2nd Stakeholder Consultation

https://www.reach-clp-biozid-helpdesk.de/SharedDo

Medicinal Products report summary:
https://www.reach-clp-biozid-helpdesk.de/media/He

Header (bold) / Question

V. Questions - Section B - Medicinal Products
Questions in relation to the use (mainly for industry associations)
[table of sub-uses, volumes, emissions]

Do you have information that indicates that the information provided on the emissions should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information that indicates that the information provided on the tonnage should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

The environmental release category (ERC) is a key REACH use descriptor to define the release factors of a chemical substance in a specific use exposure scenario. It is used in various modelling tools to derive environmental exposure estimates. ERC default factors are used to estimate emissions of PFAS in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.
Please indicate if you have information on specific emission values (SPERCs) for (groups of) PFAS, based on measurements and / or model calculations. (1000 characters)

Do you have information that indicates that the information provided on the expected trend should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

V. Questions - Section C - Medicinal Products
Questions in relation to alternatives (mainly for individual companies)
[no table]

What is the specific application/functionality of PFAS in your product(s)/processes? (1000 characters)

Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Do you have information on the alternatives' risk profile? (yes/no)

Please describe.
1000 characters

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case PFAS alternatives will be used? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

What is the average approval time? (1000 characters)

Do you actively work on finding alternatives? (yes/no)

Please specify. (1000 characters)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain. (1000 characters)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information? (1000 characters)

V. Questions - Section D - Medicinal Products
Questions in relation to impact of legislative measures
(for companies and industry associations)

What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) in 3 years (1000 characters)

b) in 10 years (1000 characters)

c) Please explain by providing your calculations. (1000 characters)

What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles. (1000 characters)

b) Obligation to label your products visibly with "Contains PFAS". (1000 characters)

c) Obligation to report amount of PFAS in use and respective emissions. (1000 characters)

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately. (1000 characters)

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production. (1000 characters)

V. Questions - Section E - Medicinal Products
Specific questions for the use

If available, please provide information that allows a quantitative estimation of tonnages of PFAS veterinary medicines and a trend in these tonnages. (1000 characters)

If available, please provide information on alternatives for (main) PFAS veterinary medicines. (1000 characters)

If available, please provide information on the EEA dependency on pharmaceutical import. (1000 characters)

If available, please provide information on PFAS emissions during pharmaceutical production. (1000 characters)

End of Questionnaire

on PFAS, July 2021

cs/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicati

lpdesk/download/Report%20summary%20medicinal%20products%20july%202021.pdf

Response Consolidated	Chars
Yes	3
The volume of API is use will also be emitted; adjustment of the volume is proposed in the appropriate section. Intermediates are handled in closed controlled systems, with low emission to the environment. All waste streams are controlled. Intermediates under REACH are even manufactured under strictly controlled conditions, so no significant emission to the environment is permitted. The mentioned 10% release for intermediates are not plausible. This is far above the worst case default release factors used by ECHA for ERC1 (manufacture of intermediates; 6% to water) and ER6a (use of intermediates; 3% to water). Workplace exposure is limited by banding: https://www.cdc.gov/niosh/docket/review/docket290/pdfs/clean-cib-niosh-oebprocess-guidancefortheevaluationofchemicalhazards_3.8.17.pdf The life cycle of PFAS components used in production of any medicinal products (filters, membranes, surface lining etc, as provided by the Life Science industry) is well controlled.	979
Yes	3

Pantoprazole as major contributor(about 250 t from 450 t in total) evades the new PFAS definition as it has a CF2H-moiety. Also applies to eflornithine, maraviroc, and roflumirast. On the other hand, certain PFAS API are missing: imported API are not registered under REACH, and some drug substance groups like anesthetics should be included here (see our comments in "Medical Devices"). An IQVIA query on PFAS medicines EU market volume are close to 1000 tons/a with a neutral trend, with inhalative anesthetics such as Sevoflurane (about 500 t/a) having much impact. They were filtered from the Top 200, so the actual figure may be somewhat higher. Registered intermediates were spot checked and some seem to be missing, as no PC code can be entered in the lifecycle description section. The actual volume is expected to exceed the given value. In general, the tonnages cannot be directly compared to other PFAS, as just a fraction of the rather large molecules is fluorinated.	983
No	2
Yes	3
The observed marketing volume increase trend in Figure 2 of the report summary is only evident for Pantopazole, which needs to be removed to reflect the current PFAS definition. All other volumes are stagnant or slightly decreasing, and no clear trend can be observed.	268
Yes	3

