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European Chemicals Agency
Telakkakatu 6, P.O. Box 400
FI-00121 Helsinki
Finland

Re: Regulation (EC) No. 1907/2006 (REACH)

Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs)

Dear Sirs and Madams:

West Pharmaceutical Services ("West") is providing the enclosed comments on the proposal for restriction on the manufacture, placing on the market and use of PFASs, for which the consultation began on 22 March 2023.

West is a trusted partner to established and emerging drug developers and provides components, solutions and services that ensure the safe, effective containment and delivery of lifesaving and life-enhancing medicines for patients. West encourages the development of chemical-regulatory policies that are protective of human health and the environment, recognizing the critical role pharmaceuticals play in treating and managing diseases, reducing hospitalizations and ensuring the functioning of healthcare systems.

West appreciates your consideration of these comments. If you have any questions relating to this submission, please feel free to contact me.

Sincerely,

Quintin Lai, Ph.D., CFA
Vice President, Strategy and Investor Relations

West Pharmaceutical Services Inc. response to ECHA's Annex XV Restriction Report, restriction on the manufacture, placing on the market and use of PFASs.

Executive Summary

West Pharmaceutical Services ('West') is a trusted partner to established and emerging drug developers and provides components, solutions and services that ensure the safe, effective containment and delivery of lifesaving and life-enhancing medicines for patients. West works with drug customers, from concept to patient, to develop products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply.

The products that West manufactures include stoppers and seals for vial packaging systems; plungers for syringe and cartridge systems; self-injection platform systems such as wearable drug delivery devices; and administration systems for the transfer of injectable drugs from one container to another. These are all products that are vital to providing critical medications to patients to address some of the most serious and challenging illnesses. Moreover, these products are a critical, irreplaceable part of the supply chain for injectable drugs, which are highly regulated and scrutinized by health care regulatory organizations such as the European Medicines Agency, the United States Food and Drug Administration, and the United Kingdom's Medicines and Healthcare products Regulatory Agency.

West By your side for a healthier world™

For reasons discussed in more detail throughout this submission, we respectfully request that a specific, time unlimited derogation that addresses irreplaceable fluoropolymers used in drug containment and delivery devices be included in any final restrictions for the following reasons:

1. **The use of fluoropolymers – a low risk PFAS - is essential to the manufacture of containment and delivery devices for medications.**
2. **If the use of fluoropolymers is restricted, patient access to lifesaving and life-sustaining medicines will be indefinitely disrupted;**
   - **10 -15 million critically ill patients in the EU use West products each year.**
3. **PFAS free alternatives with properties necessary for the safe containment and delivery of medicines do not currently exist and despite ongoing research are not anticipated to be available in the foreseeable future.**
4. **Even if alternatives to fluoropolymers are eventually identified, because of the nature of the drug approval process, re-approval of all injectable medicines in the EU supported by long term safety data to ensure patient safety with the substitution will be required, a process that will be lengthy and lead to the unavailability of critical medicines.**
5. **If the proposal were to be implemented, West facilities in the EU will need to close -- resulting in unemployment and negative economic impact.**

West is well-recognized for its efforts supporting the environment and sustainability. Consistent with that commitment, West is wholly supportive of sustainable, responsible PFAS management - and responsible policies that (1) provide assurance of long-term environmental protection; and (2) recognizes the important functional roles that certain PFAS contribute to products and technologies that protect human health. That being stated, certain PFAS substances remain uniquely essential in the medical device and pharmaceutical sector to protect patient health.

BACKGROUND ON WEST AND ITS SUSTAINABILITY COMMITMENTS

West Company was officially started in 1923 in Philadelphia, Pennsylvania, USA as a manufacturer of grinding wheels for the dental trade, and rubber droppers, plungers and stoppers for the pharmaceutical industry. During World War II, West developed novel packaging so that the US military could receive and maintain adequate supply of penicillin, a new drug at that time. Over time, West moved into using synthetic elastomers for pharmaceutical closures. West expanded internationally, initially into South America in the 1950s. West expanded into Europe in the 1960s and 1970s. West expanded into Asia in the 1970s. West changed from a privately held to a publicly held company in 1970.

West is now a global leader in containment and delivery of injectable medicines. West manufactures vial containment and syringe components, drug administration and reconstitution devices and drug delivery and diagnostic devices. In 2022, West employed over 10,000 individuals globally at over 50 locations including 26 manufacturing facilities. West manufactures over 123 million products daily for over 2,000 customers across the healthcare industry. West manufactures approximately 47 billion components and devices each year. West's mantra is: "**each component has a patient's name on it**." We remind you in this context of the same.

Close to half of West's net sales are to Europe, the Middle East and Africa. West employs over 4,100 people in the EU. In addition to facilities in North and South America and Asia, West has facilities in Germany, France, Denmark, Italy, and Ireland. West also has a long-standing partnership with Daikyo Seiko, Ltd. Daikyo Seiko is Japan's leading manufacturer of

high-quality pharmaceutical delivery system components, and has built a strong reputation for materials and manufacturing innovation.

