Johnson & Johnson

Johnson & Johnson response on: "Commission consultation on legal proposal for information to patients"

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Introduction

As the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services for the consumer, pharmaceutical and medical devices and diagnostics markets, Johnson & Johnson is fully committed to playing its part in shaping the healthcare environment. As part of this objective, we welcome the "European Commission consultation on legal proposal for information to patients" and the opportunity to share our thoughts in relation to this important topic.

General comments

Johnson & Johnson welcomes the Commission's public consultation on a legal proposal on information to patients, which will pave the way for legislative proposals to enable EU citizens to have access on Information and the industry to interact with patients under legal certainty.

Indeed, citizens are increasingly taking greater control of their own health care. Johnson & Johnson maintains that quality information on health and treatment, adapted to the needs at the various stages of the patient journey is a crucial element in improving health outcomes as well as making a contribution to patient safety and patients/carers support.

Citizens (including patients as well as carers) need reliable and user-friendly information about how to stay in good health and the effects of lifestyle on health (i.e. substance use). In that particular respect, as part of any legislative proposal, Johnson & Johnson would support the development of a comprehensive and coherent health literacy programme that could include policies and products which would enable citizens and/or patients to make better informed decisions about health and well being.

When ill, citizens need as well information about their condition and treatment options. Information is the key, enabling citizens to make the right choices.

Thus, finding a satisfactory solution to the need for better and equal access to quality information (as demanded by patient organisations and other stakeholders), prohibited by the current legal framework is of utmost importance.

As this consultation will be used as the basis for legislative proposal on Information to Patients, we are happy to offer our views on this important initiative and in particular on the following specific provisions of the consultation:

Specific comments

As chair of the EFPIA Information to patients Task Force, we fully endorse the approach developed in the EFPIA position. Nevertheless, we would like to emphasise our views on the following critical issues:

1. <u>Dissemination of product information through TV/radio channels:</u>

It is unclear in the Commission consultation document what types of communication are envisaged, but in view of the latest attempts to liberalise information to Patients (debate during the Revision of the Pharmaceutical legislation in 2004), broad political and public opposition to this specific proposal can be expected. Therefore, we do not support this option and propose to limit information

"pushed" to patients, to general health information (e.g. disease awareness), and not to specific medicines. On the other hand, we would recommend that when information is "pulled" through enquiries from patients, companies should be able to provide high-quality information.

2. Regulatory versus co- or self-regulatory models:

While giving these three options, the Commission proposal seems to favour a co-regulatory model. We would instead favour a European industry "health information code", based on self-regulatory principles with efficient governance structures and robust enforcement procedures, but also including involvement of third parties/independent stakeholders such as healthcare professionals and patient representatives. Implementation of such codes would be at the national level. The Commission should trust the establishment of such self – regulatory scheme, which should target to provide high quality information to patients on diseases and treatment options including information from the pharmaceutical industry. This non-promotional health and medicines scheme will secure the accuracy of information already provided on the Internet by non-reliable sources.

3. Developing the concept of health literacy as a preventive tool to improve healthcare outcomes:

Health literacy defined as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" should be an integrated goal of any legislative proposal to advance consumer's health understanding including risk. As proposed by the "DG-Sanco future challenges paper: 2009-2014" to add progammes in 2008-2013 on health literacy, we believe this is an approach that can further enhance engagement in health for prevention, early diagnosis and effective treatment. We believe that the ideal decision-maker for personal health ought to be the citizen and/or patient.

All should have the information necessary to make decisions to choose how we live, when to seek medical care, which over the counter medicines we should purchase, how we should take medicines for the best outcome, how to find and access innovative, quality care and how to best maximize our health care spending. We would support this concept to be addressed in any legislative proposal as clear evidence supports it value. This could include proposals for interventions advancing a health literate public such as developing evidence-based centers of excellence for research and interventions as well as innovative campaigns that advance health understanding leading to overall health and well being of society.

Conclusion

Johnson & Johnson would like to reiterate its support for the consultation. We will be happy to engage further with the Commission to help put in place - without delay - an effective health information provision in Europe, which will benefit to patients and to the society as a whole.