SUBMISSION OF COMMENTS ON DRAFT LIST OF WAIVERS [document not numbered or dated] EMEA/289856/2007SUBMISSION OF COMMENTS ON INFORMATION TO PATIENTS: PUBLIC CONSULTATION, DEADLINE 07 APRIL 2008

COMMENTS FROM <ORGANISATION: Good Clinical Practice Alliance - Europe **/ CONTACT PERSON:** Francis P. Crawley, Executive Director; fpc@gcpalliance.org>

GENERAL COMMENTS

Brussels, 7 April 2008

These comments have been prepared in consultation with the following organisations:

- Ethics Working Group, European Network for Research on Alternating Hemiplegia in Childhood (ENRAH) [FP6 funded project] / Contact Person: Tsveta Schyns, ENRAH Secretary General, ts@enrah.net

- Working Group on Ethics, Union of European Medical Specialists – European Academy of Paediatrics (UEMS-EAP) [formerly CESP] / Contact Person: David Neubauer, Chairman, david.neubauer@mf.uni-lj.si

- Research Committee, International Primary Care Respiratory Group (IPCRG) / Contact Person: David Price, Chairman, david@respiratoryresearch.org

The Good Clinical Practice Alliance – Europe (GCPA) wishes to express its appreciation to the European Commission, DG Enterprise & Industry, Unit F2 "Pharmaceuticals" for bringing forth for discussion this 'Legal Proposal on Information to Patients' for Public Consultation until 7 April 2008. As an independent and not-for-profit European organisation involved with research on medicinal products, many of which are already marketed and all of which will derive significant information from studies, the GCPA is well positioned to provide high-level comments on the provision of information to patients. The GCPA appreciates the legal context of Directive 2001/83/EC in which this Consultation has been drafted as well as the importance and contribution of the 'Communication addressed to the European Parliament and the Council on the Report on current practices with regard to the provision of information to patients on medicinal products' 20 December 2007. The GCPA also appreciates the value and potential contribution of the parallel 'impact assessment' analysing of the likely impacts of the main options and examining possible synergies and trade-offs. Our comments are provided taking into account this legal and political framework.

The proposal for a European framework for information to patients in the area of prescription-only medicinal products raises a timely and important discussion concerning the relationship between European patients, European health care authorities and professionals, and the pharmaceutical and biotech industry. The proposed legal framework should further empower the European patient and their organisations at the European and Member State level in order to further improve patient awareness and decision-making, patient care and treatment, and public health at the Member State and European levels.

The GCPA appreciates this document and the accompanying public consultation as an important step in developing a needed European legal framework for advancing information to patients.

The GCPA has 2 general comments followed by a listing of specific comments.

GCPA General Comments

General Comment 1: The GCPA considers that the forthcoming legislation should be directed at 'good quality, scientifically and medically sound, reliable, and appropriate information on medicinal products to citizens.'

Recognising that Article 88a of Directive 2001/83/EC (introduced by Directive 2004/27/EC) provides 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 the information source's liability', the GCPA prefers 'scientifically and medically sound' to 'objective'. We also prefer 'appropriate' to 'non-promotional'.

We do not see an immediate reason why the forthcoming legislation would be limited to 'prescription only' medicinal products. Directive 2001/83/EC, as quoted above, does not impose such a limitation on the Commission. European patients and health care professional would expect that all products labelled as 'medicinal' and intended for medicinal purposes should be assured being of 'good quality, scientifically and medically sound, reliable, and appropriate information' to the patient/consumer.

General Comment 2: The legal proposal does not take into consideration scientific information and the various forms in which this is published and made available to the European patient population. Scientific publications have recently been shown, repeatedly by European and international researchers, to contain specific bias and promotional tendencies. This information increasingly resourced and consulted by European patients should meet the same standards as being of 'good quality, scientifically and medically sound, reliable, and appropriate information on medicinal products'.

There should be clear consideration in the forthcoming legal proposal for the relationship between clinical trial information and information to patients. Information to patients should be founded on clear and accurate results from clinical trials concerning safety and efficacy. The proposed legal framework should indicate the role of clinical trial registries and results publications, in Europe and globally. This should include listings on the Internet and scientific publications.

As long as the information contained in the Eudract and Pharmacovigilance databases are available only to competent authorities, then these authorities have a responsibility vis-à-vis the patients to ensure that information on medicines provided to patients is founded on, and does not exceed, the results of clinical trials.

The legal proposal should take into account the 'Guidance on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation No. (EC) 1901/2006', ensuring an appropriate relationship between the information contained in the registration of clinical trials and the publication of the results of clinical trials (concerning medicines labelled for paediatric use, but not only such medicines).

In the context of a legal proposal on information to patients, the Commission might consider amending Directive 2001/20/EC with regard to public access to information contained in the Eudract and Eudravigilance databases. European patients would welcome this transparency.

