

Module 8: Commercial and Financial Considerations in the Pharmaceutical Industry

Stage	1						
Semester	2						
Module Title	Commercial and Financial considerations in the Pharmaceutical Industry						
Module Number/Reference	MSC-IPM-CFP						
Module Status (Mandatory/Elective)	Mandatory						
Module ECTS credit	10						
Module NFQ level (only if applicable)	9						
Pre-requisite Module Titles	None						
Co-requisite Module Titles	None						
Is this a capstone module? (Yes or No)	No						
List of Module Teaching Personnel	Dr. Sonja Vucen, Dr. Katie Ryan, Dr Abina Crean						
Contact Hours				Non-contact Hours			Total Effort (Hours)
Lecture	Practical	Tutorial	Seminar	Assignment	Placement	Independent work	
60		12		28		150	250
Allocation of Marks (Within the Module)							
	Continuous Assessment	Project	Practical	Final Examination	Total		
Percentage contribution	60%			40%	100%		

Intended Module Learning Outcomes

On successful completion of this module, the learner will be able to:

1. Critically evaluate the keys phases within a commercial and financial drug launch within the Pharmaceutical/Biotech landscape.
2. Evaluate financial investment metrics demonstrating understanding of their associated advantages and disadvantages plus other selection methods.
3. Critique the processes involved in building the value platform: creating, communicating, and capturing value of a new drug.

4. Differentiate the elements of a commercial launch including phases, milestones and success factors.
5. Critically analyse the position of platform technology as an emerging technology; co-developing new processes with vendors and/or other stakeholders

Module Aims

This module aims to introduce learners to the commercial and financial considerations and management experience within the pharmaceutical industry. In order to gain market access and remain competitive, pharmaceutical and medical technology manufacturers must be able to demonstrate clinical and economic evidence to providers. Now more than ever, pricing pressure and regulatory restrictions are generating increased demand for this kind of outcomes evidence.

Success in the pharmaceutical and biotech industry requires a basic understanding of the R&D, financial and commercial launch paradigms. The main purpose of the module is to explore the phases of a global commercial launch right through to KPI's and enterprise system applications. This module highlights the emergence of Biosimilars and Platform technology in a competitive and ever changing global marketplace.

Module Curriculum

- **Commercial Teams**
 - Role of the Commercial Launch Team & Launch Overview
 - Core team & extended team
 - Key Product Launch Milestones
 - Manufacturing site selection
 - Prototype development/approval
 - Registration batches /formal stability
 - FDA registration/approval
 - Graphics /labelling approval
 - Process /packaging validation
 - Commercial launch build
 - QA Testing /release
 - Ship to trade
 - Launch Work-streams & associated activities
 - Key Success Factors for Development and Commercialization

- **Biosimilars**
 - Growth of the Biosimilars market
 - Impact of LOE, Patent Expiration; Research in Biosimilars
 - The current global regulatory landscape
 - Major differences in regulations
 - Automatic Substitution or Interchangeability
 - Challenges for the development & approval of a Biosimilar (companies & regulators) and financial impact on the Pharmaceutical Industry

- **Pricing Fundamentals in the Biopharmaceutical Industry**
 - The macro-economics of pharma: the opportunities and the challenges ahead
 - The strategic role of pricing and market access to drive growth
 - The complexity of price: a concept between marketing strategy, sales and finance
 - Introduction to the concept of value based pricing and integrated value strategy: how to create and communicate value with a market access strategy and capture it with price

- **Creating Value**
 - Understanding the role played by country specific purchase decision systems in determining the relationship between price and level of access
 - Optimising the value – price – access relationship across countries and indications
 - Value messages: the concept, their role and how to use them
 - Building the value platform: developing the value proposition and testing the value story

- **Communicating Value**
 - HEOR as a tool to communicate the value of a new product
 - HTAs: what they are and how to deal with them
 - Planning the communication strategy and the role of the Global Value Dossier (GVD)
 - Generating other types of evidence to fit into an HEOR evidence plan

- **Capturing Value**
 - The challenges in implementing a pricing and reimbursement strategy within and across markets
 - Payer engagement: the role of pricing negotiation in the EU and of contracting in the US
 - Elements of negotiation strategy and negotiation training
 - Cross-country implications of reference pricing and parallel trade affecting the price negotiation process
 - Discounting, contracting and innovative pricing schemes (risk sharing)

- **Pricing and Market Access**
 - Pricing and market access overviews: a quick guide to the US and EU5
 - Pricing drugs in fast growing economies and in the developing world
 - Loss of exclusivity: generics and biosimilars - challenges and opportunities