West has implemented a Sustainability Program that is designed to target reductions in areas where we feel we can make the greatest impact: CO2 emissions, waste and increased recycling, as well as energy and water usage. West was named as one of Barron's Top 100 Most Sustainable Companies and received a Silver Stevie Award for Corporate Social Responsibility. In addition, West was pleased to maintain MSCI's highest ESG fund rating of AAA – which places West as a leader within the top 5% of the companies within the healthcare equipment and supplies industry category.

West is a signatory to the Task Force on Climate-related Financial Disclosures (TCFD), which affirms our commitment to fiscal transparency, as well as being a leader in addressing the current climate emergency. In addition, West is a proud member and active participant of the Pharmaceutical Supply Chain Initiative (PCSI) and is a signatory of the PSCI Principles, aligning with their vision for excellence in safety, environmental, and social outcomes for the whole of the global pharmaceutical and healthcare supply chain.

SECTORS AND (SUB-) USES APPLICABLE TO WEST

West does not fall neatly into any of the use sectors listed in Table 9 of the Annex XV Restriction Report. Thus, **West proposes the creation of a new sub-use category of the Medical Devices category, "Medical Containment and Delivery Devices."** While West is a manufacturer, the Manufacture use sector is broad and does not capture the specific characteristics of the products that West manufacturers, nor does it address the very specific need for use of fluoropolymers in those products. The Medical Devices sector is potentially a sector into which West products could be categorized. Section A.3.10.1.7 of Annex

A on the Annex XV Restriction Report discusses "Packaging" as a sub-use of the general Medical Devices use category. That section states:

> "PFAS, especially fluoropolymers, are widely used in medical packaging applications. Packaging components like single and multi-dose containers, bottles (also in caps and actuators), cartridges; pressurized containers, syringes and vials are known to (partly) contain PFAS, especially fluoropolymers.
>
> Liquid drug products for injection (e.g., vials, prefilled syringes) are packed in closed container systems. These types of packaging are mostly a combination of glass (vial, barrel) and elastomers (stoppers, plungers, seals). Because of the extended period of contact between the drug product and packaging, elastomer extractables could leach into the drug product, potentially affecting the product safety. ETFE or PTFE coated elastomeric components are often used to minimize interaction between the drug and the packaging, especially when the efficacy and safety of the drug can be compromised by exposure to an uncoated elastomer surface. As this kind of packaging is in direct contact with the drug product, they are part of the drug product registration."

The products described in Section A.3.10.1.7 of Annex A are the types of products that West manufactures. However, despite the discussion of these products in Annex A, they are not addressed in the sub-use categories identified in the Proposal and pertinent Annex. They are different from other "packaging" applications discussed, such as for ophthalmic solutions and packaging for medical devices, as their use is authorized as part of the drug product marketing authorization West manufactures numerous products to address varied needs for drug containment and delivery. These range from stock components that may be simply washed and sterilized, to more highly sophisticated products that are laminated and engineered to safely contain a specific product, to self-injection systems that accurately deliver critical therapeutic treatments. Accordingly, West's products are integral to the safe and effective delivery of pharmaceuticals, biopharmaceuticals and diagnostic tools world-wide. West products are essential for the provision of many medications, and regulatory approval of such medications is conditional on the use of the specific containment vehicles that West manufactures specifically for each medication.

EMMISSIONS ACROSS THE WEST PRODUCT LIFECYCLE

Emissions in the End-of-Life Phase

West products are manufactured, used and disposed of both in the EU and worldwide. As discussed below, West products containing fluoropolymers are generally disposed of at end of life using methods that are protective of patient and healthcare provider safety and minimize environmental impact. These disposal methods reduce negative impact to the environment, without negatively impacting critical drug supply chains. Consequently, concern about disposal should not be the impetus for restrictions.

Phase I - Manufacturing

West uses two different fluoropolymers, polytetrafluoroethylene ("PTFE") and ethylene tetrafluoroethylene ("ETFE") in the manufacture of its products. Waste material containing these fluoropolymers is therefore generated as part of the manufacturing process.

As mentioned, West has implemented a Sustainability Program that is focused in part on reduced waste and increased recycling. In 2022, West generated approximately 9,943 metric tonnes of waste in the EU. Of that total waste amount, 629 metric tonnes were landfilled, 812 was incinerated and 8,503 was recycled, meaning that the vast majority of waste generated by West was recycled. We estimate that PTFE and ETFE are estimated to be less than 0.5% of our total waste tonnage in the EU. This information was obtained from records that West facilities maintain concerning waste handling and disposal. The handling and disposal of waste, regardless of the method, is handled by vendors and not by West directly.

