# IATF for ePI Position paper on having a "Key Information Section" in the Package leaflet.

Position: From our perspective an additional Key Information Section should **not** be introduced in the package leaflets.

This position is based on the following considerations:

**Challenges for the selection of the content of the Key Information Section**

- Who will decide on what is key to include in this section? Every patient needs personalised information depending on their needs, so what is key for one person, may be irrelevant for another (e.g. different information sought by a young pregnant woman versus an older man with multiple medications and renal dysfunction). Also, what is not key for most patients might be highly important for a small number of patients. So, providing adequate and relevant key information for all patients and users is challenging.
- If safety information is updated, who decides what the impact for the Key Information Section is.
- It would be difficult to keep the Key Information Section to a summary format (small size), especially for complicated/specialised products, and to maintain balance between benefit/safety/risk for compliance.
- There is a risk of liability issues as it might give a false reassurance to patients that reading the Key Information Section is sufficient for the safe use of medicines.

**Concern for increase of leaflet size**

- Adding a Key Information Section will increase the size of the leaflet, while many patients already indicate that the leaflet is too long. It will thereby counteract our objective to shorten the leaflet.
- In addition, patients may rely only on this Key Information Section, therefore not reading the full leaflet and potentially missing important information relevant to them. A disclaimer would be needed, even prolonging the information more.
- There would be redundancy between information in the Key Information Section and the rest of the leaflet, meaning patients could become overwhelmed as they would need to read more information if expected to still refer to the complete leaflet (i.e. the overall length of the leaflet increases).
- Cartons/boxes may not be able to accommodate a longer leaflet and this can have impact on supply chain and manufacture (packing lines and processes). Additionally, we have to take the environmental aspect into account.
- Alternatively longer leaflets (especially multilingual leaflets) may also require smaller font sizes, which is not preferable as it jeopardizes legibility.

**Regulatory Burden**

- Adding this new section would require regulatory assessment of all leaflets, which will increase the workload for both industry and regulatory authorities when there is already a lack of resources at authorities.
- In addition, this summary would need to be 'reviewed' at every change of the leaflet which may add another level of complexity.

- The task of maintaining version control and ensuring content accuracy throughout all sections of the leaflet is considerably heightened with the inclusion of a separate section, introducing challenges to the overall integrity of information presented.

**Patients and Future potential solutions**
We can understand the fact that patients may find the idea of a summary very appealing to read only a subset of the information. However, we are afraid that they will base their opinion on the leaflet as they know it today; whereas the content of the leaflet of tomorrow should be shorter more patient centric and further taking into account patients needs. We believe it will be very difficult to implement and overall, there are more downsides than advantages. Additionally, there may be other ways to achieve this goal. For instance, the upcoming digitisation of leaflets will offer the patient the ability to search for the information which is key for them. It may also allow the option to expand some sections and it might evolve in future to select and provide information tailored to the profile of the patient.

***Pharma legislation review ENVI amendments referring to a key information section.***
*890 (Article 63 – paragraph 3 a (new)), 891 (Article 63 – paragraph 3 a (new)), 142 (Annex VI), 933 (Article 64.1a.)*

**The Association of the European Self-Care Industry (AESGP) is the official representation of manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe.**

**The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research-based pharmaceutical industry operating in Europe.**

**The Medicines for Europe is the official representative body of the European generic biosimilar and value-added pharmaceutical industry.**