.

Figure 1 · Cycle of zoonotic disease emergence and its link to Global Health crises



Based on Lawler, Odette K., et al. The Lancet Planetary Health, 2021.

2 · THE ENVIRONMENTAL BURDEN OF THE PHARMACEUTICAL SECTOR

As a major industry, the production, distribution and disposal of health technologies contribute to climate change, biodiversity loss and pollution (9). Compared to the automotive industry, pharmaceutical industry's emission intensity of CO2 is 55% higher (10). Depending on the country, the medical supply chain can account from one third up to 70% of total health sector emissions (4,11), overall contributing to 5% of global carbon emissions (12). Besides Greenhouse gasses (GHG) emissions, one of the most important effects on the environment is the production of hazardous waste, single-use plastic and pollution of water (7,13).

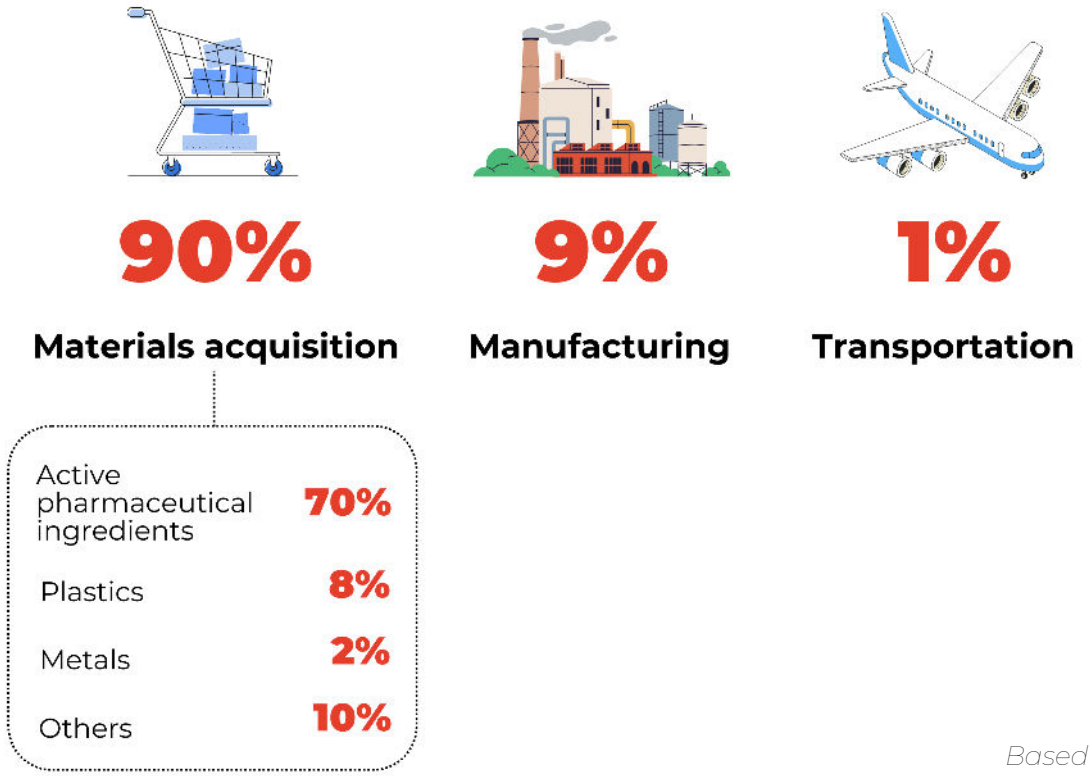
It is estimated that the sector would need to reduce its emissions intensity from 2015 by 60% to comply with the Paris Agreement (10). However, emissions are expected to increase over 25% between 2022 and 2026 (14), and the vast majority of publicly traded companies in the sector still do not have sustainability targets aligned with the 1.5°C world commitment. And those with climate objectives are not making enough progress (15).

