EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ECHA proposal to ban PFAS – potential impact on availability of medicines

F2F PCWP/HCPWP meeting
14 November 2023

Presented by Maria Alcaraz
Shortages and Availability of Medicines EMA

ECHA proposal to ban the use of per- and poly-fluoroalkyl substances (PFASs)

What are PFAS?

- Large group of manufactured substances that do not occur naturally in the environment and are highly resistant (either themselves of their degraded products)
- Very high persistence “forever chemicals” i.e., extremely resistant to degradation and accumulating in the environment
- Have been frequently observed to contaminate groundwater, surface water and soil
- Exposure to PFAS is associated with various health concerns (effects on human health and ecosystems)
- Highly used in different sectors industrial processes, textile, cosmetics, pharma industry… (thermal & chemical stability, durability, water/oil/dirt repellence..)

ECHA proposal to ban the use of PFASs

- Roughly 10,000 PFAS
- Restriction options:
  1. Full ban
  2. Ban with use-specific derogations (base on analysis of alternatives and socio-economic considerations)
- Ban of manufacture, placing on the market and use
- Transition period: 18 months after entry into force
- Use-specific time-limited derogations (two standard derogation timeframes)
  - 5 years: food contact materials for industrial food and feed production
  - 12 years: implantable medical devices
- Some time-unlimited derogations proposed: PFAs used as active substances (human and veterinary medicinal products) addressed in their respective regulations

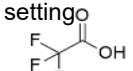
ECHA proposal to ban the use of PFASs

https://youtu.be/CXAZ3ath3To

PFAS are widely used in the development, manufacturing and supply of medicinal products

Pharmaceutical Manufacturing:

PFAS-containing materials handled in an industrial setting



trifluoroacetic acid

PFAS containing Raw Materials, Starting materials, Intermediates

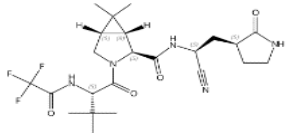
Fluoropolymer containing plant, equipment, consumables

Substitution is Challenging because of unique substance properties and manufacturing process validation

Packaging & Drug Delivery Devices

Challenge: Post Approval changes to Marketing Authorisation of Medicinal Product

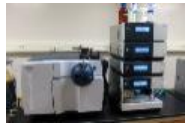
Fluorinated Drug Substance



Paxlovid

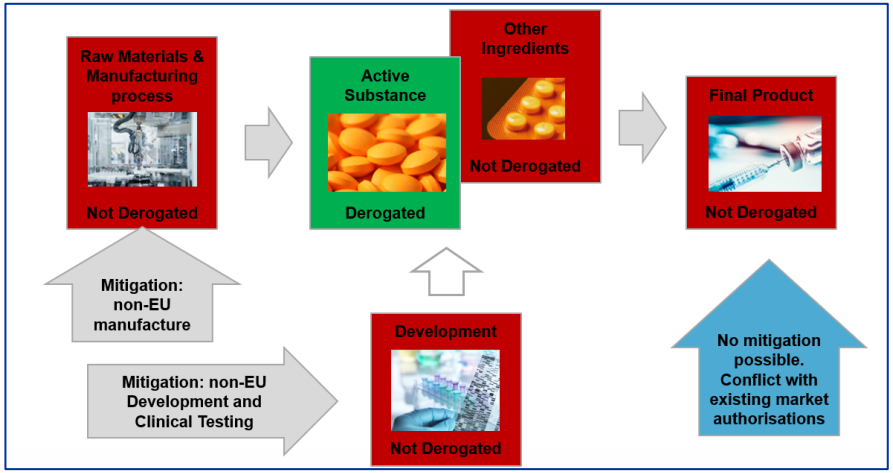
Substitution Impossible (API = molecule)

PFAS research & development + Quality control analysis



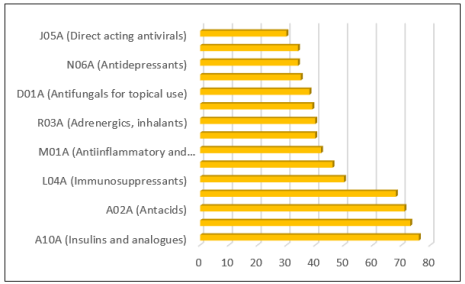
*Source: MfE regulatory affairs and pharmacovigilance conference

Impact on pharma industry and availability

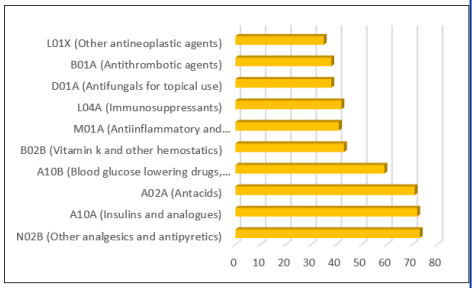


Types of products impacted:

- All 14 main anatomical/pharmacological groups
- **47 677 global marketing authorisations** across 12 product categories

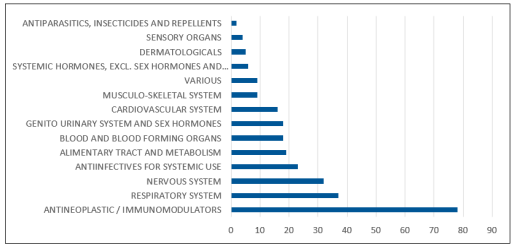


15 MOST REPORTED ATC CODES (LEVEL 3)

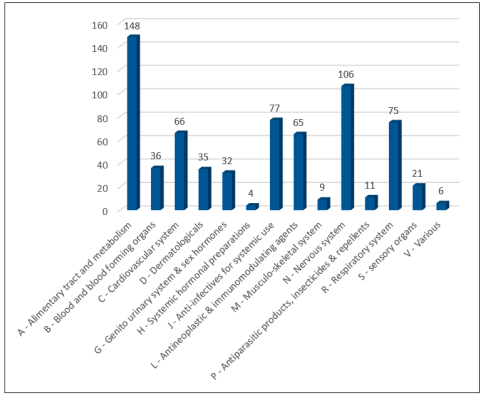


TOP 10 THERAPEUTIC AREAS ASSOCIATED WITH ACTIVE SUBSTANCES APPROVED IN THE EU

There are 276 products utilising polymeric PFAS in their packaging and listed as having a Marketing Authorisation in Europe.



Supply chains of 1794 out of 1922 (93%) active substances included in the survey involve manufacturing operations at an EU facility.



Impacted Medicines on the WHO Essential Medicines List in each ATC (1st level ATC codes) group

*Source: MfE regulatory affairs and pharmacovigilance conference

Conclusions

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- Within the proposed legislative and policy changes led by DG-Environment, EMA remit is limited
- Lack of visibility for Regulatory Authorities about the whole impact (raw materials, reagents, manufacturing equipment, primary packaging..) → Pharma industry is in best placed to evaluate the impact of the PFAS restriction on medicinal products
- Industry has shared with EMA the replies submitted to ECHA (time-unlimited derogation of non-EU APIs and development products, packaging materials and sterile barrier systems for drug delivery, fluoropolymers in industrial use..)
- Huge potential impact on the availability of medicines and pharma manufacturing activities in the EU/EEA
- For some cases alternatives do not exist / variations (stability studies, workload for industry/regulatory authorities)
- EMA is following the process closely / interaction with industry associations

Any questions?

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