Only a small number of API substances pose a risk to the environment, and they do not fall under the PFAS definition: https://www.sciencedirect.com/science/article/pii/S0160412019309493#f0005 Initiative between European healthcare, industry and student organisations on disposal: http://medsdisposal.eu/ Enrivonmental Risk Assessments are conducted prior to approval of all medicinal products. Recent and new draft EMA guideline: https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use Technical justification for integrity of each individual manufacturing equipment and transport container exists (internal company documents)	661
	0
Active pharmaceutical ingedients (API) and their production intermediates meet the PFAS definition even with a single perfluorated carbon atom. Selected fluorination modulates the binding affinity, absorption, stability and distribution in the body of the whole molecule. Fluorine is both small and has the highest electronegativity of all elements, making it an essential building block to develop safe and efficacious drugs. Additional PFAS are essential in pharmaceutical production. This applies to articles such as PTFE filters or machinery with surface treatment, but also to chemicals used in synthesis, for peptide coupling or as production aids. Examples are trifluoro acetic- acid or anhydride, nonaflates, trifluoro ethanol or the refrigerant R-134a. These chemicals and articles are not part of the product and their disposal is controlled.	855
No	2
Due to the unique properties of fluorine, a direct replacement is not available. There are other electron withdrawing groups similar to -CF2- or -CF3 such as carboxylic esters, amides, nitro, or cyano, but they differ in stability, permeability, and toxicity. Example: Sorafenib (see Lowinger, T.B.; et al. Curr. Pharm. Des. 2002, 8, 2269-2278. Design and discovery of small molecules targeting raf-1 kinase). Here a CF3 group was key to achieve suitable in vivo activity. Sorafenib is currently used worldwide for treatment of liver, kindey and thyroid cancers. Other API with PFAS elements target serious autoimmune diseases including rheumatoid arthritis and infectious diseases including hepatitus C. The efficacy of the drugs is lost when the structure is changed. In production equipment, PFAS products are chosen based on their inert and non-stick properties. No alternatives are known without impacting the product quality.	933
No	2

Drugs and API are developed for efficacy and safety. Any change of molecular structure delivers a different drug candidate. Consequently, there are no alternatives to the molecule, regardless of economic viewpoints.
Production equipment is part of the validated process, so every change requires re-validation and thorough testing. This causes high qualification effort to evaluate non-PFAS alternatives, even in the unlikely case that such alternatives are found. 465

No 3

Not applicable (see above) 26

Legal approval schemes for pharmaceuticals apply regardless of their structure (PFAS or not). Any potential alternative needs to go through EMA approvals and clinical phases, taking many years (according to Directive 2001/83/EC) 228

Source: EFPIA "The Pharmaceutical Industry in Figures - Key Data 2021", p. 6 77

It takes about 10 years for research and development of new APIs. Registration and marketing authorisation have to be added to that time.
https://www.researchgate.net/figure/Trends-in-drug-approval-timeThe-total-time-from-synthesis-of-a-compound-to-NDA_fig1_8568742 267

No 2

Fluorine is introduced in APIs when required due to stability/clearance, potency, pharmcokinetics, and/or bioavailability of the drug candidate when these cannot be adressed by other means. The introduction of fluorine is expensive and difficult from a synthetic chemistry point of view and can be considered a last resort within drug development. 348

