FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: vendredi 8 janvier 2010 13:43
To: FUEHRING Stefan (ENTR)
Subject: FW: Clinical Trials Directive, Public Consultation Paper

A/513

From: Gillian Gregory [mailto:GGregory@gf-associates.co.uk]
Sent: Friday, January 08, 2010 1:35 PM
To: ENTR /F/2 PHARMACEUTICALS
Cc: SEFryer@gf-associates.co.uk; LShaw@gf-associates.co.uk; CDunk@gf-associates.co.uk
Subject: Clinical Trials Directive, Public Consultation Paper

Dear Sir,

COMMENTS TO THE EUROPEAN COMMISSION ON THE PUBLIC CONSULTATION PAPER ON THE ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC, reference: ENTR/F/2/SF D(2009) 32674

Gregory Fryer Associates is pleased to comment on the Public Consultation Paper.

Gregory Fryer Associates (GFA) is a clinical and regulatory consultancy based in the UK. The company was established in 2003, just before the Clinical Trials Directive was implemented. Between 2004 and 2009 GFA has filed approximately 30-40 CTA applications per year throughout the EU. These applications have covered Phases I to III, single country and multi-national studies, trials with advanced therapies, new chemical entities, products of biotechnology and trials with known actives. GFA is not an SME company although many of GFA's clients fall into this category. As well as supporting EU-based companies GFA prepares and submits clinical trial approvals for companies based in North America, Australia, Israel, Switzerland and Japan.

Against this comprehensive and practical background we wish to make the following high level comments on the Public Consultation Paper whilst acknowledging that we have not addressed each consultation item.

POINT 1: The technical requirements of the Clinical Trials Directive (the IMPD) have allowed the production of a common dossier on CMC, non-clinical and clinical data and this is welcomed. However local administrative requirements in the Member States continue to be non-standard, confusing, difficult to locate and frequently vary from what is published on their web sites. If these administrative aspects were transparent and simplified that would make the current system easier to work with and remove many of the criticisms.

POINT 2: Although the format of the IMPD is standardized we disagree with the wording in section 3.1 which states that: "It has to be pointed out that there are relatively few clinical trials where the application of the regulatory framework leads ultimately to divergent decisions in different Member States" In our experience of multinational Phase II and Phase III trials there are divergent decisions which relate to a number of issues such as the choice of the comparator, protocol design issues, the level of detail required in the quality section especially for products of biotechnology or advanced therapies, the inclusion of women of child-bearing potential and the requirements relating to shedding and environmental risk assessment. The resolution of divergence would be a significant concern in any harmonized approach to clinical trial approvals

POINT 3: There is divergence among Member States as to when the 60 day approval process starts and ends. However, it is considered that this could be resolved. An approval time of any more than 60 days is not attractive, especially when considered in the context of the 30 day period for IND approval in the USA. The clinical trial approval time should not be more than the current 60 days.

POINT 4: The classification of substantial amendments does need comprehensive overhaul. This is

open to different interpretation by the Member States and results in unnecessary work and administration. A list of situations in which a substantial amendment is or is not required would be extremely helpful. Such lists already exist on the websites of the Danish and French agencies

POINT 5: A “centralized” approach is too all-encompassing especially for those companies who may wish to run trials in only 3 or 4 countries. A “decentralized” approach, involving those countries in which the trial is to be performed, is a possibility but only if it offers reliable time advantages over the current system. The overall management of such a harmonized system is a concern; the DCP system for MAAs has seen the introduction of huge delays in pick-up times in many countries, possibly exaggerated by companies “booking slots” for their submissions and a similar situation could well arise in the context of clinical trial review.

POINT 6: GFA supports the existing national clinical trial approval system provided there is transparency relating to administrative requirements in all Member States and arrangements relating to substantial amendments are consistently followed. The clinical trial approval system should focus on helping companies move through the regulatory processes as smoothly as possible and there is a concern that a system involving several countries will lead to delay and lack of flexibility both in time to start review and in time to complete the review.

We look forward to reading the contributions from other submitting parties and we will be pleased to contribute further during the consultation process.

Yours faithfully,

Gillian Gregory

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