For 2022, West received a total of 63.7 metric tonnes of PTFE/ETFE for use in manufacturing in the EU. Of that amount, West consumed, in the manufacturing process, 60.5 metric tonnes of PTFE/ETFE. In the manufacturing process, approximately 45% of used materials end up as scrap materials. The scrap materials are then either landfilled, incinerated, or recycled. In 2022, West recycled over 94% of its waste. Based on calculations of PTFE/ETFE used in product, West estimates that 23.5 metric tonnes of PTFE/ETFE were recycled and no more than 1.4 metric tonnes of PTFE/ETFE were landfilled.

When deposited in landfills, there is low risk of fluoropolymers in leachate as they are inert, non-toxic and non-mobile. Based on West's understanding, the presence of fluoropolymers in waste materials has not proven to pose any problems for recyclability of the waste product.

Phase II - Use

As mentioned, West products are used as part of the primary packaging and delivery for pharmaceutical products. The West product, together with the drug, are sent to users, such as hospitals, medical centers and pharmacies. Fluoropolymers in the West products are not released in the use phase, and consequently there are no emissions of PFAS attributable to the use of West products.

Phase III – End of Life

Once West products are delivered to users, the end-user has ultimate control and knowledge of the specific end-of-life disposition of the product. West's pharmaceuticals customers are among the most progressive industries embracing sustainability. In fact, 46% of Wests' pharmaceutical customers have committed to a goal of being net zero by 2030. However, the ultimate end users of West products are generally doctors and hospitals and

other medical treatment facilities. All EU member states have specific regulations concerning the disposal of medical waste, which provide healthcare sector guidelines on medical waste disposal, with some countries imposing mandatory incineration of hazardous medical waste. As far as West is aware, the end-users of West products comply with these regulations. West is not in a position to provide any specific data concerning end-of-life emissions from West products, as the products - and their disposal methods – are no longer under West's control.

MISSING USES – ANALYSIS OF ALTERNATIVES AND SOCIO-ECONOMIC ANALYSIS.

Alternatives to PFAS in West Products

PFAS ARE KEY TO THE FUNCTIONALITY OF PRODUCTS USED TO CONTAIN, STORE AND DELIVER MEDICINES TO PATIENTS

West's product line utilizing fluoropolymers encompasses more than 1,900 product SKUs over the past 5 years. These products include stoppers, seals, vials, self-injectable platforms, cartridges, vial adapters, syringes, plungers and bulbs.

West manufactures and distributes products worldwide. In 2022, West shipped approximately 22 billion components from EU sites, and these components were used in the primary containment and delivery of injectable medicines and diagnostics worldwide. In 2022, 43% of West's net sales were generated in Europe, the Middle East and Africa, with the majority of sales being in Europe.

West's manufacturing facilities in the EU utilize fluoropolymers. There are 6 other companies who manufacture products that compete with West's in the EU. These companies also utilize

fluoropolymers in their products. Based on data and estimates, we believe that West is the largest supplier by sales of elastomeric closures for primary containment of injectable drugs in the EU. Moreover, based on West and Daikyo's high participation rate on biologic drugs, we believe we are the largest supplier by sales and volume of fluoropolymer-laminated elastomers for primary containment of injectable drugs in the EU.

Annual Tonnage

In 2022, West received a total of 63.7 metric tonnes of PTFE/ETFE for use in manufacturing in the EU. Of that amount, West consumed, in the manufacturing process, 60.5 metric tonnes of PTFE/ETFE. In the manufacturing process, approximately 45% of used materials end up as scrap materials. The scrap materials are then either landfilled, incinerated, or recycled. In 2022, West recycled over 94% of its waste. Based on calculations of PTFE/ETFE used in product, West estimates that 23.5 metric tonnes of PTFE/ETFE were recycled and no more than 1.4 metric tonnes of PTFE/ETFE were landfilled.

Key Functionalities

High-performance fluoropolymers are vital to the containment, storage, and delivery of injectable medicinal products. The primary container/closure and delivery systems (CCDS) are integral to medicinal products, which are authorized by the European Medicines Agency (EMA). West uses a high-performance fluoropolymer film to laminate the elastomeric closure component of injectable CCDS and is subject to general EMA restrictions. Injectable medicinal products cover a wide spectrum of treatments (e.g., maintaining chronic illness, preventing infections, managing pain, treating allergic reactions, curing diseases, etc.). The fluoropolymer laminated elastomeric closures are critical to medicines because they form a

protective barrier to protect the overall quality of medicinal products. Additionally, high-performance fluoropolymers have extremely low surface energy to avoid adsorption of biological products into the surrounding material and facilitate effective delivery to patients.

A protective barrier to elastomer in contact with the medical product is key to product quality and patient safety. Fluoropolymers are unique because of a combination of beneficial physical and chemical properties that include biocompatibility with injectable drugs, ability to provide a stable, sterile fill under a variety of storage conditions and times, ability to be sterilized with various technologies required by the injectable drug, machinability to work with a elastomers that have been selected by drug companies and approved by regulatory authorities, physical benefits such as a balance between sealing and glide force for applications in prefilled syringes and cartridges, as well as other positive impacts. The fluoropolymer-medicine interface requires a precise balance of critical properties in order to reduce the risk of patient harm. The lamination process also requires a precise balance of critical properties to ensure defect free lamination of complex shapes and for the film to adhere to the elastomer interface.