Not applicable (see above) 26

No 2

0

Prohibiting PFAS pharmaceuticals would remove multiple best-in-class medications from the EU market, although they are essential for public health and well-being. Affected therapeutic domains include, but are not limited to, cardiovascular & metabolic diseases, infectuous diseases, immunology, neuroscience, oncology and pulmonary hypertension. The resulting loss of therapeutic options and access to medication prevails over financial or job-related concerns.	
Prohibiting PFAS manufacturing materials, which are not part of the end product, would move production of numerous drugs and vaccines to non-EU countries, along with the jobs in production.	652
Same as above.	14
The social impact of poorer healthcare is measurable when pharmaceuticals are lost to the patients, and when no equally suitable alternatives are available. Unlike the economic impact this cannot be mitigated.	209
Any medicinal product containing more than 0.1 % PFAS APIs, which are required to be efficient, such a threshold would mean to phase out these products (with no replacement)	173
Minimal impact if in leaflet. Should be a position which is not already occupied by other important information to the patient on the use of the medicinal product. May raise concerns by patients leading to the medication not being taken, although the labeling is not safety related. Moreover, the benefit of the labeling is unclear, when compared to e.g. clear disposal advice.	377
Moderate impact, depending on bureaucratic burden. If introduced, a minimal reporting threshold is suggested.	109
Impossible for used medicinal product, as emitted through patient. Impact of waste water emissions is subject to EMA environmental impact analysis and to the Pharmaceuticals in the Environment (PIE) initiative. Additionally, in case of use in hospitals specific waste management schemes are in place. For unused product, initiatives to reduce waste emissions are already established: http://medsdisposal.eu/ For production equipment (filters, machinery), impact is low, as waste streams are already controlled by the manufacturing company.	541
not applicable	14
	0
not applicable	14

not applicable	14	
	0	
Discharges to water of APIs that contain PFAS from Bulk manufacturing facilities, are regulated via the Industrial Emissions Directive under a permit. All solid API waste streams are collected and disposed of according to regulations. The Eco-Pharmaco-Stewardship (EPS) is an important holistic initiative to address emerging environmental concerns: https://www.efpia.eu/news-events/the-efpia-view/efpia-news/151009-eco-pharmaco-stewardship-eps-a-holistic-environmental-risk-management-program/	494	XXXXXX

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2nd Stakeholder Consultation c

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Medical Devices report summary:
https://www.reach-clp-biozid-helpdesk.de/media/Help

Header (bold) / Question

V. Questions - Section B - Medical devices
Questions in relation to the use (mainly for industry associations)
[table of sub-uses, volumes, emissions]

Do you have information that indicates that the information provided on the emissions should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information that indicates that the information provided on the tonnage should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

The environmental release category (ERC) is a key REACH use descriptor to define the release factors of a chemical substance in a specific use exposure scenario. It is used in various modelling tools to derive environmental exposure estimates. ERC default factors are used to estimate emissions of PFAS in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.
Please indicate if you have information on specific emission values (SPERCs) for (groups of) PFAS, based on measurements and / or model calculations. (1000 characters)

Do you have information that indicates that the information provided on the expected trend should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

V. Questions - Section C - Medical devices
Questions in relation to alternatives (mainly for individual companies)
[no table]

What is the specific application/functionality of PFAS in your product(s)/processes? (1000 characters)

Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Do you have information on the alternatives' risk profile? (yes/no)

Please describe.
1000 characters

Are there legal approval schemes for your product(s)/ processes, which have to be taken into account in case PFAS alternatives will be used? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

What is the average approval time? (1000 characters)

Do you actively work on finding alternatives? (yes/no)

Please specify. (1000 characters)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain. (1000 characters)

Do you have information on alternatives for any of the described applications in the attached information? (1000 characters)

V. Questions - Section D - Medical devices
Questions in relation to impact of legislative measures
(for companies and industry associations)

What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) in 3 years (1000 characters)

b) in 10 years (1000 characters)

c) Please explain by providing your calculations. (1000 characters)

What is the economic impact (euro) on your business/ company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles. (1000 characters)

b) Obligation to label your products visibly with "Contains PFAS". (1000 characters)

c) Obligation to report amount of PFAS in use and respective emissions. (1000 characters)

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately. (1000 characters)

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production. (1000 characters)