Upstream processes (e.g., procurement of materials, pre-processing and manufacturing of active pharmaceutical ingredients (APIs)) concentrate the environmental impact (7) (16). Solvent use during API manufacturing, synthesis and waste disposal is responsible of 80% of emissions(17). Additionally, R&D laboratories in the biopharmaceutical system are estimated to consume five to one hundred times more energy than a regular office building (18). Waste production, such as solvents, toxic chemicals or antibiotics, pollute the environment, and contribute to antimicrobial resistance.

Downstream activities, such as manufacturing of finished pharmaceutical products, waste treatment, and to a lesser extent, transportation, are also key contributors (19). Transportation contributions will depend on whether logistic chains involve road, sea or air transportation. Replacing all marine transportation with air freight, would entail a 17-fold increase in the total transportation emissions for the studied products in the literature (7).

Emissions not related to the manufacturing and transport of health products (corporate emissions such as R&D, administration, marketing, regulatory), were estimated higher than those of API production and medicine manufacturing (16). Finally, medicine use contributes to the global problem of microplastic waste, that ends up in trophic chains (7,20,21).

Figure 2 · Greenhouse gas emissions across the pharmaceutical supply chain



Based on (7)

PHARMA OPACITY STRIKES BACK. CHALLENGES ASSESSING EMISSIONS AND IMPLEMENTING MITIGATION POLICIES

Estimating GHG emissions of the pharmaceutical production process is a challenging task, given that these processes frequently remain as trade secrets, protected by intellectual property rights (7). Trade secrecy allows companies to protect data related to the production of products that are hard to reverse-engineer, such as complex molecules and biologics, characteristics, growth conditions and purification processes of vectors and cell lines used (22). As this data is kept secret, so does the relevant information on waste production, GHG emissions, etc. leaving society relying on voluntary sharing of this data by companies. As this voluntary sharing of data is limited for upstream emissions(16,19,23), the lack of transparency makes it difficult to properly assess and hold corporations accountable for their contribution to climate change.

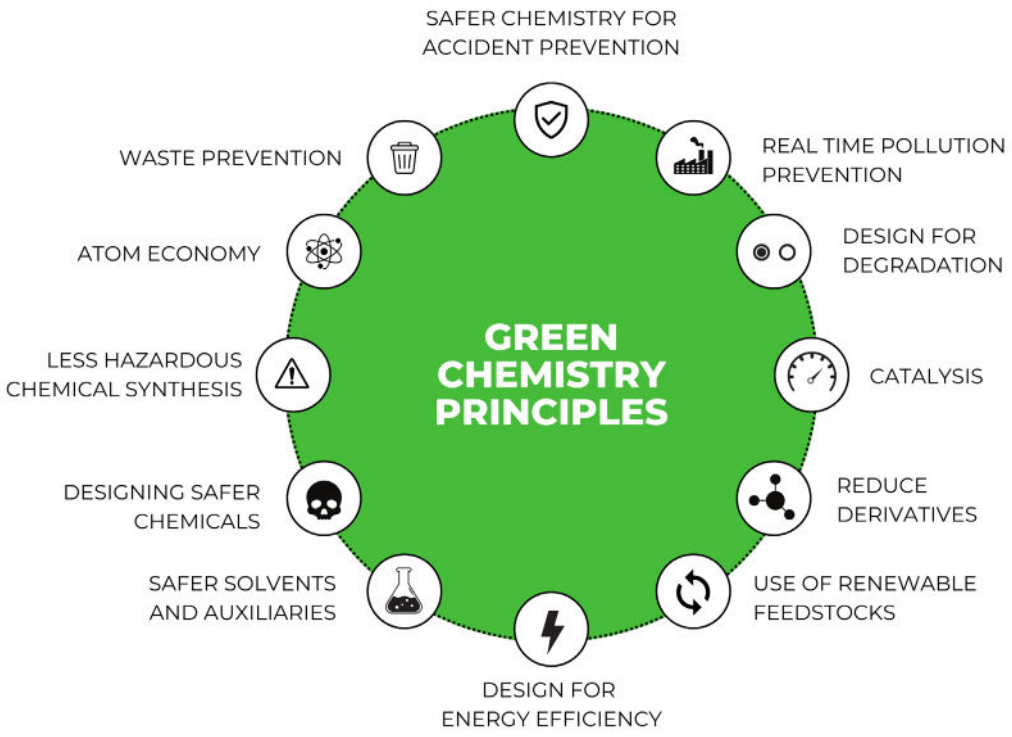
There have been recent calls to establish mandatory reporting of emissions in the health sector (24). At EU Level, the Corporate Sustainability Reporting Directive was approved in 2023. This Directive makes mandatory to report scope 3 GHG emissions (i.e., emissions that are not produced by the company but that are indirectly part of its value chain) for all large and listed companies (25). This is particularly relevant as these account for 80% of pharmaceutical companies emissions (26).

