To whom it may concern

Diabetes UK Response to the DG for Enterprise and Industry Public Consultation: "Legal Proposal on information to patients".

About Diabetes UK
Diabetes UK is one of Europe's largest charitable patient organisations. Our mission is to improve the lives of people with diabetes and to work towards a future through diabetes through care, research and campaigning. With a membership of over 175,000, including over 6,000 healthcare professionals, Diabetes UK is an active and representative voice of people living with diabetes in the UK.

Facts about diabetes
- Diabetes affects up to 2.3 per cent of the UK population, with up to 750,000 remaining undiagnosed.
- Diabetes consumes between 5 and 10 per cent of total health care resources in the UK
- The impact of living with diabetes can be devastating, if poorly controlled, leading to coronary heart disease, blindness, kidney disease and foot problems and amputations.
- Increasing evidence is showing significant need for improved education and supported self-management to improve the health outcomes and quality of life of people living with diabetes.

Summary Response
Diabetes UK welcomes the opportunity to respond to this preliminary proposal to allow pharmaceutical companies opportunities to provide greater information about medicines and treatments direct to patients.

Evidence has shown that patients wish to have greater access to high quality information about medicines and treatments. Poor access to such information can significantly on quality of care and diabetes management. (Diabetes Information Jigsaw. 2006) People with diabetes and their carers need to have greater access to the education and information about diabetes, diabetes care and treatment options. However, it is important that information provided is of high quality, accurate, understandable, up –to-date, non-promotional AND unbiased. Furthermore, information about interventions and treatments that are not pharmacologically based is also required. Appropriate regulations and controls need to be in place to ensure that patients are protected from promotional and biased information about prescription medicines.

Diabetes UK supports proposals to increase awareness of and access to information about diabetes, but does not believe that the proposals contained within this consultation make a clear enough distinction between information and advertising.

At a national level, a wide range of stakeholders are involved in the provision of information about conditions, treatments and lifestyles. These include in the UK, health and social care professionals, Government, research agencies, patient organisations, patients themselves as well as the pharmaceutical industry. These proposals do not take account of any other engagement in the activities of producing, providing and/or disseminating health or treatment/medicine specific information. It would therefore benefit from having a broader approach to information provision.

Key comments about the proposal include:

- The impact assessment referred to should be carried out and published for further comment prior to preparation of a legal proposal.
- There is a need to consider how more comparative information about risks and benefits of different products can be made available.
- A wider information strategy incorporating (and recognising the differences between) health awareness, condition specific information, self-care, access to health services and medicines involving all stakeholders is needed.
- The framework should take account of individual Member States regulations and healthcare systems.
- Further groundwork is needed to identify 'how' to differentiate between advertising and information provision and between 'allowed' and 'not allowed' information, involving all Member States.
- The purpose and objectives of this framework should be widened to specifically include information about other alternative and non pharmacological treatments.
- Increasing access to information about health and conditions to improve health awareness amongst populations should be encouraged and the pharmaceutical industry can play a key role in this. However to increase this further, legislation does not need to be changed as it is not promoting or advertising specific prescription products.
- It is unclear how the proposed monitoring structure will take account of nation specific regulations and provide independent accreditation of information provided.

Specific comments

<u>2.2 Objectives and impact assessment</u>

Diabetes UK wonders how this proposal has been made without an assessment of the possible impacts on individual Member States. It would have been far better to have published an assessment of impact prior to the consultation, to enable stakeholders to comment on identified [and potentially unidentified] impact. **The lack of any detailed information about the practical application or interpretation of the key proposals means that a further consultation, prior to preparation of a legal proposal, should be considered.**

3. Key ideas of the forthcoming proposal:

- to create a framework for the industry to provide certain information on their medicines to the public to harmonise practices on information provisions to patients in Member States.

3.1 The proposal supports the continued rules on not allowing direct to consumer advertising of prescription only medicines to the general public. This is welcomed.

3.2 States that the rules on information provided by pharmaceutical companies on prescription only medicines be revised. "…*communication not covered by the definition of advertisement, should be regarded as information. Clear criteria should distinguish the information that is allowed from the information that is not allowed*".

Diabetes UK is not aware of any single, or agreed, definition of advertisement or advertising. Indeed in the UK, advertising is generally considered to be part of information giving. The Medicines Act 1968 (amended) prohibits any advertisement of treatment products defined as information containing a 'product claim. The proposals state that the quality, safety and efficacy of medicines will be key information items that the pharmaceutical industry will make available. It is unclear how this will not be interpreted as product claims, and therefore how it will impact on the UK legislative systems. This proposal has not clarified the differences between the type of activity and the means by which it is delivered – both of which impact on whether information is, or is perceived to be advertising. The definition of advertising used within this proposal is contained within Article 86 of Directive 2001/83/EC.