V. Questions - Section E - Medical devices
Specific questions for the use

If available, please provide information on PFAS emissions during medical device production. (1000 characters)

If available, please provide information on market trends for contrast media, propellants, F-gases and/or medical devices. (1000 characters)
If available, please provide information on fluorine-free alternatives for medical devices. (1000 characters)

End of Questionnaire

on PFAS, July 2021

s/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicationFile

odesk/download/Report%20summary%20medical%20devices%20july%202021.pdf

Response Consolidated

Yes

Anesthetics, contrast media and other functional or excipient substances interact with human physiology in a drug-like manner. Like other drug substances, there are no alternatives to the molecular structure, they are thoroughly tested for human exposure and emission cannot be controlled. They should therefore be covered under "Medicinal Products". Our understanding of a "Medical Device" is an article for treatment, support or diagnosis that has an end of life and disposal aspect. The responses in this section aim at this category of products.

Yes

The Sub-use 'MDI incl. F-Gas' is listed as '24,000 - 43,000 tonnes PFAS/year in EEA'. We believe however that this value represents the much broader use category "Industrial processes including F-gas production" as stated in the report summary for Table 7 (page 10) and is not representative for the use of F-gases/propellants in the manufacture of metered dose inhalers. Manufacturers assume a volume of a few thousand tons per year, which should be covered as Medicinal Products for the reasons given above.

PTFE is widely used across the Medical Device industry, but tonnage information must be provided by PTFE manufacturers. https://news.3m.com/PFAS-in-the-Medical-Industry https://pfas-1.itrcweb.org/2-5-pfas-uses/

We do not have information on specific emission values. The only stage where PFAS could potentially be released from Medical Devices in the narrower sense as laid out above would be in the waste stage at the end of life of the device. During use or manufacture of the medical device no environmental emission of PFAS containing parts takes place.

No

Yes

No human exposure to PFAS in Medical Devices in the narrower sense. Human exposure of substances we consider Medicinal Products (anesthetics, excipients) is tested and approved in accordance to pharmaceutical regulations. Devices like injector pens are generally incinerated at end of life. Use and disposal instructions for medical devices that contain medicinal products are provided on https://www.medicines.org.uk/emc/

Typical applications of PFAS in medical devices are:
1) greases (Superlube) that are applied to parts that are susceptible to wear and create consistent forces that need to be accounted for in software (ballscrews, pistons, etc.).
2) external wear surfaces: parts have PFAS molded directly on plastic surfaces or included in protective coatings of metals to reduce sliding forces and prevent wear
3) cable insulation: used for flexibility and low wear inside assemblies.
Functional attributes of the used PFAS, mainly powdered PTFE:
1) Chemical and biological inertness
2) Physical properties such as insolubility, low friction, low conductivity
3) thermal, radiation and long-term stability

No

The primary alternative suggested for our application are silicones. These are technically no feasible replacement because they do not typically maintain their presence on the parts throughout life, they create changes in forces that need to be remain constant for device function, and they wear more so that devices do not reach lifetime requirements.
Silicones containing D4, D5 and D6 at >0.1% by weight are already included in the REACH Candidate List and must be declared and tracked, rendering them regrettable substitutes. Additionally, for use of silicones as mixtures (e.g. in grease) there is a restriction in process which most likely will restrict the use of silicones with >0.2% D4/ D5/ D6 in medical devices. However, further alternatives are under investigation.

Yes

Potential alternatives for PFAS materials in medical devices such as silicones are not expected to cost more than the high-price PFAS in use. Also, their share of the total value of medical devices is fairly low, so alternatives would economically be feasible. Still the function of these non-PFAS substances are not suitable, and no PFAS free alternatives have been identified to date.

Yes

Silicones might contain D4, D5 and D6 at >0.1% by weight. D4, D5 and D6 are already included in the REACH Candidate List as being PBT substances and must be declared and tracked. Additionally, the use of D4/D5/D6 in mixtures with >0.2% in medical devices will most likely be restricted in Europe.

yes

Approvals are required according to the EU Medical Devices Regulation (Regulation (EU) 2017/745)

Regulatory approvals under EU MDR typically take 9 to 18 months per submission.

