LTCA Response To The EU Commission Consultation On A Legislative Proposal On Information To Patients

LTCA is the umbrella body for over 100 national voluntary organisations working to meet the needs of people with long-term health conditions in the UK. Our vision is of a society in which people with long-term health conditions have control over their lives and can live them to the full.

LTCA welcomes the opportunity to respond to this consultation, and would be happy to discuss further any of the details of the response, or the wider issues raised by the consultation.

Introduction

LTCA considers that all patients, no matter their disease, condition, background or nationality, have a fundamental and legitimate human right to access quality information about their health, medical conditions and treatments and their availability, including knowledge of the best available management of their disease. It is a question of solidarity, equity, and patients' rights.

In considering the Commission's proposals we should wish to note that patients' need for quality information goes much wider than information about medicines. Patients need information about disease, treatments other than medicines, impact of disease, and risks and benefits of treatments.

We therefore note that the proposals cover only medicines, and so can, at best, only address a part of patients' need for information. With this in mind we would urge that in producing any proposals, the Commission, with due regard to subsidiarity and proportionality, take full account of any other arrangements that exist at Member State level for the regulation of health information.

In support of the European Patients' Forum submission, LTCA agrees with the view that a legislative proposal focusing on prescription medicines**, in concert** with other developments within the Pharmaceutical Forum Working Group on Information to Patients, and the new EU health strategy 'Together for Health' can make a significant contribution towards achieving this goal, when implemented effectively, with the best interests of patients in mind, and driven by the fundamental right to know.

We would therefore urge the Commission to proceed in presenting the proposal to the European Parliament and Council.

Main Policy Objectives

In this spirit, LTCA endorses the vision behind the proposal, namely;

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'to put the interests of patients first and……to aim at reducing differences in access to information and ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products'.

We also support the main policy objectives of the proposal, i.e.

1. Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.
2. Maintaining a clear distinction between advertising and non-promotional information.
3. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

Issues of Specific Concern

The distinction between quality information and direct-to–consumer advertising

This distinction will be fundamental to ensuring patient confidence in any legislative framework. Although the need for a distinction is implicit in the text and the table of proposed action, using agreed quality criteria and medicine authorisation documents (product information leaflets PILs and summaries of product characteristics SPCs) as a frame, we believe that greater clarity regarding this distinction is essential.

LTCA supports EPF's proposal, for the development of illustrative examples, contained within a supporting text, to clearly identify the key difference between "quality information" and "advertising". These examples could also be referenced within the code of practice to be developed for both industry and regulators.

The distinction between 'push' and 'pull' information mechanisms

LTCA supports EPF's proposal that 'push' information, or information received passively by citizens through printed material, TV, radio and other media, be subject to ex ante verification, to ensure that it does not fall within the definition of advertising.

Regarding 'pull' information, or information sought by patients through registered websites, or through written or oral requests to pharmaceutical companies, we similarly support the EPF proposal that the latter be monitored on the basis of a complaints procedure that is accessible and patient friendly.

Finally, regarding registered websites, we support the EPF proposal that companies should be obliged to notify the co-regulatory body regarding the development of a new webpage/section, together with a brief concept note on the nature of the information it contains.

The Quality Criteria

LTCA welcomes the proposed use and application of the quality criteria developed and adopted in the framework of the Pharmaceutical Forum to underpin the different forms

of information to patients. Given that these quality criteria will be used and implemented in other EU and national developments on information to patients, this should also help to ensure that the legislative proposal is, and is seen, as being part of a broader overall strategy on the provision of comprehensive and holistic information to patients to support them in the management of their disease and their daily life.

Proposed Structure for Monitoring

We are further in agreement with EPF's qualified support for the approach proposed for the overall monitoring structure and systems. The qualification being that it will be important to underline the transparency of all aspects of the monitoring system to further build patient and public confidence.

We believe it is important for the proposed European Advisory Body also to be composed of key stakeholders, including in particular the representatives of the target users themselves, patients. This approach would ensure that the new body reflected the structure of the proposed national co-regulatory bodies. We would like to stress the importance of a transparent and inclusive procedure in forming the Advisory Body.

We would also suggest that the European Advisory Body could provide a model code of conduct using the quality criteria, upon which national models should be based, guidance bases on scenario examples regarding what constitutes quality information and what is advertising, and also guidance with regard to sanctions and penalties to ensure parity across the Member States.

With regard to the tasks identified for the national co-regulatory bodies, 'monitoring information providers' is redundant, as goes beyond the scope of the legislative proposal. We are also of the view that it is not the role of co-regulatory bodies to 'name and shame' or insist providers change illegal information. Their focus should remain on monitoring and reporting non-compliance to the competent authorities to take action and on responding to requests for support and guidance from companies on any ' grey' areas.

In conclusion, we look forward to seeing the Commission's proposal for legislation as and when it is published, and will offer further comments as we feel necessary.

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