IFPMA

IFPMA Position: Global Plastics “Instrument”

APRIL 2024

Key points

- → IFPMA supports an overall ambitious UN Global Plastics “Instrument” that creates globally harmonized plastic regulations. This is key to securing the scale and effect needed if we are to succeed in transitioning away from plastic where it is possible to do so safely while ensuring continued access to medical and medicinal products.
- → IFPMA members are committed to driving the needed innovative change in line with the agenda for plastics, while keeping our focus on providing quality, safe and effective treatment for patients (see Annex I for examples).
- → Plastic materials and components are indispensable in every stage of the pharmaceutical lifecycle, and are crucial for medical production, quality, and safety. Currently, these cannot easily be replaced by other materials while ensuring the same levels of patient and healthcare practitioner safety.
- → The Instrument must recognize the need for targeted extended compliance periods or exceptions (when no safe or technically feasible alternative is available) for medical and medicinal products so that access to these products is maintained while the sector transitions to fulfilling the goals of the Instrument. This is absolutely key to avoid disruptions to patient access to medical and medicinal products due to bans or lack of availability of necessary plastic materials and components.
- → Ensuring that the Plastics Instrument is aligned with existing legislation where feasible will be critical for continued functioning of global supply chains that enable patient access to medicines. Globally harmonized rules will help alignment between different sectors and throughout international supply chains, will promote effective and transparent implementation of the Instrument, and will help make it easier for businesses and other stakeholders to comply.
- → IFPMA members strongly support the transition to a sustainable economy but are limited by technology and market development due to high health and safety requirements for our sector. We are committed to driving the needed changes and setting the agenda for plastics while working with global stakeholders across industries to identify practical solutions that do not compromise safety or patient access to medical and medicinal products.

→ Overall, it is essential that advancements in environmental protection in the healthcare sector go hand in hand with ensuring the highest level of patient safety and access to medical and medicinal products.

Importance of medical and medicinal products for Human Health:

Medical and medicinal products are pivotal in maintaining public health and well-being, driving healthcare outcomes, and supporting economic growth. They prevent disease, alleviate symptoms, cure illnesses, and enhance the quality of life for billions worldwide. From antibiotics and innovative biologics to the COVID-19 vaccines and cutting-edge medical devices, medical and medicinal products represent the pinnacle of scientific achievement and medical progress.

Access to medical and medicinal products underpins global health equity and social justice and, therefore, any requirements related to use and disposal of plastics must not jeopardize the uninterrupted availability of medical and medicinal products even considering the laudable objective of minimizing the negative impact of plastics on planetary and human health. The best way to do so under the Instrument is to establish targeted extended compliance periods for medical and medicinal products to assure the availability of appropriate alternatives that meet the quality, safety and access requirements needed by our patients while alternatives are developed and implemented. Exceptions to limitations on plastic use in healthcare applications must be permitted when no safe or effective alternatives are available. Throughout this process, engagement of regulators will be critical as most changes to manufacturing processes and packaging will need to be approved before being allowed to be marketed.

Plastics[1] in medical product manufacturing and packaging:

Plastic materials and components are indispensable in every stage of the pharmaceutical lifecycle, and are crucial for medicine production, quality, and safety. The use of plastics, like any material employed in drug development and manufacturing processes, follows comprehensive and intensive benefit-risk analyses, which are reviewed by experts at health authorities worldwide. Currently, plastic materials and components cannot easily be replaced by other materials while ensuring the same levels of patient and healthcare practitioner safety. For example,

→ In drug development, plastics facilitate the synthesis, purification, and formulation of active pharmaceutical ingredients (APIs), enabling precise dosing and controlled release mechanisms.

→ Plastics are used in lieu of fiber based materials to minimize contamination due to fiber particulate in pharmaceutical operations.

→ Plastics play a crucial role in the healthcare sector due to their unique properties such as versatility, durability, transparency, sterilizability and biocompatibility. In addition, they

[1] Throughout this document the term ‘plastics’ is used in a broad sense and also refers to plastics materials, components and systems.

enable aseptic and sterile environments during manufacturing of biologics and sterile injectables (for example biobags, tubing, and filters).