Yes

Information was received from EFPIA member companies that at least some are actively working on the identification of alternative substances.

After an alternative substance is identified it takes about 5 to 8 years to implement the change, depending on the number of devices per company and the number of parts which are changed. This includes R&D, functional testing, adaption of manufacturing process and stability testing (about 3 years). Additionally, for each medical device regulatory filings would be required.

No

Impact on public health as certain medical devices are no longer marketed in the EU.

Same as above, but impact might be lower if PFAS free alternatives are identified and the changes are implemented.

The social impact of losing therapeutic options is considered much higher than potential loss of revenue and jobs. For this reason, the assessment focuses on public health.

Some medical devices do contain greater than 0.1% of PFAS in parts. Those could no longer be marketed, and the consequences are similar to a ban, with the economic impact not being the predominant concern.

No direct impact, but the wording may raise concerns leading to the device not being used or the medication not being taken, although the labeling is not safety related. Moreover, the benefit of the labeling is unclear, when compared to e.g. clear disposal advice.

Low impact. To reduce bureaucratic burden, a reporting threshold would help so insignificant amounts do not need to be reported. It also requires a clear reporting duty assignment in the supply chain (PFAS manufacturer/equipment manufacturer/seller).

Low impact, as waste management is already in place: use and disposal instructions (for medical devices that contain medicinal products) are provided in https://www.medicines.org.uk/emc/

n/a

No significant environmental emission during production of medical devices takes place as all waste streams are controlled.

This is being investigated, but no alternatives for the PFAS still in use were identified yet.

&v=3

Chars

0

3

549

3

724

347

3

0

3

424

0

691

2

778

3

386

3

296

3

96

79

3

141

379

2

0

84

114

172

206

264

250

187

3

0

124

0

94

2nd Stakeholder Consultation c

https://www.reach-clp-biozid-helpdesk.de/SharedDocs

Food contact materials & packaging report summary:
https://www.reach-clp-biozid-helpdesk.de/media/Help

Header (bold) / Question

V. Questions - Section B - Food contact materials & packaging
Questions in relation to the use (mainly for industry associations)
[table of sub-uses, volumes, emissions]

Do you have information that indicates that the information provided on the emissions should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information that indicates that the information provided on the tonnage should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

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Please indicate if you have information on specific emission values (SPERCs) for (groups of) PFAS, based on measurements and / or model calculations. (1000 characters)

Do you have information that indicates that the information provided on the expected trend should be adjusted? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

V. Questions - Section C - Food contact material & packaging
Questions in relation to alternatives (mainly for individual companies)
[table of sub-uses and non-PFAS alternatives]

What is the specific application/functionality of PFAS in your product(s)/processes? (1000 characters)

Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes? (yes/no)

Please specify why.
1000 characters

Do you have information on the alternatives' risk profile? (yes/no)

Please describe.
1000 characters

Are there legal approval schemes for your product(s)/ processes, which have to be taken into account in case PFAS alternatives will be used? (yes/no)

Please specify and/or refer to literature/public sources. (1000 characters)

What is the average approval time? (1000 characters)

Do you actively work on finding alternatives? (yes/no)

Please specify. (1000 characters)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain. (1000 characters)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information? (1000 characters)

V. Questions - Section D - Food contact material & packaging
Questions in relation to impact of legislative measures
(for companies and industry associations)

What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) in 3 years (1000 characters)

b) in 10 years (1000 characters)

c) Please explain by providing your calculations. (1000 characters)

What is the economic impact (euro) on your business/ company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles. (1000 characters)

b) Obligation to label your products visibly with "Contains PFAS". (1000 characters)

c) Obligation to report amount of PFAS in use and respective emissions. (1000 characters)

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately. (1000 characters)

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production. (1000 characters)

V. Questions - Section E - Food contact material & packaging
Specific questions for the use

If available, please provide information that allows a quantitative estimation of PFAS emissions during the manufacture of consumer and industrial applications as well as food packaging material. (1000 characters)

