MODULE SPECIFICATION

KEY FACTS

Module name	Pharma Enterprise and Economic Evaluation
Module code	HMM025
School	School of Health Sciences
Department or equivalent	Division of Health Services Research and Management
UK credits	15
ECTS	7.5
Level	7

MODULE SUMMARY

Module outline and aims

The pharmaceutical industry is recognised as a dynamic and enterprising business sector generating high-quality employment and contributing to economic output. It includes an extensive and diverse group of companies. These range in size from small start-up firms to multi-national pharmaceutical corporations. Production methods include traditional pharmaceuticals manufactured through chemical synthesis and biopharmaceuticals manufactured in living organisms. Depending on size and strategy pharmaceutical companies may conduct extensive research in-house or license promising medical discoveries, often from smaller companies.

In addition to creating safe and effective products, pharma companies need to develop medications with superior results to those already on the market and demonstrate their added value to a range of stakeholders to justify prices higher than existing treatments. These tasks are complicated by the dynamics of power among industry stakeholders, each of which may require different evidence to be convinced of a product's value.

The pharmaceutical industry is one of the biggest sectors of health care, involved in huge investments in Research and Development (R&D) with the aim of developing new drugs, technologies and treatments and a crucial component of broader national biomedical ecosystems. Therefore there is government interest to ensure mergers and acquisitions are consistent with national interests to maintain economic leadership in technology and innovation. The sector is also heavily regulated regarding patents, pricing and competition, both at a national and international level. Pharmaceutical policy aims to give appropriate incentives to the pharmaceutical companies to invest in R&D ensuring that access to essential drugs is not compromised.

The aim of this module is to give a critical and selective overview of competition and stakeholder dynamics in key areas of established and emerging pharma sectors globally. It will explore issues around R&D and innovation, the market structure of the pharmaceutical sector, access to drugs, regulations and policies. An important part of the module will focus on the value chain of the pharmaceutical industry sector from research and development to clinical testing to production of goods and services to final distribution and economic evaluation. This aims to compare the costs of new treatments to the benefits they provide to patients, informing decision making on resource allocation for stakeholder within the industry, policy makers and regulators.

The module brings together multiple perspectives from the pharmaceutical industry, public sectors, health policy and regulation, governments and economic development.

Content outline

The content explores the global pharmaceutical sector from the perspectives of major stakeholders. It includes:

- An overview of the pharma*ceutical R&D* process including: drivers of innovation cost of new drugs and patents.
- Models of pharma*ceutical markets* including: monopolistic and competitive forces, merges and acquisitions, pricing of drugs.
- The *regulator's* role in the pharmaceutical policy to ensure a balance between price control, incentives for innovation and access to drugs, including the role of *NICE* in the UK.
- The role of *government* industry policy in developing and promoting domestic pharma industries in the global marketplace.
- *Economic evaluation* of the benefits of new drugs and technologies.

WHAT WILL I BE EXPECTED TO ACHIEVE?

On successful completion of this module, you will be expected to be able to:

Knowledge and understanding:

- Critically discuss the role of the pharmaceutical industry in R&D innovation for new drugs and new technologies.
- Evaluate and critically assess the sources and dynamics of market powers arising within the pharmaceutical sectors.
- Compare and contrast why companies enter merger and acquisition deals and the national concerns of governments in approving or rejecting these.
- Provide a rationale for the role of regulation in the pharmaceutical sector and the need for high-quality economic and social analysis to inform public policy.
- Explain and critically appraise the value chain of the pharmaceutical industry sector new product development, from research and development, to clinical testing, to production and final distribution of goods and services.
- Summarise and critique the merits of different economic evaluation methods applied to appraise potential innovations and new product developments.

Skills:

- Formulate and develop a critical market analysis reflecting the different powers arising within a designated pharmaceutical market sector.

- Develop and critically appraise strategies for innovating products, processes, and services.

- Critically survey and appraise potential for merging and acquisition of companies within the pharmaceutical sector.

- Undertake a value chain analysis for a pharmaceutical company, market segment, or product, evaluate primary and support activities and justify recommendations to reduce costs or make the case for new medicines.

- Select appropriate methods of economic evaluation to quantify the costs and benefits of new drugs and technologies and critically evaluate mergers and acquisitions.

- Critically evaluate the benefits of new drugs and technologies and potential mergers and acquisitions, using economic evaluation techniques and market sector analysis to make the case for new initiatives.

