SUBMISSION OF COMMENTS ON the Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines (dated Brussels, 11.03.2008)

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GENERAL COMMENTS

Brussels, 8 May 2008

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 'Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines' for Public Consultation until 9 May 2008. As an independent and not-for-profit European organisation involved with promoting dialogue between European and international clinical trial partners - including patient groups, researchers, ethics committees, sponsors/funders, and regulatory authorities - the GCPA brings extensive experience and contribution to the European and international discussion on combating counterfeit Medicines for human use, particularly with regard to the protection of the interests of patients.

The GCPA appreciates the European and international contexts in which this legal proposal has been prepared, including the

-'European Parliament Resolution on Counterfeiting of Medicinal Products', 9 September 2006

- Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, as last amended)

- Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice (OJ L 262, 14.10.2003, p. 22)

- WHO, 'Counterfeit Drugs: Guideline for the Development of Measures to Combat Counterfeit Drugs', Geneva, 1999.

- WHO IMPACT (International Medical Products Anti-counterfeiting Task Force), 'Principles and Elements for National Legislation against Counterfeit Medicinal Products', Lisbon, 12 December 2007.

The GCPA is concerned with the growing number of reported cases of counterfeit medicines entering the European Union medicinal products market place and their effect on the health of patients and the European health economy. The expansion of the EU borders, the growth in commercial and human transportation, and the increased use of the Internet for purchasing consumer goods have contributed to increased vulnerability to counterfeit and substandard medicinal products with the EU and a potential threat to consumer and patient confidence.

The GCPA wishes to express support for the measures outlined in the Commission proposal. This proposal will help to provide additional assurances to the European citizen and patient that the medicines sold within European borders are safe. The proposal will also help to ensure the protection of the legitimate interests of European manufacturers of medicinal products.

The GCPA, however, has two general considerations it wishes to bring to the discussion:

1. The GCPA believes that an effective European approach to combating counterfeit medicines requires individual Member State action *within* an overall Community framework supported by European law. In the context of this proposal, the GCPA has considered and proposes a 'Schengen-like Agreement' among Member States and supported by the Community to ensure oversight and enforcement of European-legislation regarding the Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), inspections, and importing & exporting regulation of medicinal products entering or exiting the European Union. Within such an agreement the understanding of European Union borders should be expanded to include a legally defined concept of 'electronic marketing borders' (e.g., Internet).

2. The GCPA is concerned that only the interests of European citizens/patients and the pharmaceutical industry are taken into consideration within this legal proposal to combat counterfeit medicines. While counterfeit medicines pose a serious threat to the European medicines market place, in some parts of the world outside Europe counterfeit medicines indeed dominate market places and have been attributed by the World Health Organization as a major cause for morbidity and mortality. The clear and vigorous statements in the EU Parliament's Resolution of 9 September 2006 and the IMPACT Guidelines of September 2007 with regard to the need for international cooperation to fight the scourge and criminality of counterfeit medicines in developing economies seemed to have been underlined by the European Commission support for this work initially but there is no consideration expressed here in this legal proposal. As the European Parliament and the members of IMPACT have clearly stressed, countries share a mutual obligation in fighting counterfeit medicines. The GCPA has had this concern repeatedly expressed in it collaboration with officials in Eastern Europe, Asia, Africa, and Latin America. We would propose that the concerns for Third Countries expressed by the Parliament not be ignored in the Commission's final legal proposal to combat counterfeit medicines. The GCPA is willing to assist the Commission in the preparation of such a consideration for assisting in the protection of Third Countries from counterfeit medicines originating in and/or trafficking through the Community.