Different estimates suggest that 35% to 40% of pharmaceutical production emissions can be reduced without increasing costs (7,17). Measures may include efficient use of renewable energy, increased solvent waste recovery, continuous manufacturing, adoption of green solvents, introduction of recycled PET, or the adoption of green chemistry principles (7,17,27).

The pharmaceutical industry claims that incorporating these measures would increase the cost to develop and manufacture a drug (28). However, if the cost of the green transition and waste management is to be built into the drug prices, then much greater transparency will be needed to understand how these and other factors contribute to the final net price of the medicine (29). Furthermore, the cost of pollution and waste management is already being paid by the public, through waste management processes, and through the consequences of climate change, particularly in low-income countries, which are more exposed to its effects (30,31).

Minimizing pharmaceutical waste is also critical. Rational use of drugs, medical devices and health technologies in general is essential. On the industrial and regulatory side, how to extend product stability is also a relevant mechanism. Increase heat-stability studies for vaccines --and the public disclosure of the results— can allow the use of existence vaccines in controlled temperature chain (CTC) (32). Likewise, studies to extend shelf life of pharmaceutical products, have shown that shelf life for a significant number of pharmaceuticals can be extended beyond the expiration date (33–35). Conducting long-term stability studies in order to extend expiry dates is a measure that regulators could use to reduce healthcare costs, mitigate shortages, reduce environmental impact and drug disposal(34) and reducing manufacturing volumes.

Figure 3 · Principles of green chemistry



Based on Anastas, P. T. and Warner, J. C. Green Chemistry: Theory and Practice. , 1998

3 · WHEN A PANDEMIC HITS, THE PRESSURE ON THE ENVIRONMENT INCREASES

Adding decarbonization and nature positivity3 (7) as a public health objective (8) is essential, in addition to the policy focus on making pharmaceuticals affordable and accessible. In the case of pandemics and infectious disease outbreaks, these objectives also help breaking the vicious cycle in which climate change increases the risk of an outbreak, and outbreak response increase the sector's contributions to climate change.

During COVID-19, total imports and exports of medical goods grew 14% between 2019 and 2021 (36) and global exports of personal protective equipment in 2020 increased by 44% (36). Unpredictable demand of medical goods aggravated waste management pressure (37). Downstream carbon footprint increased as well during COVID, particularly the carbon footprint per admission at hospital level (38). In the same line, it was suggested that there is positive relationship between CO2 emissions and daily vaccination rates, as reported in the EU region, partly due to increase emissions of the pharmaceutical supply chains (39).

The environmental footprint of specific medical countermeasures will depend however on the specificities of each technology. The next section explores the footprint of vaccines, monoclonal antibodies and diagnostics.

VACCINES

Regional manufacturing is not only an opportunity to increase autonomy, resilience, and potentially more affordable and accessible health products, but a mitigation measure (7), since haul distance was the main driver of supply chain energy consumption (40).

Emergency transport of 7,8 billion vaccine doses was estimated to require 8000 Boeing 747 flights (41), and transporting of mRNA vaccines accounted for up to 99% of the total carbon footprint during the pandemic response (42).

