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LSCP Position as to EMEA eCTD Roadmap 0208

To Whom it may Concern

From : **LSCP** Global Management Team
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Subject : EMEA eCTD adoption Roadmap as of February 2008

Introduction

In November 2007 we informed our customer base of a forthcoming announcement from the EMEA on Guidance and timelines for eCTD-only submissions under the Centralized Procedure (CP) in EU Member States (MS).

Today our **LSCP SME** for **European Agencies, Dr. Malcolm Barratt-Johnson*** summarizes the **formal EMEA announcement** as follows:

Implications and opportunities of eCTD adoption by the European Medicines Agency (EMEA)

On the 22 January 2008 (posted February 5), the European Medicines Agency (EMEA) announced plans to accept from 1 July 2008, the electronic-only submission of information in support of marketing authorization applications (MAAs) under the CP: eCTD is the recommended electronic format. This will apply to **all applications** (new and existing) and all CP submission types in line with the "rolling submission" concept (e.g. requests for supplementary information, variations and renewals, ICSRs, and annual reports).

This is a key announcement by the EMEA paving the way for the Electronic Common Technical Document (eCTD) **format *and* structure** being the expected template for all centralized MAA submissions by 1 July 2009. Paper and other electronic formats will be the exception, with Rapporteurs and CHMP Members declining paper copies or other electronic formats from July 2009. A common implementation is expected across all Agencies with the eCTD format valid though not presently mandatory, for **all European procedures including decentralized / mutual recognition and national procedures**.

In the EU alone it is estimated that in 2005 between 272 and 350 million pages of printed documentation were submitted by pharmaceutical companies to European Regulatory Agencies in support of new agents: an average of 135,000 pages per new agent. (This estimate increases to approximately 500,000 pages in the US where additional baseline data is usually required by the FDA.)

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The format and structure of the eCTD as a standard template for regulatory submissions in the USA, Europe and Japan, was based upon and developed under ICH (Topic M4) in parallel with that of the Common Technical Document (CTD). The hierarchical structure of the eCTD, together with the ability to hyperlink between parts of the dossier, brings several distinct advantages over both paper and simple pdf based submissions. In addition to the Centralized MAA submissions themselves, the EMEA also intend that documents such as Type-I/II variations, Periodic Safety Update Reports (PSURs) and Follow-up Measures (FUMs) to Centralized submissions, will also be expected to adopt an eCTD format.

To fully implement and benefit of the opportunities presented by the format and structure of eCTD, it is essential to consider the implications of this fundamental change outside of those traditionally considered under the remit of “Regulatory Affairs”.

The management of electronic-only dossiers and relevant submission types, especially those adopting an eCTD format, will bring several advantages over paper documentation and already established eCTD “point solution” processes:

- The standardization and ability to rapidly update several of the general administrative tasks involved in dossier composition during product lifecycles, starting with the IMPD/IND or even the Biomarker validation (VGDS) process.

- Increased ease with which documentation can be managed by multiple teams prior to submission, from Phase I through to Phase IV. Core data can be reused through the product lifecycle using a single electronic data repository.

- Flexibility in submission type/dossier evaluation and management by multiple Regulatory Agencies, with the ability to rapidly cross refer, track and conduct key word searches.

- A substantial reduction in handling, printing and archiving costs by both the submitting Company and Agencies.

- Rapid access to data sets across products and portfolios.

- An ability to add to the data set during both regulatory FUMs and post–marketing surveillance. In accordance with the recommendations of both Working Groups VI and VII of The Council for International Organizations of Medical Sciences (CIOMS), benefits will also be seen in the standardization of PSUR and Annual Safety Reporting (ASR) for Phase III and IV studies where a new indication is sought.

- Increased ease in modifying data sets for regulatory submissions in all ICH regions

- Ability to translate standard nomenclature from multiple dossiers, allowing for decreased translation costs (e.g. PIM) especially in the current EU countries.

- A greater ease in conducting the “due diligence” process of the Product Lifecycle Dossier (PLD) on agreement of cross Company product transfer or co-promotion, adding to shareholder value and a reduction in timelines.

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A substantial challenge is the need to review and optimize current RA and submission strategies. The process will call for new roles and responsibilities in dossier management from basic research (e.g. VGDS), through market launch and patient communication.

The announcement by the EMEA of timelines under which eCTD will be adopted over the next one and half years provides both an impetus and challenge to both the Industry and National Agencies. eCTD adoption is substantially more than a switch from saving trial and submission documentation from a Word document to a pdf format. **Content** (any type of data) **needs to be classified and searchable** against strict criteria as laid out under ICH Guidance. The benefits though are many, leading to a greater transparency and ease in dossier submission across the major world markets.

For further information and official documents (EMEA eCTD-only guideline to follow), please contact

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LSCP and its SMEs will be happy to discuss with you, considering your starting point, the best way forward.

About Dr. Malcolm Barratt-Johnson:

A UK registered physician with 10 years pharmaceutical experience in medical & regulatory affairs. Extensive experience within both Industry and Governmental Bodies - National and International, leading decision making in the Medical and Marketing Departments of three top ten Pharmaceutical Companies. Primary medical input into the launch of two, key co-promoted products in the Neurosciences. Former Lead Medical Assessor to the MHRA Clinical Trials Unit.

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