Values and attitudes:

- Appreciate the need to look beyond the boundaries of economic evaluation models to consider ethical issues, and social and societal well-being in evaluating business decisions.

- Demonstrate appropriate collaborative and team working skills.

- Show respect and tolerance for other participants.

- Adhere to University regulations regarding referencing, plagiarism and academic misconduct.

HOW WILL I LEARN?

Teaching and learning will take place via a mix of lectures, group activities and discussions which allow you to examine the issues in more detail, providing both lecturer and peer led input, promoting discussion and developing communication and group working skills. Key role in the teaching and learning process will be the input of key stakeholders, including representatives of the pharmaceutical industry, the regulatory body, and NICE.

Teaching sessions will take place over four days (typically 10am to 5pm), and are supplemented by self-directed study, which allows you both to gain a deeper understanding of the subject generally, and to pursue topics which are of particular interest to you in greater detail.

Teaching and learning are facilitated by Moodle, the University's online Virtual Learning Environment.

Teaching pattern:

Teaching component	**Teaching type**	**Contact hours (scheduled)**	**Self-directed study hours (independent)**	**Placement hours**	**Total student learning hours**
Lectures, group activities, exercises and discussions	Lecture	28	122	0	150
Totals:		28	122	0	150

WHAT TYPES OF ASSESSMENT AND FEEDBACK CAN I EXPECT?

<u>Assessments</u>

The assessment comprises two elements:

- A group presentation on current issues related to the pharma sector. Students will be allocated to groups and given a topic to explore and present in front of their colleagues and academics. It requires that you work collaboratively and communicate effectively with as a member of a group. The presentation medium is flexible. You may use Prezi, PPTplex, PowerPoint (without Prezi, PPTplex), Poster, or any alternative medium approved by the lecturer.

- An individual report on one of the topics presented (you may continue with the topic presented by your group, or select from the alternative topics presented by other groups). You will be asked to submit a report of 2,500 words excluding appendices and references.

These will require you to think critically and fundamentally about how to evaluate pharma sector developments.

Assessment pattern:

Assessment component	Assessment type	Weighting	Minimum qualifying mark	Pass/Fail ?
Group presentation	Oral assessment and presentation	30%	50%	N/A
Individual report	Written assignment	70%	50%	N/A

Assessment Criteria

Assessment Criteria are provided for each module and are descriptions, based on the intended learning outcomes, of the skills, knowledge or attitudes that you need to demonstrate in order to complete an assessment successfully, providing a mechanism by which the quality of an assessment can be measured.

Grade- Related Criteria are also provided for each module and the programme and are descriptions of the level of skills, knowledge or attributes that you need to demonstrate in order achieve a certain grade or mark in an assessment, providing a mechanism by which the quality of an assessment can be measured and placed within the overall set of marks.

Assessment Criteria and Grade-Related Criteria will be made available to you to support you in completing assessments. These may be provided in programme handbooks, module specifications, on the virtual learning environment or attached to a specific assessment task. Module leaders will inform you at the beginning of each module where these be provided.

Feedback on assessment

Feedback is usually provided in verbal or written format for each module. All written feedback is posted onto Moodle to enable you to access this easily.

Feedback will be provided in line with current university assessment and feedback policies. In particular, you will normally be provided feedback within four weeks of the submission deadline or assessment date in line with the university guidelines for end of module examinations or an equivalent significant task. Feedback would normally include a provisional mark that requires ratification at the assessment board by the external examiners. If you have failed a component the assessment board will normally confirm the requirement for resubmission and set a date for this.

Assessment Regulations

The Pass mark for each assessment is 50%.

If you fail an assessment component or a module, the following will apply:

Resit: you will normally be offered one resit attempt. However, if you did not participate in the first assessment and have no extenuating circumstances, you may not be offered a resit.

If you are successful in the resit, you shall be awarded the credit for that module. The mark used for the purpose of calculation towards your Award shall be calculated from the original marks for the component(s) that you passed at first attempt and the minimum pass mark for the component(s) for which you took a resit.