Cold chain requirements is a well-described obstacle to expand vaccine coverage and access (43), but also pose environmental challenges, such as carbon emissions, and waste associated with complex storage conditions (44). Cold supply chain requirements such as need for dry ice and hydrofluorocarbon (HFC) gasses are determinants of carbon footprints (40,42) (45). Cold storage of more thermostable vaccines such as Oxford University's vaccine has 35 times less environmental impact than BioNTech vaccine (46). The use of an oral thermostable COVID-19 vaccine under development would have been the equivalent to eliminate more than 17.000 cars off the streets in the US alone.

Routine vaccine supply chains contribute greatly to carbon emissions. The largest drivers of UNICEF's emissions come from vaccine supply chain (47). Improved recycling of packaging, glass vials, and measures to improve energy efficiency and process optimization can achieve a 15% emission reduction in the vaccine lifecycle (47).

Production of vaccines for influenza, mpox, Ebola and yellow fever relies on fertilized chicken eggs (48) (49), which have a large environmental footprint. Producing four eggs equates to 1kg of CO2, and vaccine manufacturing facilities process approximately 600.000 eggs per day (50). Raw production materials including eggs, account for 65% of estimated CO2 emissions of a regular vaccine value chain(47).

As an alternative, in cell-based vaccine production processes, one thousand-liter bioreactors could substitute the production of 31.000 eggs (50). However, because companies producing these vaccines have already invested in egg-based production facilities, they are not incentivized to move away from it (51), despite cell-based vaccines being considered more flexible and faster alternatives during pandemics(52).

MONOCLONAL ANTIBODIES

Monoclonal antibodies (mAbs) offer a number of advantages in the context of outbreaks (53). Unlike vaccines, which require weeks to trigger an immune response, mAbs provide immediate protection. They can be rapidly generated from recovered individuals and once the target antigen is identified, their production can be completed within a few months (54,55).

However, its development and production is more resource-intensive (56), given the high consumption of water. The environmental footprint of producing a mAb using single-use technology is equivalent to the emissions of five cars per year (17,57), with electricity used in the cleanroom being the main contributor, followed by the impact of single-use technology.

The use of single-use bioreactors during the upstream processing of mAbs allows for a fast production pace, which is recommended during pandemics (55), and is also linked to greater sustainability, especially in areas where water is scarce (58). The introduction of new production methods, (i.e., continuous processing and process intensification), are promising to reduce environmental impact. Process intensification allows for increased cell culture titer, which translates into higher yielding processes and therefore reductions in the environmental impact (57). Continuous bioprocessing is a faster, cheaper way to develop better quality finished mAbs (59), which can also lead to significant reductions of the carbon footprint (60), making it a good option both for pandemic response and diversified local production in lower-income settings.

Addressing end-of-life (i.e., recycling) of single use materials, is challenging. Some evidence points that recycled materials present the same properties as new ones (61), but existing processes (58), are not widely implemented. Reasons for that is that the combination of materials used do not allow for easy separation and recycling (58). This is particularly worrying, as 30.000 tons per year of pharmaceutical single-use technology is burned or landfilled (58).

Another obstacle is that single-use plastics such as bioreactors are protected by intellectual property, and therefore the conditions of use may prohibit the necessary steps for recycling (or up/downcycling) them (62,63).

DIAGNOSTICS AND PERSONAL PROTECTIVE EQUIPMENT (PPE)

Access to diagnostics (including rapid diagnostic tests) is an important and neglected aspect of PPR (64–66), with a clear environmental footprint. Between March 2020 and November 2021, more than 140 million COVID-19 test kits procured through the UN supply system could have generated as much as 2,600 tons of plastic waste (67). This has been the case with other public health emergencies, and decentralized testing via RDTs aggravates the waste issue (30).

Different COVID-19 tests were reported to contribute differently to direct emissions, with the lowest CO2 eq per test found for self-testing RDT and the largest amount for single-well PCR (68). While the manufacturing emissions were stable across different tests, factors such as consumables, or the need for human resources or PPE, increased the carbon footprint. Furthermore, PCR test cartridges create hazardous emissions due to its content in guanidine thiocyanate (69). When diagnostics are incinerated at low temperatures, a toxic mix of furans, dioxins and particulate matter is emitted (70), with negative impacts in human health (71).