The significant high performance fluoropolymer requirements include:

1) creating a barrier layer to inhibit the migration of elastomer chemicals into the medical product,
2) provide a smooth surface with low surface energy to avoid potential for adsorption of medicine onto the closure surface or absorption of liquids,
3) enable delivery of medicines with a laminate that will not delaminate, flake off or deteriorate.

The unique properties of fluoropolymers e.g., resistance to chemical, biological, and physical degradation. Based on the years of research and development done to date, and the current state of the science, there is no single non-fluoropolymer film that can achieve all the same properties.

The Availability, Technical and Economic Feasibility, Hazards and Risks of Alternatives.

PFAS FREE ALTERNATIVES WITH PROPERTIES NECESSARY FOR THE SAFE CONTAINMENT AND DELIVERY OF MEDICINES DO NOT CURRENTLY EXIST AND DESPITE ONGOING RESEARCH ARE NOT ANTICIPATED TO BE AVAILABLE IN THE FORESEEABLE FUTURE.

Fluoropolymers films are fabricated from thermoplastic resins produced by upstream suppliers. The resin is converted into film by secondary suppliers and processed for adherence onto thermoset elastomers. Fluoropolymers possess certain parameters necessary for the lamination onto elastomeric closures to achieve requirements for end use with medical products. This is a specialty application with a unique set of material properties that only exists with fluoropolymers. Alternative materials recognized in Annex XV will have some similar properties, but they lack all the necessary properties described below.

Technical Functionalities	End Use Features
stretchability, moldability, tear resistant	smooth surface to contact medicinal products.
specific melting range for production process	high temperature stability for adhesion
high molecular wt., interlaminar shear strength	resist delamination and flaking due to wear particles
mechanical strength and toughness	resist abrasion, wear, and particles for machinability
flexibility, tensile and elasticity	resealability for multipuncture
chemically inert and non- toxic	resists swell, low process residuals and extractables
low oligomers, process residuals and oxidation	low potential for chemical mobility and leachables
low permeability and high density	molecular mass transport barrier, resists absorption
stability at high and ultra-low temperatures	non- degradable and stable for cryogenic applications
low moisture and potential for hydrolytic attack	resistant to hydrolysis and absorption post processing
low coefficient of friction	provides lubricity for processing and functionality
low surface energy	resist adsorption of medicinal products
high durability service life and low aging	gamma and steam sterilizable and long-term shelf-life

Examples of non-fluoropolymer film include polyesters, polyether, polyurethanes, polyamides, polyvinyl chloride, polyvinyl alcohol, ethylene vinyl alcohol, silicones, polystyrene, polyacrylates polyethylene, polypropylene. These materials do not have the exact same functionalities. We note that none of these examples have ever been

commercially used as a protective barrier coating for elastomeric primary packaging for injectable drugs in the same manner and effectiveness as fluoropolymers. We doubt that even a combination of multiple materials to achieve all the necessary properties would be a substitute for high-performance fluoropolymer films and would increase risk for 1) efficient and reliable medicinal manufacturability, 2) additional chemical substances and complexity compromising quality, 3) impact physical and functional performance, and 4) incompatibility impacting medicinal product safety and delivery to patients.

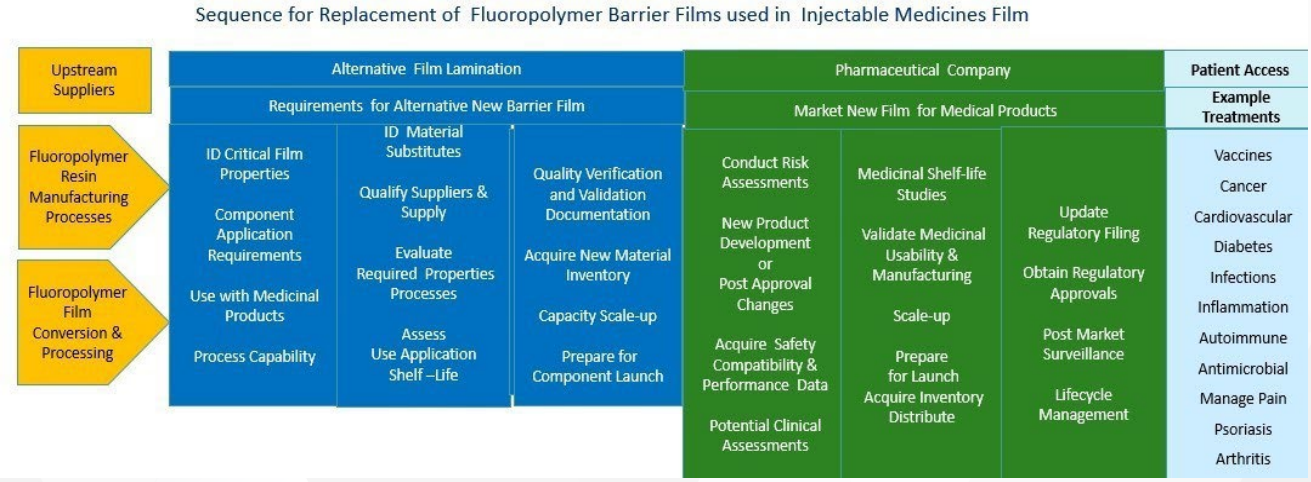
Identified sub-use categories using fluoropolymer coatings include metered dose inhalers containers and packaging for ophthalmic products. These applications were acknowledged in Annex XV to have low substitution potential should the restrictions be entered into force and derogations were granted. It is recognized in Annex XV in the discussion concerning the coating for metered dose inhalers that such fluoropolymer coatings lack technically feasible alternatives, and the high societal value of the medicinal product indicates that a full ban would lead to high socio-economic costs.