SPECIFIC COMMENTS ON THE TEXT		
GUIDELINE SECTION TITLE		
Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
p. 2, 2.2, 2.	Under Objectives 2, it would appear difficult to maintain the distinction between 'advertising', on the one hand, and 'non-promotional information', on the other hand. The distinction would be difficult to define and enforce, especially in the context of a legal instrument designed to promote information to patients from the pharmaceutical and biotech industries. This too, in particular, in an age of an increasing global media (Internet, global & satellite television & radio, dvd's, and international popular and scientific press). If the criteria of 'good quality, scientifically and medically sound, reliable, and appropriate information on medicinal products' would be firmly established for all information provided to patients, the distinction between 'advertising' and 'non-promotional information' would appear needed and would help to ensure less controversy.	
p. 3, 1.3 & 1.4	The GCPA appreciates the publication of the comments and an analysis of the comments on the "Pharmaceuticals" website of the Directorate General Enterprise and Industry. The GCPA would further encourage the Commission to organise a public roundtable/conference on 'Information to EU Patients on Medicinal Products'.	That the Commission organise a public roundtable/conference on 'Information to EU Patients on Medicinal Products'. The GCPA would be willing to assist the Commission in the organisation of such a roundtable/consultation.
p. 4, 2.1	The GCPA appreciates the need to regulate the provision of information as provided by marketing authorisation holders. At the same time, information on medicinal products provided by competent authorities, healthcare providers, healthcare professionals, and other responsible parties should fall under the same set of rules. The	Amend the last paragraph of 2.1 as follows: 'The forthcoming proposal would amend Directive 2001/83/EC and, in keeping with the scope of this directive, would set rules on the provision of information by marketing authorisation holders, competent authorities, healthcare providers, healthcare professionals, and other responsible parties.

[1] Where available

	European patient is concerned that all authoritative and responsible parties ensure that correct and appropriate information is provided to patients and consumers on medicinal products.	This would be without prejudice to the form and manner of the provision of information and the Commission's declared intention that healthcare professionals should remain, as they are today, the primary source of medical advice [see below] to patients and consumers.'
p. 4, 2.1	Healthcare professionals are not in all cases, indeed in many cases, today the 'primary source of health information' to patients. The European patient currently relies on a large panorama of information for addressing healthcare for diagnosis, prophylaxis, and treatment. It is unrealistic to consider or want to enforce the healthcare professional as the primary source of health information. Rather, the healthcare professional should be considered the 'primary source of medical advice' to patients.	Amend the last paragraph of 2.1 as follows: 'This would be without prejudice to the form and manner of the provision of information and the Commission's declared intention that healthcare professionals should remain, as they are today, the primary source of medical advice to patients and consumers.'
p. 5, 2.2	The GCPA would like to be consulted on this topic during the preparation of the impact assessment. The results of the impact assessment should be made available to patients, their organisations, and other interested parties for comment.	
p. 6, 3.3	The distinction between 'passive (push)' and 'active (pull)' information provision appears artificial and difficult to maintain. It also does not appear to serve a clear purpose.	Rewrite section 3.3. to eliminate the distinction between 'passive (push)' and 'active (pull)' information provision and revise the table in section 6 in accordance with the elimination of the distinction.
p. 8, 5	If, as stated in early on the forthcoming legislative proposal is intended to put the interests of the patient's first, such that it is indeed patient-centred and takes into account patient needs and expectations in order to empower patients, then another structure for monitoring and oversight would appear more appropriate. The GCPA would propose that the EU Advisory Committee be chaired by the representative of an EU patient organisation and include representatives of competent authorities, healthcare professionals, industry, and other patient organisations. The forthcoming legislation should recommend the same structure for the National Advisory Committees. There would be no need for the so-called 'National Co-regulatory Bodies' (which, as presented here, do not appear to be properly named a 'regulatory' body).	Rewrite as follows: • EU Advisory Committee • National Advisory Committees The EU Advisory Committee should be chaired by a patient representative and composed of representatives of competent authorities, healthcare professionals, industry, and other patient organisations. The National Advisory Committees should be advised to have a similar structure. Both the EU and the National Advisory Committees would be responsible for - monitoring of information providers - adopting the EU and national codes of conduct

		- informing about non-compliant information - advising and monitoring activities of medicines information providers (from, for example, industry, competent authorities, healthcare institutions, health insurance providers, healthcare professionals, patient organisations)
p.10, 6 Table	This document should be prepared in a patient-friendly manner for comment. 'SPCs and PILs' are, without further definition and explanation, not clear to all EU patients. The regulators' and industries' language should be clarified in public documents intended to promote and empower patient interests.	

Please feel free to add more rows if needed.