Prohibition proposals will affect the pharmaceutical industry

At our company, a wide variety of Fluoropolymers (e.g. PTFE, Viton, Gylon, PVDF) are used as production plant components in the manufacturing of pharmaceuticals as well as in analytical equipment for testing those pharmaceuticals. Moreover, TFA (trifluoro acetic acid) is a critical component used in chemical analysis of our active pharmaceutical ingredients. At one of our affiliated companies, PFA (Perfluoralkoxy polymers) is used for the storage of pharmaceutical products (drug substance) at the site.

Fluoropolymers are used in the above-mentioned applications due to their unique properties, namely the resistance to high temperature and aggressive chemicals. In detail, these are: • Ozone, which is used for the production of WFI (Water for injection) which is e.g. necessary for the production of parenteral drugs • Steam (with temperatures ranging between 140 and 200°C) • Solutions of sodium hydroxide and citric acid used for cleaning purposes In case of the storage of pharmaceutical products, chemical inertia as well as temperature stability are critical material properties. TFA (trifluoro acetic acid) is used in testing of active pharmaceutical ingredients. The relevant procedures are mandatory from a regulatory perspective for release of the substances to the market.

Due to the unique properties of fluoropolymers, replacement in pharmaceutical manufacturing context is – at least in the short term – impossible. Membranes or seals made of EPDM (Ethylene-Propylene-Diene-Monomer rubber) are not suitable as alternatives in these applications. This is due to their limited stability in hot and / or corrosive environments which can lead to degradation of the material and – worst case – contamination of pharmaceutical products. Moreover, the lifespan of EPDM under the prevalent conditions would be very limited. This would not only potentially compromise product quality, it would also pose a serious risk of exposure of staff to aggressive chemicals. Furthermore, it would drive up costs as well as waste quantity due to a higher replacement frequency.

TFA used for analytical purposes cannot be replaced. If this were necessary, it would imply the development of a completely new analytical method which would also be subject to approval by the FDA (US Food and Drug Administration). Analytics carried out according to guidelines from pharmacopoeias require the use of the specified reagents which cannot be changed without the underlying pharmacopoeia being changed. Concerning the storage of pharmaceutical product, a replacement of the material is currently impossible. Apart from required properties (e.g. inertia), any change of the material would be subject to lengthy validation procedures and approval by the relevant regulatory authorities.

The planned ban would thus have massive consequences on our company, since fluoropolymers are used in the media production and distribution virtually throughout the whole company site including various production plants. They are also used in a variety of analytical equipment. The new development of analytical methods for our major product would not only be very costly and time-consuming, but also subject to approval by the FDA. In consequence, the ban would result in a shutdown of nearly the whole site with 500+ jobs affected and the inability to supply

important pharmaceuticals to markets in the EU, Northern America and others. As the restrictions would not apply to producers outside the EU, this could ultimately lead to dependence on non-EU producers for the supply of the aforementioned pharmaceuticals.

In conclusion, a replacement of fluoropolymers in addition to a ban of TFA in the manufacturing of pharmaceuticals is neither technically nor economically feasible for our company and would put the company as a whole at risk.