Brussels, 26th May 2006

1st EFCG Pharma Business Conference
Barcelona 27-28th April 2006

Conclusions

EFCG welcomed 120 participants to its 1st Pharma Business Conference in Barcelona held on 27-28 April 2006. 23 countries were represented, including regulators from 8 EU countries. Representatives from the Fine Chemicals industry, the Pharmaceuticals industry and traders engaged in extensive informal dialogue with representatives of Medicines' Agencies, the EMEA, the EU Commission, the German Ministry of Health and the USP. 16 inspectors were at hand to provide feedback on their expectations of how pharmaceutical companies should conduct their affairs in light of the new laws for GMP compliance.

EFCG presented the findings of its Benchmarking Questionnaire (BQ) to assess the readiness of the Medicines' Agencies of Europe to enforce the new provisions contained in Directives 2004/27 and 2004/28. The 6 respondents get high marks for clarity and consistency on the key principles and courses of action, but inconsistency is apparent on the "how to do" detail of the implementation. The BQ responses, conference materials and summary may be found on www.efcg.cefic.org.

Overall, the conference demonstrated that there was general alignment between all stakeholders, and that the occasion provided a much-needed forum for awareness raising and discussions. As a result of the conference, EFCG has identified 3 key issues that remain open and need addressing if the safety of medicines in Europe is to be properly safeguarded:

1. Action Following the Suspension of a Certificate of Suitability (CEP)

The European Directorate for the Quality of Medicines (EDQM) has issued over 2000 Certificates of Suitability (CEPs). Through these EDQM certifies that the API produced in a particular facility, per a described process, is likely to consistently deliver a product that meets the relevant EP monograph. Such CEPs are widely used in Europe to support the applications for Marketing Authorizations (MA) primarily for generic medicines. Because CEPs result from EDQM's expert evaluation, the Medicines' Agencies in the Member States do not raise additional questions. Yet the CEP is just a paper evaluation that assumes that "The Filing Equals Reality". Over the recent years EDQM has become concerned that "The Filing Does Not Equal Reality" and has taken the initiative to inspect the facilities that have CEPs to check whether they are GMP compliant and whether "The Filing Does or Does Not Equal Reality". EDQM has therefore installed an inspection program setting priority for those facilities whose submitted filings triggered suspicion. To date a total of about 80 firms have been inspected. About 25% of those located in India and China were found to have significant enough GMP and/or submission-related non-compliance issues for EDQM to suspend the CEP. There were no suspensions related to facilities located in Europe while the number of inspected firms in Europe is roughly equal to the ones inspected in India and China.

However, the conference attendees were amazed to hear that once a CEP is suspended by EDQM there is no automatic regulatory action by the EU Medicines' Agencies. While the

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EDQM does send out an alert, there appears to be no system in place to quickly identify the Marketing Authorisations (MA) that contain API from a source whose CEP was suspended. There is no automatic suspension of the MA, an action that would seem obvious to safeguard patient safety. Indeed, if the valid CEP was pre-condition to the MA approval, then it follows that if the CEP is suspended, the MA should also be suspended.

EFCG will take this matter up with the Heads of Agencies as the limbo that surrounds suspended CEPs does little for patient safety, or for the EDQM's credibility, and offers little deterrence to those who choose to ignore the new laws.

2. The Increased Responsibilities of the Qualified Person

The new laws attribute squarely the legal responsibility for GMP compliance of the API on the shoulders of the Qualified Person (QP) of the MA holder. However, this heavy responsibility is not in line with the role and seniority of the QP in most firms. In addition, the QP's legal liabilities in adverse events connected with non-compliance appear not to be in proportion with the designs of the legislator. The conference heard legal opinion to the effect that the QP has no personal legal liability, as have, for example, a company's financial auditors. Could shareholders be better protected than patients?

EFCG will pursue this matter with the Heads of Agencies, the EU Commission and with the associations representing Qualified Persons.

3. European GMP Inspections of Asian API Manufacturing Facilities

The new laws have moved the obligation to verify GMP compliance onto the private sector: QPs have added responsibilities, contracts need to be in place and audits performed so that roles and obligations are defined, and diligence is evidenced. The conference learnt that, other than the EDQM, no European body seems intent on performing a sufficient number of inspections in Asia to bring about credible verification of the requirements of the new laws.

EFCG will continue to bring this matter to the attention of the Competent Authorities, to press for more inspectors to be hired and to seek to ensure that the geographic distribution of EU GMP inspections reflect the fact that 80% of the volume of the APIs that make up EU medicines today come from India and China.

EFCG is preoccupied that the downward pressure on the price of generic medicines by the national health authorities and health care providers, the intensity of competition in the generic pharma industry, coupled with the high level of globalization of the API industry, are allowing low cost, Asian API producers to dominate the provision of medicines to Europe. This trend has not seen a corresponding change in the geographic focus of the EU's regulatory supervision. Inadequate enforcement is taking the risk component in medicines to an unacceptable level.

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