→ Plastic packaging ensures the integrity, stability, and sterility of medicines, safeguarding their potency and safety during storage and transportation. Whether in the form of vials, blister packs, or infusion bags, plastics offer versatility, reliability, and cost-effectiveness in pharmaceutical packaging that is not easily replicable with other materials.

Broadly speaking, the use of plastics in manufacturing provides a number of important benefits: (i) facilitates installation and qualification of equipment, especially in low-income countries; (ii) reduces the amount of electricity and water needed; (iii) increases productivity and scalability; and, (iv) facilitates production in more diverse locations, especially in lower-income countries.

Conscious of the negative impacts that plastic use has on the environment and human health, many companies committed to and are already working to reduce or eliminate the amount of plastic waste as well as supporting more sustainable alternatives, such as recycling and long-term circularity (see Annex).

Challenges in reformulating and redesigning medical and medicinal products to reduce plastic dependency

Plastic consumption is a global challenge, as the world today produces around 430 million tons of virgin-fossil based plastic annually, and the number is growing. Approximately 7 billion tons of plastic produced from 1950 – 2017 ended in landfills or was dumped as plastic waste in the environment.[2] The pharmaceutical sector is fully committed to contribute positively to combat the global plastic challenge.

Despite our commitment and the positive actions taken by the innovative pharmaceutical sector due to the growing concerns about plastic pollution and environmental degradation, the industry faces significant hurdles in reformulating medicines and processes to minimize plastic usage:

1. Regulatory approval processes and quality standards

Medical and medicinal products and their packaging are subject to stringent legal and regulatory requirements, which dictate the criteria for design, safety, quality, and performance, and which includes alternatives assessment and validation.[3] While crucial for patient protection, national regulatory frameworks are an additional challenge faced by companies when looking for compliant alternatives in each different phase of the product life-cycle. At the same time, existing regulatory requirements provide confidence that plastics, like all materials used in drug development and manufacturing, meet strict safety standards.

Any modification of the composition of our products and packaging requires a revision of the registration file which must also be accompanied by additional studies – of compatibility,

[2] See: https://www.unep.org/plastic-pollution

[3] For example: FDA, Directive 2001/83/EC and Regulation (EC) No 726/2004. For a more complete list please see Annex III.

extraction, interaction, migration, sorption, toxicological analyses, photostability, guarantee of sterilization conditions – proving that the new elements do not interfere with the integrity/quality of the health product. For packaging, this process could last between approximately 5 years for secondary packaging to 10 years for primary packaging.

The Global Plastics Instrument should be consistent with existing sector-specific arrangements to ensure that it can be implemented effectively. The complex interplay between the benefits to human well-being and the costs to the environment necessitates a nuanced approach that balances medical necessity with ecological responsibility as well as through consultation with medicines regulators at regional and national levels.

2. Lack of effective alternatives available at scale

In addition to this stringent existing regulatory framework, the healthcare sector faces the challenge of finding proper alternatives that are fit-for-purpose while balancing the need for chemical resistance compatibility, durability, cost, processing requirements, and availability. Polymers and plastic materials are used in medical and medicinal product packaging because of their functionality. Assuming alternatives are feasible, finding and implementing them at a scale that would support a smooth substitution of that specific material or chemical with no impact to the efficacy, safety, affordability and access is a complex and lengthy process.

3. Recycled content and recyclability

Currently there are limited feasible options for using mechanically recycled content for any pharmaceutical primary packaging, contact sensitive packaging or contact sensitive parts of devices. IFPMA members are exploring current and future potential but are limited by technology and market development due to high health and safety requirements for the pharmaceutical sector. Therefore, legal requirements on pharmaceutical use of plastic should be drafted in close collaboration with medical product regulators to ensure alignment and continued access to medical and medicinal products while new processes and formulations are established.

