The University of Manchester

MODULE 1

Introduction to the Healthcare Industry

This module forms part of the PLG MSc course in Pharmaceutical Business Development and Licensing. It can be studied on its own for a module credit or as part of a Certificate, Diploma or MSc degree.

It will provide students with an overview of the structure and function of the Healthcare Industry with an emphasis on the role and relevance of business development. The module comprises eight separate units and is supported by a workshop.

CONTENT:

Unit 1: **Industry Overview and Historical Perspective,** reviews the growth of the industry from its origins in traditional therapies. It charts the role of pharmacists in the development of the drug industry and the progression from the antibiotic revolution through the emergence of biotechnology to the current trend of industry consolidation.

Unit 2: **The Pharmaceutical industry's Key Statistics and Metrics,** addresses the economics and statistics underpinning the pharmaceutical industry and considers R&D investment and expenditure in depth. The major players, key pharmaceutical market and the importance of blockbuster drugs are reviewed as well as the role of the generics industry in delivering cost effective medication to the masses. The role of government and industry organisations such as ABPI, JPMA is also considered.

Unit 3: **The Structure of Healthcare Systems**. The finances behind the markets are reviewed in this unit, with the role of mechanisms for control of healthcare expenditure via NICE, pharmaco-economics and the fourth hurdle. The influence of non-governmental organisations (NGOs) and patient advocacy groups are assessed.

Unit 4: **Drug Discovery.** Are there any remaining unmet therapeutic needs? This unit studies the current aims of drug discovery and issues around testing and safety and the ethics of using animals in research. The Human Genome Project and the role of genomics and informatics are also evaluated.

Unit 5: **Clinical Development**, addresses the costs of clinical development and the need for paediatric trials. Study design, clinical trial ethics, safety assessment of marketed medicines and health economics are considered. The current drive for outsourcing of clinical trials and transparency is also addressed.

Unit 6: **Regulatory Issues.** The role and organisation of the MHRA, EMEA and FDA, regulatory strategy and the regulatory processes in Europe and the US are covered in this unit.

Unit 7: **Market Dynamics, Companies Strategies and the Role of Business Development,** is a review of corporate development from start ip to mid cap. The potential role of biotech's as engines for R&D. The need for alliances or acquisitions in managing product life cycles and planning the portfolio.

Unit 8: **The Industry in the Future.** Where will the industry go in the future - continuation of mega-mergers? What is the role remaining for mid cap companies? What are the new market trends, are there any more new niche markets? Disease trends—the emergence of AIDS, SARS, the next flue pandemic. Cost containment measures, and new pathways to reach the patient