As mentioned in the Sector and Sub-use section of our comments above, there is no discussion of Medical Containment and Delivery Devices. Consequently, there is no mention in Annex XV of the use of fluoropolymer laminated elastomeric closures which are integral to injectable medicinal products. Due to the prevalence of injectable dosage forms, a significant number of lifesaving medicines would not be accessible to patients should the use of fluoropolymers be restricted.

At the present time, suitable non-fluoropolymer alternatives for elastomers lamination cannot meet the inherent properties of fluoropolymer films. Non-fluoropolymer alternatives would involve considerable costs, replacement and approval time and potentially compromise the health and wellbeing of patients. Continued and unrestricted use of high-performance barrier film for injectables products with a time unlimited derogation is justifiable based on following the premises:

- Medicinal products are sensitive to their environment and the fluoropolymer laminated elastomer component is integral to maintain the safety and effectiveness of the final medicine that is approved by EMA.
- High-performance fluoropolymer film used for lamination of elastomer closures have been used for decades to provide a protective barrier to inhibit the migration of chemicals from elastomers into medicinal products. Despite research and development efforts, no suitable replacement has been identified.
- Fluoropolymers are relatively costly, so, to the extent that alternatives are feasible, substitution has already occurred.
- The high-performance fluoropolymer film used by West has been deemed inert by Organisation for Economic Cooperation and Development, as well as designated as such on the film manufacturers' MSDS reports. The fluoropolymer laminate has a long history of use which has not presented intrinsic chemical exposure or known hazards associated with toxicity, irritation or sensitization related to injectable medicinal products.
- Replacement of fluoropolymer films for lamination of elastomeric closures in contact with medicinal products will involve a long-term timeframe based on 1) upstream supplier innovation and environmental management, 2) elastomer compatibility trials, verification/validation of lamination process, scale-up production, and distribution, and 3) qualification and validation for manufacture and use of medicinal products; and 4) approval from the relevant regulatory authorities.

Replacement of the currently used fluoropolymer film with a non-fluoropolymer film to meet current performance requirements for injectable medicines is not technically feasible. As discussed, alternatives have not been identified. There are numerous reasons why alternatives have not been identified. Existing non-fluoropolymer films would require multiple layers of materials to achieve the necessary combination of properties encompassed in a high-performance fluoropolymer film. If a multi-layered laminate could be assembled to closely match the fluoropolymer properties, other use problems may be encountered. For example, there is an increased likelihood of microbial contamination from poor resealing and elastomer particle formation due to dull needles or because of multiple punctures. Furthermore, a typical cycle to innovate/ develop a new laminated elastomeric closure with the same functionalities would encompass a series of steps starting with a commercial supply of resin and film from upstream suppliers. The sequential steps to be taken to substitute and an alternative fluoropolymer film are depicted below. The length of time from development to patient access can only be gauged once a new material becomes available.



Activities associated with the restriction dossier proposed by the REACH authorities of 5 EU member states and currently assessed by ECHA will impact availability of the supply of fluoropolymers, depending on the scope of change. Upstream supplier changes can occur due to availability of raw materials or development of innovative solutions related to the polymerization, process aids, manufacturing or fabrication which could affect the film properties and fabrication. Replacement time upstream materials cannot be estimated. Material or manufacturing changes to the fluoropolymer film will trigger requalification of the lamination process and verification performance properties. This includes validation of the final product's performance, qualification within the current manufacturing process and potentially development of new products or processes to overcome any differences identified due to the implementation of the new film. **Depending on the scope of change and impact to the film received, the time for West to verify a replacement, in the hypothetical case that one could be identified, is estimated to be at least 6-12 years depending on scope of change.** This extended timeframe would also have an impact on inventory of the current fluoropolymer film and risk to uninterrupted supply to pharmaceutical manufacturers. Once the laminated elastomer is qualified and verified, the pharmaceutical manufacturers would need to demonstrate compatibility, requalification, and validation for use with every marketed medicinal product across their portfolio as well as those in clinical phases and obtain the necessary regulatory approvals. **These actions and requirements by drug customers and regulators could take an additional 6-12 years per product.** The accessibility of medicinal products will depend upon the number of products and capacity to be revalidated. The total replacement time and costs cannot be estimated.