Recycling of healthcare packaging waste faces further constraints as such waste is often contaminated with hazardous chemicals, biological agents or body fluids, which render it non-recyclable and subject to stringent regulations on its disposal and waste management. Achieving “recycling at scale” requires time to allow for the implementation of workable ecosystem solutions for the safe and innovative waste management that ensure that health hazards are eliminated and no adverse impacts arise, in addition to ensuring adequate collection and sorting.

4. Need for alternative formulations and plastic products

The ability of IFPMA members to transition to plastic products with less environmental impact relies heavily on upstream suppliers and producers of plastics to innovate and adapt while maintaining stringent quality and safety standards. Pharmaceutical companies must prioritize both efficacy and environmental sustainability in their design process, chemical resistance compatibility, packaging and product formulations. Suppliers play a critical role in this balance by continually proposing alternatives and developing new formulations that meet these dual

requirements. Whether it's designing bio-based packaging with less environmental impact or developing new materials for drug delivery systems, we rely on plastic and chemical producers to propose feasible alternatives and are already actively collaborating with our suppliers to explore and test alternatives.

5. Environmental trade-off

It is important to remain cognizant of the impact that transitioning to alternatives can have on the environment. The use of plastics for the pharmaceutical sector is further complicated as the use of plastics in manufacturing processes, particularly single-use technologies, offers solutions that require much less energy and water usage than for traditional stainless steel and glass equipment.[4]

Moreover, we recognize the potential adverse effects of plastics on human health and emphasize the importance of adopting a risk-based approach when considering their use in medical and medicinal products. By carefully assessing risks relative to benefits, we can ensure the safe and appropriate utilization of plastics in healthcare, while ensuring patient well-being and safety. Alternatives to plastics may be less efficient (e.g. in avoiding cross-contamination or protecting medicines from degradation) and the impact changes may have on patients should be considered. By applying a risk-based approach to this shift, stakeholders will be able to make sound decisions based on measurable parameters relevant to human health and the environment.

Positive efforts by the pharmaceutical industry towards environmental sustainability

The innovative pharmaceutical industry is proactively addressing its environmental footprint and embracing sustainable initiatives. For instance, several leading pharmaceutical companies are committed to reducing the impact of plastic waste through the adoption of recyclable and biodegradable packaging materials. Furthermore, innovative technologies such as green chemistry and continuous manufacturing hold promise for reducing plastic usage and minimizing environmental impact throughout the pharmaceutical supply chain. See Annex I for more examples.

However, as mentioned above, plastics are used for a number of different purposes and at different points in the manufacture, distribution and use of medical and medicinal products. The specific function and point at which plastics are used strongly influences the feasibility of replacement of these materials. Specifically, the different quality and safety requirements between primary packaging, secondary packaging and plastics used in production processes affect the ability of manufacturers to replace or reformulate such plastics.

[4] Figures range to as high as a 90% savings in water use, a 50-60% savings in energy use and a 30% smaller physical footprint of the manufacturing facilities. See: https://cen.acs.org/articles/94/i28/Single-use-becomes-stateart-bioprocessing.html

IFPMA asks: Targeted extended compliance periods for medical and medicinal products; Globally harmonized rules

Targeted extended compliance periods

For the above reasons, IFPMA urges INC negotiators to ensure that medical and medicinal products are addressed in a manner that will not result in an interruption to the pharmaceutical supply chain including by assuring that targeted extended compliance periods for medical and medicinal products are embedded in the final Instrument, specifically for measures that require changes to product design or existing approval from authorities. More specifically, extended compliance periods will be critical for pharmaceutical primary and secondary packaging, manufacturing and R&D, to avoid the license to operate being at risk (see Annex II).

This is crucial for the pharmaceutical industry to adapt due to the complex regulatory landscape, technological requirements, and the imperative to ensure continued access to medical and medical products during the transition. The pharmaceutical sector operates within stringent regulatory frameworks, requiring thorough testing and approval processes for changes in materials and processes.

