INTRODUCTION

Since the initial publication of this Report, the ethical pharmaceutical industry has been part of, and confronted with, considerable change. In view of the very high risks, which particularly result from the high investments and serendipitous nature of its research activities, the industry has increasingly seen the need for co-operation through licensing, joint ventures, acquisitions including mergers. Compared to other industries, the ethical pharmaceutical industry still remains rather fragmented. Currently, the industry is in the process of facing or embracing the competition from venture-capital funded biotech companies. It is worth considering some of the major developments, since the initial publication of this Report, that have significantly impacted the professional debate about, and responsive activities towards the transfer pricing of ethical pharmaceutical enterprises:

1. the new opportunities as well as the high risks associated with the development of genetically engineered medicines since the 1993 mapping of the human genome [1];
2. the 1994 US regulations on inter-company transfer pricing;
3. the 1995 OECD "Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations";
4. the 1995 World Trade Organization (WTO) agreement "Trade Related Aspects of Intellectual Property Rights" (TRIPs);
5. the national transfer pricing legislation and/or regulation of a number of countries such as Brazil's significant deviation from international standards with its 1996/1997 legislation/regulation;
6. the UK's 1998 transfer pricing legislation, which adopted in its entirety the OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations. Additionally, the UK Department of Health's 1999 Pharmaceutical Price Regulation Scheme with guidance on transfer pricing;
7. the 2001/2002 South African AIDS/HIV crisis resulting in the UN's recognition of a supranational funding responsibility, and the 2002 WTO (Doha) access to medicines compromise formula;
8. the serious distrust in accounting practices as a result of the 2002 debilitating accounting scandal in the US which was epitomized by Enron and its auditing firm Arthur Andersen;
9. the 2002/2003 initiatives of the OECD for updating the Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations;
10. the 2002 creation by the European Commission of the "European Union Joint Transfer Pricing Forum" mainly aiming at reducing the risk of double taxation and undue compliance costs;

[1] Some of the "products" resulting from this development for diagnostic, therapeutic or "genetic engineering" purposes will be vastly different than the medicines of the past and so will be their price and risk profile which in turn affects the scope for innovatory transfer pricing concepts.

11. the 2003 draft of German Transfer Pricing Documentation Regulations, which appear to pre-empt the latter of the EU Forums' core objectives; and
12. the 2003 Cancun agreement expected of WTO member states to allow poorer nations access to cheap medicines also beyond the originally agreed diseases – HIV/AIDS, tuberculosis and malaria – if need be via compulsory licensing.

The relevance of these developments to the ethical pharmaceutical industry, and particularly to its transfer pricing, will be addressed and become evident throughout the Report.