

Exemption of West Pharmaceutical's Medical Devices from the PFAS Restriction

1. West Pharmaceutical ("West") is a world leader in providing primary containment and delivery components, solutions and systems for injectable drugs. West produces stoppers and seals for vial packaging systems, plungers for syringe and cartridge systems, and self-injectable systems for medicinal delivery.
2. West products are utilised with over 100 medications, including to treat chronic illness, prevent infections and treating allergic reactions. Most producers of COVID-19 vaccines and other vaccines use West's components of stopper and seals for vial containment.
3. All these drugs and vaccines are approved by EMA/FDA *not just as a substance but together with their containers and injection systems as a package*.
4. Any changes to West's products due to a PFAS ban would require readmission or withdrawal of all vaccines and drugs by EMA/FDA.
5. For the containers and injections systems, West uses two different fluoropolymers, polytetrafluoroethylene ("PTFE") and ethylene tetrafluoroethylene ("ETFE").
6. West uses fluoropolymer lamination as a barrier film to prevent chemical migration of extractables and leachable from the container elastomer into the drug and to ensure medical quality. Moreover, fluoropolymer films have a long-track record of safety, quality and reliability as they are used in over 1,900 SKUs made by West to contain numerous injectable drugs. We conservatively estimate 14-15 million patients per year in the EU use injectable drugs packaged with a West fluoropolymer-coated component.
7. There are currently no alternatives for the fluoropolymer films used in West's products that can offer similar benefits supporting medicinal products.
8. West's products don't create PFAS concerns with waste. End of life is handled by users such as hospitals, medical centres and pharmacies who comply with specific rules concerning disposal of medical waste and recycling.
9. West employs over 4,100 individuals at 14 facilities in Germany, France, Denmark, Italy, Ireland and Serbia which depend on a respective PFAS restriction exemption.
10. The PFAS restriction proposal foresees three options: a) full ban, b) time-limited derogations of five and twelve years, and c) time-unlimited derogations for active substances in plant protection, biocidal and medical products.
11. West's products use fluoropolymers which are PFAS of low concern. West's products should be exempted from the scope of any PFAS restriction.
12. In any case, West's products need a time-unlimited derogation as foreseen in option 3 of the PFAS restriction proposal to avoid vaccine and drug shortages in the EU.