- **Platform Technology**

- Pros / Cons Platform Technology vs. Custom technology
- New technology co-development; Vendor partnering
- Process flow (using worked example)
 - Proof of Concept (POC)
 - Implementation Phase
 - Key GO /NO Go steps
 - Governance & Roles and Responsibilities & Communication
 - Knowledge Management
 - Vendor Interaction
 - Return-on-Investment

Teaching plan

Weeks 1&2	Commercial teams
Week 3&4	Biosimilars
Week 5&6	Pricing fundamentals in the biopharmaceutical industry
Week 7	Creating value
Week 8	Communicating value
Week 9	Capturing value
Week 10	Pricing and market access
Week 11&12	Platform technology

Reading lists and other learning materials

Abbott, F.M. and Dukes, G. 2011. *'Global pharmaceutical policy: ensuring medicines for tomorrow's world'* Cheltenham: Edward Elgar.

Anon 2008. *'The SAGE handbook of healthcare: global policies, business opportunities, scientific developments'*. London: SAGE.

Edwards, L.D. et al. 2011. *'Principles and practice of pharmaceutical medicine'*. Oxford, UK: Wiley-Blackwell.

Grüne G., Lockemann S., Kluy V., Meinhardt S. (2014). *'Business Process Management within Chemical and Pharmaceutical Industries'*, Springer ISBN: 978-3-642-11716-9

Hübel A, Schmelcher T., Storz U., (2014) '*Biopatent Law: Patent Strategies and Patent Management*', Springer, ISBN: 978-3-642-24845-0

Williams, D.R. 2013. '*The funding of biopharmaceutical research and development.*'

Zaheer-Ud-Din Babar '*Pharmaceutical Prices in the 21st Century*', Springer, ISBN: 978-3-319-12168-0

Articles

Athanasios Zikopoulos (2015). '*Pharmacoeconomics for the Pharmaceutical Industry in Europe*', International Journal of Pharmaceutical Medicine, Volume 17, Issue 5, pp 201-209

Erwin A. Blackstone, PhD and P. Fuhr Joseph, Jr, PhD, '*The Economics of Biosimilars*', American Health Drug Benefits. 2013 Sep-Oct; 6(8): 469–478.

Gorecki P.K, Nolan A.,Brick A., and Lyons S. 2012. '*Delivery of Pharmaceuticals in Ireland, Getting a Bigger Bang for the Buck*', Research Series Number 24, ESRI, Ireland.

József Bodrogi and Zoltán Kaló, (2010). '*Principles of pharmacoeconomics and their impact on strategic imperatives of pharmaceutical research and development*', Journal of Pharmacol, Apr; 159(7): 1367–1373.

Module Learning Environment

A classroom setting is used for the delivery of the module through a series of lectures and associated case studies. Supports for learners include a set of printed notes incorporating syllabus, lecture notes, activities, short self-administered questionnaires, a case study, and related assessment tasks. These are supplemented with a module set book and online reading materials, PowerPoint presentations, and other activities using Moodle, the College's Virtual Learning Environment (VLE) provide additional support materials to help with self-study.

Module Teaching and Learning Strategy

This module is specifically designed to develop the learner's understanding of the commercial and financial considerations within the pharmaceutical industry. The module is delivered through lectures, case studies, supporting tutorials and online resources. The module is supported by guest lecturers including senior leaders from the pharmaceutical and related industries. A key strategy is exposure to industry-based experts and reinforcement of programme material by use of case studies and practical work.

Module Assessment Strategy

Element Number	Weighting	Type	Description
1	30%	Presentation (workshop 1)	Case study based assessment
2	30%	Written Report	Case study based assessment
3	40%	Examination	End of semester examination

Learners are required to work on two 30% weighted assignments.

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Assignment 1: This is a Work Based Activity (WBA) which requires learners to review the presented pharmaceutical industry case studies (x5) and deliver a regulatory strategy/framework in a written presentation in each case. This is a team based activity completed in Workshop 1.

Assignment 2: This is a Work Based Activity (WBA) which requires learners to apply appropriate financial appraisal of the case study and develop a written commercial launch plan.

Learners sit an end of semester examination which contributes 40% towards their final mark for this module. The exam paper has three sections focusing on personal leadership, leadership in the case study organisation, and leadership processes.

Constructive Alignment of Assessment

Module Learning Outcomes	Assessment Strategy		
	Element 1	Element 2	Element 3
Module Learning Outcome 1		Yes	
Module Learning Outcome 2			Yes
Module Learning Outcome 3	Yes	Yes	Yes
Module Learning Outcome 4	Yes	Yes	Yes
Module Learning Outcome 5		Yes	Yes