Given these challenges, targeted extended compliance periods provide the necessary flexibility for companies to ensure continuation of production and availability of high quality and safe medical and medicinal products for patients worldwide; while collaboratively exploring fit for purpose circular economy opportunities. When alternatives are identified and tested but found infeasible for technical or safety reasons, exceptions must be allowed to maintain patient access to medicines.

Harmonized global regulations

The Global Plastics Instrument provides countries with a clear opportunity for harmonization of global regulations, clearly defined criteria and definitions, and awareness raising with health regulatory authorities, which can create a more effective policy landscape and will be key for reducing compliance risk for businesses. Where feasible, alignment with existing global legislation (see Annex III) will help with harmonization and convergence of existing framework efforts. Leaving too much flexibility for national regulation can be counterproductive by allowing jurisdiction shopping and avoidance. Ensuring a global level playing field and a common understanding of the key parts of the Instrument, including under the proposed national action plans, will be vital for success.

ANNEX I

Case studies

Plastic materials which have been in contact with certain drug product process streams present some unique challenges from a waste management standpoint as they can be considered regulated medical waste. Some pharmaceutical companies have been working with waste and materials vendors who are able to treat and recycle this material to produce plastic lumber.

Necessary components are often shipped to pharmaceutical manufacturers in plastic boxes instead of fiber-based boxes to reduce potential contamination of pharmaceutical operations due to particulate. While the material (i.e. polypropylene) typically used is recyclable, suppliers servicing our industry are starting to change the material to 100% recycled polypropylene which reduces greenhouse gas emissions, contributes to demand of recycled material and is also recyclable.

Industry efforts at reducing plastic waste and working towards a circular economy[5]

ASTRAZENECA

From single use to reusable thermal packaging

Each year, Astra Zeneca sends 60,000 products to hospitals and clinics for clinical trial distribution. It involves a huge amount of packaging. The original process used a box the size of a small table, each containing 15kg of packaging that had to be thrown away after delivery with recipients being responsible for its disposal. AstraZeneca decided to work with its distribution partner to develop a new approach involving a returns process and make it workable. Some simple ideas like using the brightest coloured paper for returns instructions – a pink envelope gets more attention than just a white sheet of paper. After a pilot, the initiative was rolled-out across 35 countries. **The results: 98% return rate and reduced packaging waste equivalent to the weight of a 747-jumbo jets**.

SANOFI

Eco-design – Plastic-free packaging for Vaxigrip® vaccine

The new Vaxigrip® packaging has been designed to be plastic-free, thanks to a complete cardboard packaging. This new packaging halves the size of the box, which optimizes its storage and reduce its environmental footprint: - 30% reduction of the number of transportations needed (air, sea and road) - 50% reduction of CO2 per box - 25 to 50% reduction of environmental impacts according to the indicator

[5] Source: https://www.efpia.eu/media/554663/circular-economy.pdf

BOEHRINGER INGELHEIM

Eco-design - Switch from single use to re-usable inhaler

Respimat® re-usable is the result of patient feedback, providing an inhaler with enhancements such as simplified handling and an easy-to-read dose indicator, and significantly reduced impact on the environment. It reduces waste and product carbon footprint (PCF) can be used with up to six medication cartridges before needing replacement. Respimat® is also propellant-free, meaning its CO2 emissions are 20 times lower than those of commonly used pressurized metered-dose inhalers. **By 2025, it is expected that 776 tons of plastic waste and 14,300 tons of CO2 emissions will be prevented as a result.** 776 tons of plastic waste equals more than 77.6 million 0.5-liter PET bottles

GSK

Complete the Cycle

73 million respiratory inhalers are prescribed every year in the UK and not disposing of them correctly can be harmful to our environment. GSK created an inhaler recycling scheme, Complete the Cycle, which was the first of its kind for respiratory inhalers in the UK. 2 million inhalers had been collected by 2019 and the scheme led to a wider discussion on how a national inhaler return scheme could be created in conjunction with the wider health care system. By working together with patients, pharmacies and healthcare professionals, we can all help to reduce waste and greenhouse gases, moving towards a more environmentally sustainable treatment of respiratory disease.