Additionally, a significant amount of research and development into new medications is conducted assuming the availability of specific containers and delivery devices. As discussed, many of these use fluoropolymers. Should the use of fluoropolymers be restricted, it could potentially lead to a slowing of the development of new medications, as either the needed containers and delivery devices are not available, or the reliability of new substances (if any) in container and delivery devices would be unknown and unproven. Consequently, newer and potentially more effective medications may not find their way to the marketplace should the use of fluoropolymers in these applications be prohibited.

The Dossier Submitters have acknowledged that the concerns mentioned above exist for certain categories of medical device applications. In Annex E, its noted that for implantable medical devices, tubes and catheters, coatings of Metered Dose Inhalers and diagnostic lab testing, the evidence is sufficiently strong and the technically and economically feasible alternatives are not generally available, and that the substitution potential is low. The point is also acknowledged from earlier industry responses that "Fluoropolymers are generally relatively costly compared to alternatives. For applications where alternatives are technically feasible, substitution of fluoropolymers is already ongoing or finished" (Annex E, page 317). In all these applications, many of the same qualities of fluoropolymers mentioned above are essential for proper performance. The Dossier Submitters also mention that if an alternative is identified, the process prior to approval under EU regulations can be expected to take several years. The complete process from identification of alternative to approved product takes at least 5-10 years if alternatives are identified at all. The Dossier Submitters concluded that in cases where technically and economically feasible alternatives have not already been

identified, there is sufficiently strong evidence that identification, development and certification of alternatives would take more than five years to complete.

However, even if replacement products are identified and then authorized, there is no guarantee as to the safety of the use of the product with a fluoropolymer replacement in the long term. Fluoropolymers have been used for many years, are well-studied and effects of use are well characterized. Fluoropolymers do not dissolve in or contaminate water or generate microplastics. Fluoropolymers meet the OECD criteria for "polymers of low concern" as they do not present significant toxicity concerns and do not degrade into other PFAS. However, if their use is nonetheless restricted, industry would be compelled to find an alternative. The experience with the use of any such alternative would necessarily be limited, it will not be as well-studied, and long-term effects will not be known. In those circumstances, there is relatively high potential for a regrettable substitution.

SOCIOECONOMIC AND PATIENT IMPACT

Availability of Medicinal Products

The primary container and delivery systems manufactured by West are integral to medicinal products authorized in the EU either by national authorities or by the EMA, primarily injectable medicinal products. Injectable medicinal products cover a wide spectrum of treatments (e.g., maintaining chronic illness, preventing infections, managing pain, treating allergic reactions, curing diseases etc.). Pharmaceutical manufacturers must demonstrate to the relevant regulatory authorities at the national or EU level that the container or delivery system chosen for a specific medication is compatible with the medication and it will ensure

continued efficacy of the medication. Should the use of fluoropolymers be restricted, the availability of medications in the EU would be significantly impaired.

The availability of medications is important to Member States in the EU for several reasons. Firstly, medications are essential for maintaining public health and ensuring that individuals can access the treatments they need to manage illnesses and diseases. Without access to medications, individuals may experience poor health outcomes, which can have significant economic and social consequences. West products are utilized in conjunction with over 100 medications authorized by EMA, to treat conditions such as:

- Alzheimer's,
- Anemia,
- Arthritis,
- Asthma,
- Breast Cancer,
- Cervical Cancer,
- Colorectal Cancer,
- Crohn's Disease,
- Depression,
- Diabetes,
- Ebola,
- Epilepsy,
- Heart Failure,
- Hemophilia,
- Leukemia,
- Lymphoma,
- Malaria,
- Multiple Myeloma,
- Multiple Sclerosis,
- Obesity,
- Opioid Dependence,
- Ovarian Cancer,
- Pancreatic Cancer,
- Pandemic Infections,
- Rabies,
- Renal Failure, and
- Schizophrenia, among many others.

Based on market data, West estimates that these medications are used by between 11 - 15 million patients in the EU every year. For cancer patients alone, West estimates that medications utilizing West products are used by approximately 4 million patients in the EU per year and is expected to grow by an additional 1.2-1.6 million patients per year with population growth and ageing. If these patients were unable to obtain the medications they need, the consequences – both individual and societal – would be drastic. Patients would be left with limited treatment options, leading to poorer health outcomes, reduced quality of life, and increased mortality rates. Reduced access to medicines could also lead to increased healthcare costs for patients, as they may need to seek alternative treatments, which can be more expensive.