There have been promising advancements in the development of “eco-friendly” tests, such as biodegradable tests made out of bacterial cellulose for COVID19 (72), or a plant-based biodegradable multiplex test for Influenza A and B, Respiratory Syncytial Virus and COVID19(73). These tests, capable of detecting multiple diseases, are gaining recognition as a valuable tool for disease management, and as waste reduction measures improving diagnostic efficiency (30).

Diagnostic waste in LMICs has spurred debate about where the responsibility for its management lies. While at the moment national governments are responsible, the notion of extended producer responsibility (ERP) can be more adequate in terms of equity, which places the actual responsibility on the manufacturer(30).

BOX II - Applying Extended Producer Responsibility in the Pharmaceutical Sector

Extended Producer Responsibility (EPR) is a policy approach that holds producers accountable for the environmental impact of their products throughout their lifecycle, including material selection, production, usage, and disposal. By adopting EPR, producers are encouraged to design products with minimal environmental impact and take responsibility for managing waste that cannot be eliminated through design.

The key environmental objectives of EPR are:

- **Encourage eco-design –** Promoting resource-efficient, low-impact product design.
- **Enhance waste management –** Ensuring proper collection, treatment, reuse, and recycling of end-of-life products.(74)

This approach is the cornerstone of current EU initiatives such as the Urban Wastewater Treatment Directive, that will require pharmaceutical and cosmetic companies to bear the majority of the cost of wastewater treatment to remove chemical microcontaminants. Strongly opposed by the industry (75), the directive is aligned with "polluter pays" principle.

An additional impact of the COVID19 response was the plastic waste generated by single-use facemasks. The production of 900 billion masks between 2020 and 2022 resulted in 18 million tons of carbon emissions and 27.000 DALYs (76). Daily discarding of 3.4 billion facemasks in 2020 contributed to the 1.6 million tons of biomedical plastic waste produced every day (77).

Notably, the ear-loop of surgical masks has the largest environmental impact, given the energy-intensity of producing the thermoplastics that they are made from (76). In addition, one of the main environmental challenges of face masks is waste disposal, (78) which can generate micro and nanoplastics, altering marine and land life, including human (79).

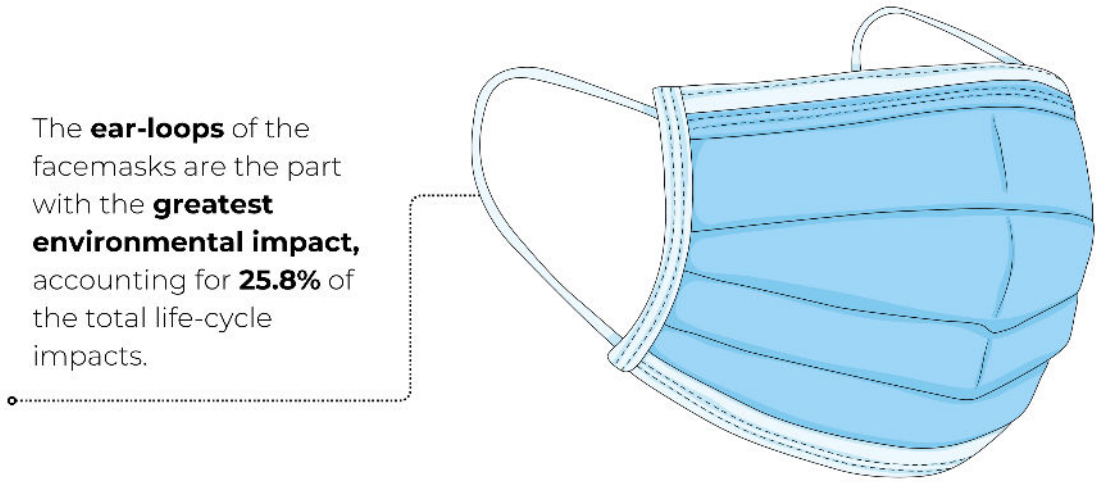
The use of incineration of medical waste in places like Europe (80) also contribute to GHG emissions, although there are innovative methods to phase down incineration(81). Circular economy initiatives (e.g., reprocessing FFP2 face masks through steam sterilization) can reduce climate change impact at low cost (82). Optimizations in mask design, use of clean energy in production plants and the use of new fabrics can also reduce the environmental impact by nearly 45% (76).