CHIESI

Take back pilot - Take Action for Inhaler Recycling

Chiesi launched the Leicestershire Take AIR (Take Action for Inhaler Recycling) pilot scheme in January 2021, to enable inhaler users to recycle their empty, unwanted or out of date inhalers safely and effectively through the post. Any inhaler, brand and type, is accepted. The pre-paid, pre-addressed envelopes are provided by community pharmacies within the area.

The scheme is funded by Chiesi and supported by University Hospitals of Leicester NHS Trust and Leicestershire and Rutland Local Pharmaceutical Committee (LPC).

Inhalers are sent through the postal system, directly to a waste management company, where the component parts of pressurized metered dose inhalers are recycled, and non- recyclable inhalers are disposed of using the most environmentally appropriate process. Through the scheme, the aluminum canisters are crushed and recycled. The plastic components are recycled into the plastic supply chain and any remaining propellant gas is extracted and reused in the refrigeration and air conditioning industry. Non-recyclable materials are converted into energy through a process called energy-from-waste by high temperature incineration.

Scheme data as of 11th April 2022:

→ 147 pharmacies and 3 hospitals participated

→ Patients have returned 6,491 envelopes, containing 24,469 inhalers and

→ 144 tons of CO2e have been captured

The results from the pilot are being evaluated including quantitative and qualitative analysis, lessons learnt and recommendations for potential upscale through system-wide collaboration. This enables the findings to be shared with relevant stakeholders to support the development of a future sustainable recovery and recycling process for inhalers

Industry collaboration through Innovative Health Initiative project (EU/EFPIA/Medtech Europe)[6]

Safe & Sustainable by Design (SSbD) packaging and single use device solutions for healthcare products

The project is expected to strengthen and make more competitive the European healthcare industry by positioning at the forefront of the development of medical technologies, products, and services of the future, those that generate less waste, require less waste treatment, have reduced carbon footprints, increased circularity and other approaches that reduce the environmental impact of healthcare. The project should accelerate the implementation of alternative eco-packaging and device materials, promote the management of waste from packaging and single-use devices (including complex devices), all in a collaborative manner with policymakers and relevant stakeholders, including patients and healthcare professionals.

The Circularity in Primary Pharmaceutical Packaging Accelerator (CiPPPA)[7]

Industry wide collaboration to enable recycling of medical devices, primary pharmaceutical packaging and meter dose inhalers in the UK

The CiPPPA is a Not for Profit industry wide initiative operating in the UK market with a mission of enabling companies, as well as members of the public, to recycle their primary pharmaceutical packaging and delivery devices waste, thereby contributing to the elimination of waste. CiPPPA will achieve this by:

→ Focussing on primary pharmaceutical packaging and delivery devices (blister packs, injector pens, and inhalers).

→ Coming together as an industry to pool resources and adopt corporate commitments to establish industry-wide standards and collection/recycling practices.

→ Setting goals for and measuring our success by, the absolute reduction of waste in primary packaging and delivery devices in the UK and beyond.

CiPPPA is wholly funded by the member companies and provides an independent project management office (PMO) function as well as providing a platform for peer-to-peer learning, debate, and discussion on packaging circularity. CiPPPA aims to initiate, manage, and

[6] See EU Funding & Tenders Portal (europa.eu)

[7] https://www.tdi-sustainability.com/cipppa/

coordinate concurrent action-oriented programmes of its members (Product Action Task Forces) throughout the value chain to enable the tactical delivery of strategic change, and to establish a clear strategy and plan for recycling in the industry.

RETURPEN (Novo Nordisk, Lilly, Sanofi and Merck)

Recycling initiative for injection pens

Each year, millions of injection pens containing glass and plastics are used and disposed of worldwide. To find a solution for recycling used injection pens, Novo Nordisk initiated a collaboration between the Danish government, businesses, and patient organisations in 2020. While it may seem a simple initiative, it requires extensive collaboration between several actors across the supply chain, new user behaviour, regulatory compliance, innovative waste treatment technology, and sustainable recycling of the recovered resources.

