Module 6: Regulatory Strategy from Development to the Market Place

1st – 3rd July 2020

Location: to be delivered online

Module Leader: Vina Mistry

Date: Wednesday 1st July 2020

Time	Activity	Speaker
09:30	**Registration**	Kay Platt
09:45	**Welcome & Introduction to the Module**	Vina Mistry Module Leader
	DEFINING THE PRODUCT AND ITS PLACE ON THE MARKET	
	Lecture 1: Developing the Brand and Shaping its Market Place.	
10:00 – 11:15	**Part 1:** The needs of the Market: what is the Market place, what does marketing want from regulatory. The input of the Regulatory representative in shaping a successful brand throughout the development stages.	**Vina Mistry** Pharmistry Consulting Ltd
11:15 – 11:30	***Break***	
11:30 – 12:45	**Part 2:** Maintaining and extending brand awareness. The input of the Regulatory representative in maintaining and extending the brand throughout its lifecycle stages.	**Amanda Roche** Biogen Idec Ltd
	LEGAL FRAMEWORK: PROTECTING THE BRAND	
14:30 – 15:45	**Lecture 2: Protecting the Brand: Intellectual Property and Data Exclusivity** The importance of protecting the brand through its marketing life by use of patents, supplementary protection certificates, data exclusivity, brand names and trademarks.	**David Knight** FieldFisher
15:45 – 16:00	***Break***	
	SUCCESSFULLY LAUNCHING THE PRODUCT ON THE MARKET	
16:15 – 17:30	**Lecture 3: Demonstrating Value and Market Access** Pricing and reimbursement policies Pharmacoeconomics Formularies, NICE Designing the clinical development programme with pharmacoeconomics in mind	**Daniel Jackson** UCB Biopharma

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Date: Thursday 2nd July 2020

Time	Activity	Speaker
	SUCCESSFULLY LAUNCHING THE PRODUCT ON THE MARKET	
09:30 – 10:45	**Lecture 5: Falsified and Counterfeit Medicinal Products** The key issues, provisions and handling of falsified medicinal products. Overview of Falsified Medicines EU Directive. Key Challenges for the agency and any insight to the international collaboration efforts in tackling this issue. Real examples of types of issues seen and safety feature requirements on medicines	**Lynda Scammell** MHRA
10:45 – 11:00	***Break***	
11:00 – 12:15	**Lecture 4: Pharmacovigilance and Risk Management** Safety reporting requirements Maintaining the prescribing information Risk management	**David Lewis** Novartis Pharma GmbH
	COMMUNICATING WITH THE MARKET	
14:00 – 15.15	**Lecture 6: Advertising and Controls on Prescription Only Medicines (POMs)** Key provisions and controls for advertising and promotion of POMs in the EU and US**.**	**Tannyth Cox** PMCPA
15:15 – 15:30	***Break***	
15:30 – 17:30	**Case Study: Advertising and Controls on Promotional Materials for POMs** Feedback from individuals /groups	**Tannyth Cox** PMCPA

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Date: Friday 3rd July 2020

Time	Activity	Speaker
	COMMUNICATING WITH THE MARKET (Cont'..d)	
09:30 – 10:45	**Lecture 7: Issue Management** Issues and crisis management, including communication strategies. Maintaining supply to the market and the role of the Regulatory Representative.	**Janet Worrell** JensonR+ Limited
10:45 – 11:00	***Break***	
11:00 – 12:15	**Lecture 8: Communicating with Patients and Prescribers** The importance of the information contained in the SmPC and its use in communications with patients and prescribers. Patient information, public assessment reports and educational materials. The role played by patient organisations and key opinion leaders	**Anne Vinther Morant** Regulatory Science Consultant; Anne Morant Consulting
	EXTENDING THE LIFECYCLE OF THE PRODUCT	
14:00 - 15.15	**Lecture 9: OTC Switching** Strategic and practical considerations for changing legal status and critical success factors. Advertising of over-the-counter (OTC) products in the EU and US	**Helen Erwood** ESPL Regulatory Consulting
15:15 – 15:30	***Break***	
15:30 – 17:30	**Case Study: OTC Workshop** Feedback from individuals /the group	**Helen Erwood**
17:30	**Close of Module**	**Vina Mistry**