MEDICAL OXYGEN

Medical oxygen is essential for treating both acute and chronic conditions. The COVID-19 pandemic exposed global inequalities accessing this life-saving therapy (83). Only in 2021, the 370 million people that require oxygen each year increased by 52 million additional patients (83).
One of the most common large-scale oxygen production methods consists of using cryogenics to separate oxygen from other air's components, and many healthcare settings depend on cryogenic air separation units for its medical liquid oxygen supply(84).

It has been argued that cryogenic processes are less energy-intensive than other methods such as adsorption or membranes (85) (86). However, its significant electricity consumption has a large carbon footprint(87,88), which puts membrane technology as a preferred option in terms of cost, efficiency and environmental impact (86). Innovations in this area to provide large volumes at low cost and lower carbon impact(89), are already being explored(90).

Figure 4 · Unseen consequences: the environmental burden of facemasks



900 billion facemasks produced between 2020 and 2022 resulted in **18 million tons of carbon emissions** and 27.000 DALYs.

4 · HOW DO WE INCENTIVIZE PHARMA TO GO GREEN?

THE CASE FOR GREEN PROCUREMENT AND DRUG REPURPOSING

Green procurement is increasingly recognized as a strategic tool to attain objectives under the Paris Agreement(91), promoting environmentally sustainable practices in the pharmaceutical industry. Integrating sustainability criteria into procurement policies, would incentivize pharmaceutical companies to reduce greenhouse gas (GHG) emissions, limit water pollution, and minimize waste (92). Green procurement can encourage the use of renewable energy, resource efficiency, and circular economy models, while ensuring affordability and availability of medicines (93,94).

Some governments and procurement agencies have taken steps in this direction. For example, Norway's hospital procurement agency has introduced environmental requirements that account for 30% of the decision-making criteria in pharmaceutical tenders for high-impact medicines (e.g., antibiotics and chemotherapeutics) (94) . Sweden requires companies to report environmental risks associated with their manufacturing processes (94). In the UK, all National Health System's suppliers will be required to publicly disclose their emissions targets and provide a carbon reduction plan by 2027(95).

Multilateral organizations may play a crucial role in shaping and enforcing sustainable procurement standards in the pharmaceutical sector. Given their large purchasing power, organizations such as PAO, UNICEF or the Global Fund have significant leverage to push pharmaceutical companies toward greener practices.(5). By adopting green procurement practices, these organizations could create strong market incentives for manufacturers to adopt sustainable production methods . UNICEF has taken steps to engage with suppliers on sustainability and it is expected that in the future suppliers will need to report on GHG emisions, although it is still lacking specific metrics(93), and PAHO has also committed to cut its carbon footprint in half by 2030 through more sustainable logistic practices and promoting regional manufacturing sources through its Revolving Fund (93).

The Global Fund's Responsible Procurement Framework (RPF) provides another key example of sustainable procurement practices in global health. The framework builds on previous sustainability efforts by embedding environmental, health, and safety (EHS) compliance standards into long-term agreements with suppliers, such as artemisin or mosquito net manufacturers. Furthermore, the Global Fund has taken steps to reduce packaging waste across procurement categories. Under this framework, suppliers would be expected to provide baseline sustainability data, minimize their environmental footprint, and align with internationally recognized standards (96).

