Making dementia a priority:
changing perceptions, practice and policy.

Alzheimer Europe contribution to the European Commission public consultation on its legal proposal on information to patients

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1. Alzheimer Europe welcomes the opportunity to contribute to the European Commission's public consultation of a legal proposal on information to patients.

2. Alzheimer Europe regrets that **the scope of the Commission's proposal is limited**. **It does not constitute the much awaited for "information strategy"** mentioned in Article 88a introduced to Directive 2001/83/EC by Directive 2004/27/EC which states that "*the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of information source's liability*." Any comprehensive proposal must not limit itself to the role and rights of the pharmaceutical industry while key information providers in which patients have the most confidence (i.e. health care professionals, patient organisations and regulatory authorities) are not included.

3. Alzheimer Europe considers **the proposal to be premature**, since the Commission did not wait for the results of its own **impact assessment** or the **outcomes of the Pharmaceutical Forum**. In particular, the proposal only proposes co-regulation whereas the impact assessment had asked for opinions on regulation and self-regulation as well.

4. Alzheimer Europe considers that the current **proposal fails to achieve the three objectives** stated by the Commission:

    a. The proposal does not constitute a **framework that will enable all EU citizens** to have access to objective, evidence-based, up-to-date, reliable, understandable, accessible, transparent and relevant information, consistent with statutory information, from a wide range of sources as it limits itself to enumerating rules for the pharmaceutical industry only.

    b. The proposal will not provide **a clear distinction between advertising and non-promotional information**. Defining information in the negative as everything that is not advertising fails to achieve that objective.

    c. The proposal will not avoid **unnecessary bureaucracy**. The proposed co-regulatory system would provide a hybrid of national co-regulatory bodies and a European advisory committee with no real powers thus only creating more bureaucracy with little added advantage.

5. Alzheimer Europe considers that **the proposal also fails to harmonise information practices in Member States.** The proposal will not harmonise practices in information provision to patients, as national co-regulatory authorities may come to completely different interpretations.

6. Alzheimer Europe agrees **with the proposed continued ban on advertisement** on medicinal products. For that to be successful though, the organisation believes

that advertising and information must be clearly defined to avoid any misinterpretations.

a. The organisation agrees with having a clear **distinction between information "pull" and "push" mechanisms** and calls on the European Commission to continue with the ban on the latter and to define modalities for patients actively seeking information to be able to access such information.

b. Alzheimer Europe considers **information provided by market authorisation holders on their medicines in the media such as radio, TV and print media as advertising** and does not support the Commission proposal in this respect.

7. Alzheimer Europe **does not support the suggested co-regulation system** with sanctions only for "repeated and severe cases of non-compliance". The organisation would prefer a system involving EMEA and national competent authorities in the verification of information on medicines with adequate sanctions for all cases of non-compliance.

8. Alzheimer Europe **welcomes the possibility of industry answering individual requests** and the introduction of a system where this information provision can be verified.

9. Alzheimer Europe regrets that the proposal **does not address one of the G10 recommendations on public-private partnerships** that must be considered in a comprehensive information strategy.

10. In conclusion, Alzheimer Europe does not support the proposal as it is seriously flawed in many aspects and invites the Commission to come back with a new proposal taking full account of previous consultations, the impact assessment and the outcomes of the Pharmaceutical Forum.

11. In particular, the organisation refers the Commission to proposals made by Alzheimer Europe in previous consultations, as well as the contributions made by patient organisations involved in the Working Party with Patient and Consumer Organisations of the European Medicines Agency.