If available, please proivde data on (PFAS impurities in) polymer production aids emission during the production of consumer cookware & industrial applications. (1000 characters)

If available, please provide information on the use of fluorinated gas or fluorinated processing aids in plastic packaging production (food as well as non-food packaging). (1000 characters)

End of Questionnaire

ɔn PFAS, July 2021

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ɔdesk/download/Report%20summary%20food%20contact%20materials%20and%20packaging%20july%202021.pdf

Response Consolidated

No

No

No

No

No

The pharmaceutical industry package solid dose (tablets) in 'Blister' packaging to preserve and protect products from numerous external factors. There are two forms of blister packaging (thermoform and coldform). PVC, PVDC, PCTFE (Polychlorotrifluoroethylene) are materials used for 'thermoform' types of blisters. The unique features of PCTFE (high barrier to moisture, transparent, thermoformable, chemically very stable and inert, non-sticking, non-aging and sterilizable) make PCTFE the ideal solution for products that require a high level of protection. PCTFE is currently not listed under the OECD definition of PFAS, but the broader definition of “substances containing at least one -CF2- or CF3-group" would include it.
http://www.pharmanet.com.br/pdf/blister.pdf

Beyond blisters, packaging of liquids (rubber, plastic, coatings) is also impacted. Examples are PFAS (ETFE, PTFE) coatings on vial stoppers or syringe elastomer surfaces or as liners in glass bottle caps:

No

PVC is the primary structure used in a thermoform type blister; 100% PVC is an alternative but adding a layer of PCTFE gives technical advantages (see above) for those medicines that require a higher level of protection. Coldform foil (CFF) blistering is also a feasible alternative in terms of product protection, but there are technical limitations and other impacts vs thermoforming. CFF requires bigger pockets to contain the same medicinal product; bigger pockets = larger blister cards (up to 300% blister footprint increase for each product). The possibility to produce smaller blister cards via thermoforming allows the web-layout of the blister packaging line to have more blister cards, which translates into higher speed in the blistering process (CFF packaging is up to 500% slower). The pack size for PVC/PCTFE blister cards reduces storage space, transport and packaging materials to pack/store/ship the same quantity of medicinal products, therefore using less natural resources

No

N/A See documents attached (Blister word.doc)

No

Yes

Materials used in Primary Packaging (blisters) are included in the Regulatory Submission documentation for each medicinal product. Any modification (e.g in European Union and countries/regions depending upon EU approval) would require a resubmission and reapproval by the European Medicines Agency.
https://www.ema.europa.eu/en/plastic-primary-packaging-materials

3-5 years depending on which global Health Regulatory Agencies. This time would include R&D and stability testing requirements and approval timings.

No alternatives being sought (to PCTFE)

No alternatives (to PCTFE) have been identified so far. Estimated timeline for a complete transition, if needed, following establishing feasibility, is around 5-10 years (including stability studies generation). This is due to numerous SKUs for each Medicinal Product and the fact there are hundreds of impacted Medicinal Products.

No

The impact in 3 years is to interrupt the supply of medicines that are currently registered with PVC/PCTFE material. These products would have to be pulled from the EU market as 3yr transition is not long enough (see above)

Economic impact would be on investment in new packaging lines and regulatory submission time/effort. This will be different for each company depending upon their Packaging strategy.

These medicinal products would have to be pulled from the EU market as PCTFE is in thermoforming blisters >0.1% w/w

This is feasible but would take time/resource to complete.

This is feasible to calculate but would take time/resource to complete. We can confirm waste blisters (containing PCTFE) are incinerated.

The Pharma Industry encourage the collection and incineration of Waste blisters (containing medicinal products) across the EU. These are generally collected via Pharmacies and other health settings.

N/A

This will vary depending upon each Companies inhouse packaging losses.

N/A

N/A

Chars

0

2

0

2

0

2

2

0

2

0

0

981

2

993

2

45

2

0

3

364

148

39

0

331

2

0

223

181

0

115

58

137

199

3

0

70

3

3