On 1st May 2023, returpen™ became a collaboration between four pharmaceutical companies Novo Nordisk, Lilly, Sanofi and Merck, as well as the 14 additional partners. All four pharmaceutical companies believe this is a milestone on the journey towards more sustainable healthcare and are committed to exploring ways to reduce the environmental impact of pharmaceutical products. The collaboration aims to reduce the amount of medical waste sent to incineration with heat recovery in Denmark, and over the longer term to create an integrated solution that can handle different types of medical waste, while remaining as user-friendly as possible.

Recupera e Respira (Take Back and Breathe) (Chiesi)

Multistakeholder inhaler recycling pilot project in Italy

In 2022 Chiesi introduced Recupera e Respira (Take Back and Breathe), a multistakeholder collaboration in the Friuli Venezia Giulia region in Italy.

Through local pharmacies, people can return used inhalers, which are then collected by specialized operators and taken to certified waste-to-energy facilities for incineration, with energy recovery. Recupera e Respira collects and disposes of all kinds of used inhalers, regardless of the brand.

In the first 9 months of the 2 years pilot project, 400 pharmacies were involved and 30,225 used inhalers were collected. It was estimated that 4 in 10 people took their used devices back to the pharmacy, allowing them to be disposed of correctly.

ANNEX II

Use of plastics in the pharmaceutical industry

The role of single-use technology in the pharmaceutical industry

The adoption of single-use technology in pharmaceutical manufacturing can contribute to increased access to essential medicines by reducing costs, improving flexibility, ensuring product quality, facilitating localized production, and enabling rapid response to emergencies.

1. **Flexibility and Scalability**: Single-use systems offer greater flexibility and scalability compared to traditional fixed stainless-steel equipment. Pharmaceutical manufacturers can easily adjust production capacities, switch between different products, and respond quickly to changes in demand. This agility allows for faster ramp-up of production to meet increased demand, leading to improved access to pharmaceuticals during times of high need or emergencies.
2. **Reduction of Cross-Contamination Risks**: Single-use systems are pre-sterilized and disposable, significantly reducing the risk of cross-contamination between batches. This is particularly important for biopharmaceuticals and vaccines, where product purity and safety are critical. By minimizing the risk of contamination, single-use technology helps ensure the quality and efficacy of pharmaceutical products, enhancing patient access to safe and reliable products.
3. **Facilitation of Localized Manufacturing**: Single-use technology enables the establishment of smaller-scale, decentralized manufacturing facilities closer to patient populations. This can be especially beneficial in underserved regions or developing countries where access to pharmaceutical products may be limited due to logistical challenges. Single-use technology can improve access to essential medicines for local communities by facilitating decentralized manufacturing and reducing reliance on centralized production hubs.
4. **Rapid Deployment in Emergencies**: Single-use systems can be rapidly deployed in emergency situations such as disease outbreaks, natural disasters, or pandemics. These systems allow for quick establishment of temporary manufacturing facilities to produce vaccines, therapeutics, or other pharmaceutical products to address urgent public health needs. By providing a flexible and efficient manufacturing solution, single-use technology contributes to rapid response efforts and helps ensure timely access to life-saving medications.
5. **Cost Reduction**: Single-use technology eliminates the need for expensive cleaning, validation, and maintenance procedures associated with traditional stainless-steel equipment. This reduces capital investment and operational costs, making pharmaceutical manufacturing more affordable. As a result, drug production costs can be lowered, leading to more accessible pharmaceutical products.

