Module 6: Regulatory Strategy from Development to the Market Place
26th – 28th September 2018

Location: Radisson Blu, Malmo, Sweden

Module Leader: Vina Mistry

Date: Wednesday 26th September 2018

Time	Activity	Speaker
14.30	**Registration**	
15.00	**Welcome & Introduction to the Module**	Vina Mistry Module Leader
	DEFINING THE PRODUCT AND ITS PLACE ON THE MARKET	
15.10 – 17.10	**Lecture 1: Developing the Brand and Shaping its Market Place.** **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. **Part 2:** Maintaining and extending brand awareness. The input of the Regulatory representative in maintaining and extending the brand throughout its lifecycle stages.	Vina Mistry Pharmistry Consulting Ltd Amanda Roche Biogen Idec Ltd
	LEGAL FRAMEWORK: PROTECTING THE BRAND	
17.10 – 18.25	**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.	Emma Fulton Hogan Lovells International LLP
18.30 – 19.00	New Student Tutorial	Dr Laura Brown Course Director
19.00	**Dinner**	

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Date: Thursday 27th September 2018

Time	Activity	Speaker
08.30 – 08.35	**Module Leader's Introduction**	Vina Mistry
	SUCCESSFULLY LAUNCHING THE PRODUCT ON THE MARKET	
08.35– 09.50	**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
09.50 – 10.15	**Refreshment Break**	
10.15 – 11.30	**Lecture 4: Pharmacovigilance and Risk Management** Safety reporting requirements Maintaining the prescribing information Risk management	Morell David The Lewis David Consultancy Ltd
11.30 – 12.45	**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
12.45 – 13.45	**LUNCH**	
	COMMUNICATING WITH THE MARKET	
13.45 – 15.00	**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	Paul Woods Independent Consultant
15.00 – 17.00	**Case Study: Advertising and Controls on Promotional Materials for POMs** Feedback from groups	Paul Woods
19.00	**DINNER**	

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Date: Friday 28th September 2018

Time	Activity	Speaker
08.30 – 08:45	**Module Leader's Introduction**	Vina Mistry
	COMMUNICATING WITH THE MARKET (Cont'd)	
08:45 – 10.00	**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 Independent Consultant
10.00 – 10.30	**Refreshment Break**	
10.30 – 11.30	**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 H. Lundbeck A/S
	EXTENDING THE LIFECYCLE OF THE PRODUCT	
11.30 – 12.45	**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
12.45 – 13.45	**LUNCH**	
13.45 – 15.45	**Case Study: OTC Workshop** Feedback from the group	Helen Erwood
15.45 – 16:00	**Close of Module**	Vina Mistry