This section states that "*information available should be compatible with approved summaries or product characteristics… and should not go beyond the key elements specified in them*". **We question the benefit of producing further information if it cannot present anything different than that already contained within patient information leaflets. More comparative information about risks and benefits is needed to fully inform patient choices.**

The proposal is unclear and inconstant in the terminology and definitions of 'information'. Diabetes UK supports increased information provision about conditions to raise awareness and understanding and involvement of industry would help considerably in this area. However, this proposal appears to relate to information about specific products only. **A wider information strategy is needed to improve access to information on health, conditions and medicines, involving all relevant stakeholders.**

3.3 Clear criteria or detailed clarification/ interpretation to define the difference between where a patient is passively receiving information (push) or actively searching for information (pull) is absent from this proposal. Therefore no definition is available to define the differences (or perceived differences) between information provision and advertising. The examples

of advertising, push and pull information techniques listed in the table do not adequately reflect the differences. The means of disseminating information impacts on whether information is considered, or perceived, as advertising as well as the claims made. For example, the use of TV or radio to provide information about specific products can generally be considered as advertising. Diabetes UK supports the need for people with diabetes to have greater access to high quality information about the medicines they are using (over the counter and prescription) and signposting people to it, providing professionals with better information to give out with products or providing better information within the product would help. Furthermore many local patient groups are keen to be provided with unbiased and comparative information about new products. It is unclear how the proposals here will facilitate this.

Further groundwork is needed to identify 'how' to differentiate between advertising and information provision and between 'allowed' and 'not allowed' information, involving all Member States.

The point at which a person needs information about a particular prescription medicine should be supported by professional advice and signposting. This is a 'pull' mechanism where a joint decision is made by the person with diabetes and their healthcare professional about using a prescribed medicine. At which point the person with diabetes can be signposted to further information about the product and how to use it. This could come directly from a company providing the product or via other independent sources e.g. Medicine Reviews and patient organisations.

Improving access to information about health and conditions to raise health awareness and understanding amongst populations should be encouraged and the pharmaceutical industry can play a key role in this. However to increase this further, legislation does not need to be changed as it is not promoting or advertising specific prescription products.

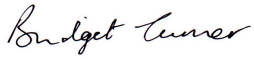
4. Quality criteria. The proposal recommends that all information fulfil specific criteria. This is welcomed. However, the means of assessing whether the information is objective, unbiased, patient oriented, evidence based, up-to-date, accessible, transparent, relevant and consistent with approved information, is not defined. The statement saying that 'comparisons between medicinal products should not be allowed' contradicts the previous sentence saying that the information will not be promotional or biased. Diabetes UK questions how this can be achieved if product specific information is not compared. Furthermore there are few consistent ways of assessing the quality of information content without asking the patient using the information themselves. It is information about different products and interventions that people with diabetes would benefit from to enable comparison and informed choices to be made. The UK Information Accreditation programme is developing a Standard for accrediting organisations that provide information (not the information content itself) and there may be lessons to learn from this model.

This proposal does not provide any indication of if and how information about 'non-pharmacological' products will be provided. The management of diabetes is as much about lifestyle and non-medicinal interventions and information must be provided about these alternative treatments, e.g healthy eating, physical activity, to fully inform patients and allow choices between different options. People with diabetes need to have information on the different treatment options so that they can make a proper choice. This also requires that patients have access to information to compare treatments – those provided by different companies as well as lifestyle interventions. Comparisons between medicine products can only be helpful, and encourages the philosophy of patient empowerment. Diabetes UK is concerned that this proposal does not fulfil all the information needs of people living with diabetes as it currently stands. Furthermore, we question how this proposal fits in with previous consultations to provide a European 'Diabetes Information Package' – to which comment was made by Diabetes UK in 2007. **We recommend that the purpose and objectives of the framework proposed are widened to include information about conditions, awareness raising, self-management and self-care as well as access to healthcare services. This information should be disseminated to take account of individual Member States regulations and healthcare systems.**

5. The proposed structure for monitoring and sanctions does not show how it will take account of individual Nation specific rules and regulations. **There is a strong need for the monitoring of all information which is governed by clear rules.** However the resourcing of any monitoring framework must not be at the expense of direct patient care. These rules have not yet been defined and need to be to progress. Monitoring of complaints only is not a satisfactory means to quality for patients when adopting such a new venture. The process and criteria for monitoring such a proposed change in legislation needs to be clearly defined to allow comment and assessment of impact. **Diabetes UK has concerns about how the EU Advisory Committee ensure the appropriate provision of independent, non-promotional information about prescription medications if it represents the interests of the pharmaceutical sector.** It is essential that independent accreditation of information is undertaken to protect patients and avoid inappropriate promotional activities.

We hope these comments are helpful in your deliberations. We look forward to commenting further as this progresses.

Yours sincerely



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