Product specific uses:

1. **Packaging**: Plastic is chosen over alternatives such as glass or metal due to its lightweight nature, shatter resistance, and flexibility. Plastic packaging is also cost-effective to produce and transport compared to glass, and it provides excellent barrier properties against moisture and contaminants.
2. **Blister Packs**: Plastic blister packs are preferred over alternatives like aluminium or paperboard due to their versatility, cost-effectiveness, and ability to provide a visible barrier for individual doses. Plastic blister packs offer superior protection against moisture, oxygen, and light compared to paperboard, and they can be easily customized for different product shapes and sizes.
3. **Bottles and Vials**: Plastic bottles and vials are chosen over glass alternatives for their lightweight, unbreakable nature, and cost-effectiveness. Plastic containers are also less prone to breakage during transportation and handling, reducing the risk of product loss or contamination.
4. **IV Bags and Infusion Sets**: Plastic IV bags and infusion sets are preferred over glass containers due to their flexibility, compatibility with various medications, and reduced risk of breakage or leakage. Plastic IV bags are also easier to handle and dispose of compared to glass bottles, making them more convenient for healthcare providers.
5. **Syringes and Needles**: Disposable plastic syringes and needles are chosen over glass or metal alternatives for their safety, sterility, and cost-effectiveness. Plastic syringes are lightweight, easy to handle, and reduce the risk of needlestick injuries and cross-contamination compared to reusable glass syringes.
6. **Autoinjector Devices**: Autoinjector devices utilize plastics for their housing, injection mechanism, safety features, needle cap, ergonomic design, and medication compatibility. Plastics are preferred for their durability, lightweight nature, ease of moulding, compatibility with medications, cost-effectiveness, and ability to meet safety and ergonomic standards.
7. **Medical Tubing and Catheters**: Plastic tubing and catheters are preferred over alternatives like rubber or metal due to their flexibility, biocompatibility, and ease of manufacturing. Plastic tubing is also lightweight, kink-resistant, and compatible with various medical procedures, making it suitable for a wide range of applications.
8. **Respiratory Masks and Inhalers**: Plastic respiratory devices are chosen over alternatives like metal or rubber for their lightweight, portable nature, and ease of use. Plastic inhalers and masks are also more cost-effective to produce and dispose of compared to metal devices, making them accessible to a larger population of patients.
9. **Transdermal Patches**: Plastic transdermal patches are preferred over alternatives like creams or gels for their controlled drug release, convenience, and improved patient compliance. Plastic patches offer a discreet and non-invasive method of drug delivery, reducing the risk of systemic side effects compared to oral medications.

10. **Implants and Drug-Eluting Devices**: Plastic implants and drug-eluting devices are chosen over metal or ceramic alternatives for their biocompatibility, flexibility, and ability to deliver medications locally to specific tissues or organs. Plastic implants are also lightweight, durable, and less prone to rejection or infection compared to metal implants.
11. **Labware and Consumables**: Plastic labware and consumables are preferred over glass or metal alternatives for their lightweight, disposable nature, and cost-effectiveness (including for electricity and water). Plastic labware reduces the risk of cross-contamination and breakage compared to glassware, improving workflow efficiency and experimental reproducibility.
12. **Bioprocessing Equipment**: Plastic bioprocessing equipment is chosen over stainless steel alternatives for its flexibility, scalability, and reduced risk of cross-contamination. Single-use plastic components also eliminate the need for cleaning and sterilization, reducing downtime and improving productivity in biopharmaceutical manufacturing.
13. **Safety Equipment**: Plastic safety gear such as gloves, goggles, and face shields are preferred over alternatives like rubber or metal for their lightweight, flexibility, and chemical resistance. Plastic safety equipment provides comfortable and reliable protection for workers in pharmaceutical manufacturing facilities, laboratories, and healthcare settings.

