

From: Filip Godlewski[REDACTED]@albergeiger.com]

Sent: 29.02.2024 16:32:48

To: Audun Heggelund[REDACTED]@miljodir.no]

Subject: Exemption of Medical Devices from the PFAS Restriction

Det er ikke ofte du mottar e-post fra [REDACTED]@albergeiger.com. [Finn ut hvorfor dette er viktig.](#)

Dear Mr Heggelund,

I am writing to you on behalf of Alber & Geiger, a EU government relations law firm. We are currently representing West, a US company that produces packaging for drugs. West is a world leader in containment and injectable medicines. Most West products are integral to the medicinal product and approved together (packaging and active substance) by EMA/FDA. West products were used in most Covid-19 vaccines and are used regularly in treatment of, among other conditions, allergic reactions, arthritis, diabetes and epilepsy, by approximately 11-15 million patients in the EU alone.

West uses two fluoropolymers to make these essential products: PTFE and ETFE. Both are covered in the ongoing PFAS restriction. As West products are used in essential drugs, the proposed total ban could jeopardize the availability of critical medicines. Most West products will have to be withdrawn 18-months after the entry into force of the ban.

West is seeking an exemption from the proposal restriction for medical products like the ones it produces, while acknowledging the necessity of control over the use of fluoropolymers. It should be readily apparent the proposed restrictions on PFAS must be substantially modified to provide in any final restrictions a permanent derogation for the irreplaceable fluoropolymers used by West and other producers of drug containment and delivery devices. West believes the pharma laws currently in the pipeline, as well as the medical devices regulation would be best placed to deal with PFAS in medicinal products and medical devices.

For more information, please see enclosed our 1-page summary of the issue and concrete ask. I would appreciate it if we could have a short meeting at your earliest convenience.

Yours sincerely,

Filip Godlewski

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