INDICATIVE READING LIST

Books:

- Brent, R., 2014. Cost - Benefit Analysis and Health Care Evaluation. Edward Elgar Publishing Ltd.
- Brown, L., Grundy, T., 2011. Project Management for the Pharmaceutical Industry. Gower Publishing, Ltd.
- Drummond, M.F., 2005. Methods for the Economic Evaluation of Health Care Programmes. Oxford University Press.
- Ellery, T., Hansen, L., 2012. Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand. Wiley.
- Glick, H., Doshi, J., Sonnad, S., Polsky, D.,2014. Economic Evaluation in Clinical Trials. Oxford University Press.
- Jacobsen, T., Wertheimer, A., 2010. Modern Pharmaceutical Industry: A Primer. Jones & Bartlett Learning.
- Mehdi, Z., Bahman, B., 2014. Pricing Strategies in Pharmaceutical Companies. Lambert Academic Publishing
- Morris, S., Devlin, N., Parkin, D., Spencer, A., 2012. Economic Analysis in Health Care. John Wiley & Sons.
- Rascati, K, 2013. Essentials of Pharmacoeconomics. Lippincott Williams & Wilkins.
- Slatter, S., 2014. Competition and Marketing Strategies in the Pharmaceutical Industry. Routledge.

Journals:

- Bastianelli, E, Eckhardt, J, & Teirlynck, O 2001, 'Pharma: Can the middle hold?', Mckinsey Quarterly, 1, pp. 116-125
- Hess, A.M., Rothaermel, F.T., 2011. When are assets complementary? star scientists, strategic alliances, and innovation in the pharmaceutical industry. Strateg. Manag. J. 32, 895–909. doi:10.1002/smj.916
- Hogerzeil, H.V., Liberman, J., Wirtz, V.J., Kishore, S.P., Selvaraj, S., Kiddell-Monroe, R., Mwangi-Powell, F.N., von Schoen-Angerer, T., 2013. Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration. The Lancet 381, 680–689. doi:10.1016/S0140-6736(12)62128-X
- Husereau, D., Drummond, M., Petrou, S., Carswell, C., Moher, D., Greenberg, D., Augustovski, F., Briggs, A.H., Mauskopf, J., Loder, E., 2013. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. BMC Med. 11, 80. doi:10.1186/1741-7015-11-80

- 'INDIA, CHINA CHALLENGE BIG PHARMA IN AFRICA' 2014, African Business, 414, pp. 43-46
- Jessop, N 2012, 'Germany's New Pricing Policy Loses Appeal With Pharma', Pharmaceutical Technology Europe, 24, 12, pp. 12-14
- Kirchhoff, M, & Schiereck, D 2011, 'Determinants of M&A Success in the Pharmaceutical and Biotechnological Industry', IUP Journal Of Business Strategy, 8, 1, pp. 25-50, Business Source Complete
- Kesič, D., 2009. Strategic analysis of the world pharmaceutical industry. Manag. J. Contemp. Manag. Issues 14, 59–76.
- LaMattina, J.L., 2011. The impact of mergers on pharmaceutical R&D. Nat. Rev. Drug Discov. 10, 559–560. doi:10.1038/nrd3514
- Paul, S.M., Mytelka, D.S., Dunwiddie, C.T., Persinger, C.C., Munos, B.H., Lindborg, S.R., Schacht, A.L., 2010. How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nat. Rev. Drug Discov. 9, 203–214. doi:10.1038/nrd3078
- Miller, JE 2013, 'From Bad Pharma to Good Pharma: Aligning Market Forces with Good and Trustworthy Practices through Accreditation, Certification, and Rating', Journal Of Law, Medicine & Ethics, 41, 3, pp. 601-610
- Price, D, Keininger, D, Costa-Scharplatz, M, Mezzi, K, Dimova, M, Asukai, Y, & Ställberg, B 2014, 'Cost-effectiveness of the LABA/LAMA dual bronchodilator indacaterol/glycopyrronium in a Swedish healthcare setting', Respiratory Medicine, 108, 12, pp. 1786-1793
- 'SOUTH AFRICA: Leading the Pharma Model for a Continent' 2012, Pharmaceutical Executive, 32, 5, pp. S2-S27
- Sternitzke, C., 2010. Knowledge sources, patent protection, and commercialization of pharmaceutical innovations. Res. Policy 39, 810–821. doi:10.1016/j.respol.2010.03.00

Version: 1.0
Version date: March 2015
For use from: 2015-16

Appendix:

CODES

HESA Code	Description	Price Group
133	Business and Management Studies	D

JACS Code	Description	Percentage (%)
N200	The study of managing organisations.	30
N212	Techniques for creative problem solving and the management of creativity in others.	35
N214	The specific techniques involved in the planning and	35

		management of change within an organisation.	