ANNEX III

Medical and Medicinal Product relevant regulations and guidelines

Jurisdiction	Regulation	Relevant scope
International	Basel conventions	Plastics waste (polymers, mixture of plastics)
	Rotterdam conventions	PIC procedure for internation trade of hazardous chemicals (some are associated with plastics)
	Stockholm conventions	Control of POPs (17 listed are associated with plastics)
	ISO Standards: ISO 11607 part 1 and part 2: Packaging for terminally sterilized medical devices ISO 13485: Medical devices — Quality management systems	
	WHO Guidelines: WHO Annex 9 Guidelines on packaging for pharmaceutical products WHO Annex 9 Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products WHO Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical products	
	International Council for Harmonisation (ICH) Guidelines:	

	ICH Q8 Pharmaceutical Development ICH Q3E Guideline for Extractables and Leachables	
Country-specific legislation	EPR (including but not limited to): • Philippines Extended Producer Responsibility (EPR) Responsibility Act (RA 11898) • Turkey Amendment to WEEE Regulation establishing EPR Framework • UK EPR Packaging Waste Reporting Regulations • Chile Framework Law for Waste Management, Extended Producer Responsibility, and Recycling (EPR Law)	
EU	Extended producer responsibility legislation	Plastics involved in product life cycle
	Packaging and packaging waste Directive and upcoming Packaging and Packaging Waste Regulation	
	REACH microplastics restriction regulation	Impact on pharmaceutical industry: labelling or reporting requirements
	REACH PFAS Restriction	Impact on pharmaceutical industry: labelling or reporting requirements; ban on PFAS in medical device parts
	EU Plastic Pellet Regulation	Impact on pharmaceutical industry: indirect (impact is on the plastic resin manufacturers that the Pharma industry relies

		upon). Additional controls on losses and monitoring, reporting.
	Medicine directive (2001/83/EC), Annex 1, Guidelines for GMP, GDP	Set packaging requirement to ensure quality
	MDR (2017/745/EC)	Set packaging requirement to ensure medical device product quality, safety and environment protection
	IVDR (2017/746/EC)	Set packaging requirement to ensure in vitro diagnostics devices quality, safety and environment protection
	EMEA/CVMP/205/04 Guideline on Plastic Immediate Packaging Materials	
	European pharmacopeia monograph 3.2.2	Plastic containers and closure for pharma use
	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance	Although this legislation does not directly concern medical/medicinal products, there are potential knock-on effects as it affects plastics producers who produce food, cosmetic and medical plastics on the same production lines.
	Eudralex – Volume 4 Good Manufacturing Practice Annex 1 “Manufacture of Sterile Medicinal Products”	
	Guideline on Pharmaceutical Quality of Inhalation and Nasal Products (EMEA, June 2006)	
	Single-use plastics directive	
	European green deal	

	Circular economy action plan	
	Corporate sustainability reporting directive	
	Taxonomy regulation	
USA	US FDA CRF Title 21: regulations for Drug, Medical Device and combination products	Several provision apply to plastics in medical and medicinal products
	USP 7: labelling requirement for pharmaceutical product	
	USP 1207: CCIT requirement for pharmaceutical product	
	FDA Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics (May 1999)	Impact on pharmaceutical industry: Page 17 Qualification and Quality Control of Packaging Components: Postconsumer recycled plastic should not be used in the manufacture of a primary packaging component. If used for a secondary or associated component, then the safety and compatibility of the material for its intended use should be addressed appropriately.
	USP <1661>, European Pharmacopoeia (v.10.8), Ch 3	Pharmacopoeias define analyses/tests to be done on plastic material as primary packaging, e.g., presence of some substances (heavy metals) or additive types with specifications
	USP <1663> and BPOG	About the detection of leachables in extraction studies

	(US) 21CFR part 211.94:	(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.
	Container Closure Systems for Packaging. Human Drugs and Biologics. Chemistry Manufacturing, And Controls (FDA, May 1999)	
	Metered Dose Inhaler and Dry Powder Inhaler Drug Products Chemistry, Manufacturing and Controls Documentation (FDA, Oct 1998)	
	Industry Nasal Spray and Inhalation Solution Suspension, and Spray Drug Products Chemistry, Manufacturing and Controls Documentation (FDA, July 2002)	
Japan	Pharmaceutical and Medical Device Act	
	Japanese Pharmacopoeia, General Rules for Preparations; [2] General Notices for Packaging of Preparations	