Impact on Healthcare Systems in the EU

Additionally, the availability of medications is important for ensuring the functioning of healthcare systems in the EU. Treatments and medicines are essential for managing chronic diseases and reducing hospitalization rates. Without access to medications, healthcare systems would be overburdened, leading to increased healthcare costs and reduced access to care. As was recently seen with the COVID-19 pandemic, access to care and needed medications are critical for a properly functioning healthcare system. West products were essential in fighting COVID-19, with West products being utilized with vaccines manufactured by Moderna and Johnson and Johnson, as well as products that supported the Pfizer vaccine.

Economically, restricting the availability of medications could disrupt the pharmaceutical industry's supply chain, leading to shortages and increased costs for the production of medicines. The pharmaceutical industry is an important sector of the EU's economy, with a significant contribution to employment and innovation. Any disruption to the industry could have significant economic consequences, leading to job losses and reduced research and development of new treatments.

Economic Impact to the EU Labor Force

Prohibiting the use of PFAS would result in significant impact to West and other companies in the Medical Containment and Delivery Device as well, which in turn would impact the economic wellbeing of employees and local economies. West employs over 4,100 individuals at 14 facilities located in Germany, France, Denmark, Italy, and Ireland. Should West be prohibited from using fluoropolymers in products, West facilities would not be able to manufacture products in the EU or import manufactured articles for use in the EU. Consequently, West employees potentially face unemployment. Closure, or reduction of operations in facilities, would have secondary economic consequences as well stemming from a reduction in economic activity with EU located businesses with whom West previously did business.

ADDITIONAL CONCERNS WITH THE PROPOSAL

Per- and polyfluoroalkyl substances (PFASs) are a group of thousands of synthetic chemicals that are used widely in the EU as well as in the rest of the world, in a broad range of applications. For purposes of the Proposed Restriction, the Dosser Submitters have defined PFAS using a structural definition approach as “Any substance that contains at least one fully

fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)." The Dossier submitters explained that this definition was used as it is aligned with the OECD definition of PFASs that was published in 2021, and that has been scrutinized by the international scientific community and is widely accepted. This definition encompasses more than 10 000 PFASs.

However, chemically and physically, PFAS differ widely. Included in the category as PFAS are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols) and gaseous (e.g., hydrofluorocarbon refrigerants) forms. The fundamental physical, chemical, and biological properties of solids, liquids and gases are clearly different from one another. Furthermore, PFAS vary substantially in their physicochemical properties and may include polymers and nonpolymers; solids, liquids, and gases; volatile and non-volatile compounds; and compounds that are water soluble and water insoluble substances. In fact, when OECD released the definition of PFAS that is utilized in the proposal, they stated that "As PFASs are a chemical class with diverse molecular structure and physical, chemical and biological properties, it is highly recommended that such diversity be properly recognized and communicated in a clear, specific and descriptive manner." Consequently, grouping all PFAS together as a class and proposing a restriction applicable to every substance in that class fails to recognize that there are significant differences between the unique substances included in that class, and that many may not pose a risk of harm to human health or the environment.

The Dossier submitters state that all PFAS in the scope of this restriction proposal are either very persistent themselves or degrade into very persistent PFASs in the environment. This, they state, is the key hazardous property common to all PFASs in this restriction proposal. The articulated concern is, if releases of PFASs are not minimized, humans and other

organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects become inevitable. Although the ECHA Proposed Restriction reflect an impressive degree of awareness of many materials, chemical products, and the markets, the presumptions concerning persistence of the entire scope of PFAS captured by the structural definition provided are not based on a comprehensive study of the effects of all PFAS; indeed, no such study exists.

However, fluoropolymers have been studied, and have not been shown to present the same hazards as non-polymeric PFAS. Fluoropolymers are not toxic or water soluble. Fluoropolymers are generally considered safe because they are highly resistant to chemical and thermal degradation, have low surface energy, and are non-reactive to most chemicals. Fluoropolymers are also considered safe because they are inert and stable. This means that they do not release toxic substances into the environment or into food or beverage products that come into contact with them. Fluoropolymers meet the OECD criteria for "polymers of low concern" as they do not present significant toxicity concerns and do not degrade into other PFAS.

Fluoropolymers should not be subject to the same restrictions as substances that do not share the same safety profile. It is neither sound policy nor sound science to treat a group of substances the same simply because they fit into an extremely broad chemical characterization that, it is acknowledged, does not consider their hazard profile. Doing so creates a situation where the restriction is not in proportion to the risk posed, and the benefit conferred is not in proportion to the societal harm that would result from the imposition of the restriction. Consequently, all PFAS uses that utilize fluoropolymers should be granted a time unlimited derogation from any restriction that may be imposed.

PROPOSAL FOR DEROGATION

West proposes that a time unlimited derogation be granted to the proposed sub-use of Medical Containment and Delivery Devices of the Medical Devices use category.