Green procurement is also highly relevant to pandemic preparedness and response, given the stockpiling of large volumes of vaccines, emergency medicines or other medical devices, and the use of joint procurement agreements (e.g., EU Joint Procurement Framework(97) or rescEU (98)). Likewise, contracts facilitated or performed by HERA are also tools for green public procurement. In this sense, it has been argued that the EU Public Procurement Directive could be used as the legal framework to promote procurement of health technologies with lower carbon footprint (94).

DRUG REPOSITIONING FROM A CIRCULAR ECONOMY LENSES: GOOD FOR PATIENTS, FOR HEALTHCARE SYSTEMS AND FOR THE PLANET

Investigating new therapeutic uses of a drug during pandemics can benefit patients, healthcare systems, and the environment. Existing drugs have well-established safety and pharmacokinetic profiles (99), and production and supply chains already in place for rapid deployment (100). This translates into a faster development timeline (101), lower development and commercialization costs (99), and increased access to affordable therapies (102). Early COVID19 clinical trials of repurposed drugs exceed those of new drugs (103), and drug repurposing is being studied for viruses with pandemic potential, such as Ebola virus(104) or Nipah virus(105).

Repurposing medicines aligns with the principles of the circular economy by minimizing pharmaceutical waste and reducing the environmental footprint associated with drug R&D and production(106). Leveraging existing medications optimizes resource efficiency while supporting sustainable healthcare innovation. However, IP related barriers, lack of repositories for abandoned compounds, inappropriate pull incentives or insufficient regulatory support (103,107) are some of the obstacles for a strategy that is not only medically and economically beneficial but also environmentally responsible.

This review shows that we need to incorporate a “greener pharma lenses” into the development of all PPR policies and tools. Without addressing the environmental challenges posed by health technologies’ value chain, future pandemic prevention, preparedness and response risk exacerbating the very anthropogenic factors that contribute to the increased probability of spillover events. Responding to a pandemic contributes to cause the next one.

5 · NEXT STEPS AND FUTURE AREAS OF ADVOCACY

This non-systematic review comes timely as there are a number of political process where these reflections may take shape. Discussions to finalize the Pandemic Agreement are close to finish but PPPR will continue to be prominent in global health debates and policies. The G20 is a relevant space for pandemic-related discussions, and the South African presidency is committed to advance the establishment of an Alliance for Regional Production and Innovation, where environmental sustainability should be a key component. Expanding regional production should be coupled with increased investments in renewable energy and adapted climate-sensitive, end-to-end supply chain infrastructure.

Debates at the World Health Organization on PPPR must reflect this reality and bridge the evidence between corporate emissions and pandemic prevention. More broadly speaking, the adoption of Climate Change as one of the six strategic objectives in WHO's General Programme of Work opens the opportunity for greater action to decarbonize health systems, and supply chains of medical products, as the 2024 World Health Assembly Resolution on Climate Change and Health urges Member States to do(108).

At EU-level, ongoing negotiations of the Pharmaceutical package are addressing the role that environmental risk assessments should have in the market authorization, refusal or revoke (109). Initiatives such as the forthcoming Critical Medicines Act should incorporate clear environmental objectives to strengthen EU manufacturing capacity.

In addition, key industrial policy packages are worth following. The EU Clean Industries Deal sets out the revision of the Public Procurement Directive, which could allow for sustainability criteria to be included in EU public procurement. The Circular Economy Act could enable circularity of health technologies. A key area of focus is likewise the deregulation initiatives by the European Comission, such as the new EU Corporate Sustainability Due Diligence Directive, to exempt the majority of companies from EU corporate responsibility reporting (110).

Extending circularity and green public procurement to the join procurement mechanisms included in the regulations on serious cross-border threats to health and ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

At national level in Spain, the new Health Technology Assessment Act, the revision of the Medicines Act and the forthcoming Spanish Global Health Strategy are tools to highlight green public procurement's capacity to pharmaceutical companies' behavior. Finally, the role of the Spanish Public Health agency in coordinating countermeasures' supply chain should be explored to incorporate environmental criteria.

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DECARBONIZING PHARMA

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