As discussed, the Medical Containment and Delivery Devices that are manufactured by West are critical to ensuring that ill individuals are able to receive the medical treatment they need. Given that they utilize fluoropolymers, they pose little to low risk to human health and the environment. The Proposal recognizes the need for a continued supply of medications by granting a time unlimited derogation for active substances in human and veterinary medicinal products. However, the goals to be achieved by the grant of that derogation would not be met if the drugs could not be delivered and administered to patients as the needed drug containment and delivery devices were not available due to a restriction. There is currently no sub-use category into which West products can be appropriately included. West proposes to create a new sub use category, that of Medical Containment and Delivery devices. To ensure the continued availability of these products that are absolutely necessary to ensure that people receive the needed healthcare, as mentioned above, a time unlimited derogation should be granted to the sub-use of Medical Containment and Delivery Devices.

Additional Recommendations

ECHA should think beyond restrictions and prohibitions and focus on solutions such as:

- Programs requiring certain manufacturers or product uses to collect and responsibly process PFAS-containing wastes;
- Reporting requirements, designed to ensure that regulators receive useful information about PFAS in products;
- Enhancing and empowering research on effective PFAS destruction technologies and methods for addressing and mitigating current sites where contaminations exist; and,

- Exploration of recommendations for incentives to ensure new facility design and construction (and existing facilities undergo retrofitting) to enable limited PFAS uses in essential (societally-critical) applications while ensuring human exposures and environmental releases of PFAS do not occur (or are eliminated).

Legal and Procedural Concerns

The PFAS Proposal does not satisfy requirements of Article 68 because the Proposal fails to identify an" unacceptable risk to human health or the environment" that can only be addressed in a "Community wide basis" through the proposed restrictions. As posited, the Proposed Restrictions would effectively ban as many as 10,000 PFAS on the basis of what is fundamentally a persistency concern, and without a careful, science-based demonstration that each substance within the structural definition provided (or even careful groupings of sub-categories) present an unacceptable risk. Consequently, the Proposed Restrictions simply do not satisfy the criteria for a restriction under Article 68.1 of REACH.

Furthermore, the Proposal operates as a ban which is premised on a theoretical basis that the PFAS within the definition all are sufficiently similar that it becomes necessary to prohibit them all to avoid regrettable substitutions. However, without an objective assessment of the actual risk of such of the substances the prohibition is both disproportionate and legally unfounded, making it contrary to the basic principles of REACH concerning proportionality, objective examination, and basic principles of good administration.

Moreover, the structural definition approach to defining the scope of PFAS subject to Proposed restrictions will capture, according to the proponents, as many as 10,000 individual substances. In fact, numerous PFAS substances falling within the scope of the Proposal do not share similar *p*hysicochemical, toxicological and ecotoxicological properties, hazards,

and exposure (and consequently, do not pose equivalent risks, if any). Furthermore, the failure to identify with specificity the actual substances which are currently on the market in the EU (or elsewhere, given the restriction proposed on imports) also is in opposition to Article 68.1 and its insistence that entities subject to regulation should have a legal certainty with regard to the terms of a restriction. By failing to identify by more appropriate means (e.g., IUPAC names, CAS or EC numbers) any of the potentially 10,000 substances within its scope, the Proposal also is contrary to the requirements of section II.3 of Annex XV REACH, and well-established regulatory practices requiring specificity on such matters."

Finally, the breadth of the Proposed Restriction and its scope (which puts in jeopardy as many as 10,000 [unspecified] substances), and its social consequences (which will effectively make the production and safe and effectively delivery of countless medicinal treatments impossible), violate REACH's requirement that restrictions imposed must be in proportion to the objective ECHA seeks to achieve.

While West is itself not a small or medium enterprise (SME), it is concerned that the regulatory approach of a broad restriction of over 10,000 substances based on chemical structure will disproportionately impact SMEs (including e.g., SMEs that develop new medications and that provide testing and compliance services) and effectively exclude them from the market. Regulations that restrict the use of a substance should be clear, specific and capable of being understood and followed by SME economic operators who do necessarily have the support of large technical and regulatory teams. A clear, and periodically updated list of substances impacted by a restriction, identifiable by CAS number or similar, is a minimum requirement to prevent significant disadvantage to SMEs.

CONCLUSION

As discussed in these comments, West is actively engaged in ongoing and continually expanding efforts to identify technically feasible alternatives to PFAS for use in the production of the components and devices it manufactures. However, such alternatives remain evasive.

Furthermore, West is committed to responsible use and sustainable business practices with regard to its use and management of PFAS, including PFAS-containing wastes.

West also supports a more orderly and chemical-specific approach to REACH restrictions, rather than the broad-strokes approach the current Proposal reflects.

Nevertheless, upon review by the scientific committees for Risk Assessment and for SocioEconomic Analysis of the information being provided in this submission, it should be readily apparent the proposed restrictions on PFAS must be substantially modified to provide in any final restrictions a permanent, time unlimited derogation for the irreplaceable fluoropolymers used by West and other producers of drug containment and delivery devices.