PHARMATRAIN BASE COURSE **MODULE BCM 1a (INT): INTRODUCTORY MODULE**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Outline the process of drug development and identity of critical factors and decision points.
2. Explain the importance of the patient in drug development.
3. Describe the background to the development of the regulation of medicines and the role of the competent authorities.
4. Outline the monitoring of drug safety.
5. Describe the principles & practice of medical marketing.

PHARMATRAIN BASE COURSE **MODULE BCM 1b: PRINCIPLES OF DISCOVERY OF MEDICINES AND DEVELOPMENT PLANNING**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
6. Outline the role of pathophysiology and molecular biology-based pharmacology in drug development.
7. Describe the principal steps in discovering, modifying, assessing and patenting new chemical and biological compounds (including advanced therapies) according to their therapeutic indication.
8. Discuss the resource planning (in terms of project management, budgeting and cost-control) involved in the management of a drug development programme.
9. Describe the principles of translational research and its role in drug development.
10. Outline the functions and elements (including business aspects) involved in the integrated development of a new drug.

MODULE BCM1a: INTRODUCTORY MODULE			
BCM 1a	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 1.1	Setting the scene: Medicines market overview and the Industry we are in.	1, 2, 3, 5	13.6, 13.8
BCM 1.2	Meeting the challenges of developing new, more effective, safer medicines.	1, 2, 3	
BCM 1.3	The highly regulated and ethical environment of medicines development.	1, 3	2.2, 8.1
BCM 1.4	The patient's view.	2	
BCM 1.5	The discovery process and non-clinical development.	1	
BCM 1.6	The target product profile (TPP) as the blueprint; satisfying the patients, doctors, regulators and payors.	1, 2, 3, 5	
BCM 1.7	A helicopter view of Integrated drug development including: attrition, orientation of the phases (0, 1, 2a, 2b, 3 & 4); modern approaches (learn, confirm) and conditional approvals.	1	
BCM 1.8	Exploratory Development: translational medicine; predictive science and personalised health care.	1, 2	
BCM 1.9	Confirmatory Development.	1, 2	
BCM 1.10	Principles of drug regulation and approval.	3	
BCM 1.11	Patient safety, pharmacovigilance and pharmacoepidemiology.	4	
BCM 1.12	The payors, market support activities and health economics.	5	

MODULE BCM1b: PRINCIPLES OF DISCOVERY OF MEDICINES AND DEVELOPMENT PLANNING			
BCM 1b	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 1.13	Strategy and organisation of research including collaborative approaches e.g. with academia.	10	1.1
BCM 1.14	Disease models; target identification, validation and selection. Principle steps in discovering, modifying, assessing and patenting new chemical and biological compounds.	7	1.2, 1.4
BCM 1.15	Pathophysiology and molecular biology-based pharmacology. Molecular-based approaches: agonists, antagonists, enzyme inhibitors; genomics, proteomics, epigenetics.	6	1.3, 3.1
BCM 1.16	Chemical and biological medicinal agents, natural medicines, medicine-coupled devices and advanced therapies.	6, 7	1.5
BCM 1.17	Lead optimisation and development candidate selection; testing for biological activity.	7	1.6, 1.7
BCM 1.18	Principles of translational medicine: relationship between animal and human pharmacology, molecular biological and physiological approach e.g. biomarkers, functional imaging, modelling &simulation.	9	1.8, 1.9
BCM 1.19	Global integrated development of new medicines, including quality management.	10	2.1, 2.2, 2.5
BCM 1.20	Project management techniques: central role of development plan, project teams, tools and decision-making from target product profile (TPP) and target product claims (TPC) to registration dossier submission. Resource planning, budgeting and cost control, in-sourcing and out-sourcing.	8	2.3, 2.7
BCM 1.21	Development programme planning for small and / or special populations.	7	2.4
BCM 1.22	R&D portfolio planning; in-licensing and out-licensing of medicines.	10	2.6
BCM 1.23	Therapeutic Topic 1		14.1 – 14.10
BCM 1.24	Therapeutic Topic 2		14.1 – 14.10

PHARMATRAIN BASE COURSE **MODULE BCM 2: NON-CLINICAL TESTING, PHARMACEUTICAL AND EARLY CLINICAL DEVELOPMENT**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Discuss the choice and predictive value of the non-clinical testing programme as part of the overall drug development plan for chemical and biological compounds.
2. Describe the integration of non-clinical tests into the overall drug development plan (including scheduling of toxicology tests with respect to clinical trials).
3. Outline the steps in the pharmaceutical development of a drug substance and final drug product (including chemical and biological compounds).
4. Describe the planning of clinical trial supplies for test substance(s) and comparators (active and placebo).
5. Provide an overview of non-clinical study requirements prior to First-in-Man studies.
6. Discuss the molecular and cellular basis of toxic reactions.
7. Outline the principles and practical application of pharmacokinetics & toxicokinetics.
8. Outline the early exploratory development in man.
9. Discuss the principles of clinical pharmacology and their application to clinical development.
10. Describe the influence of genetic factors in drug development and drug response.

MODULE BCM 2: NON-CLINICAL TESTING, PHARMACEUTICAL AND EARLY CLINICAL DEVELOPMENT

BCM 2	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 2.1	Principles of non-clinical testing: differences & similarities between small molecule and biological macromolecule active agents and between the pharmacology & toxicology of compounds and their metabolites in animals & man, and their qualitative & quantitative assessment.	1	3. 2, 3.3

BCM 2	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 2.2	Descriptive & quantitative *in vitro* & *in vivo* testing of new compounds; the choice and predictive value of these tests for acute, chronic, reproductive, genetic & immune toxicology, and carcinogenicity.	1	1.7, 3.4, 3.5
BCM 2.3	Common mechanisms of damage to organs: their detection and elucidation. Molecular and cellular basis of toxic reactions.	6	3.6
BCM 2.4	The scheduling of toxicology tests linked to development plans, regulatory needs, human & animal pharmacology, and to intended clinical uses & route(s) of administration. The size, cost and administration of the toxicology programme, its data management, quality assurance and report writing.	2	3.7, 3.8
BCM 2.5	The continuous review of toxicology, its inclusion into clinical trial protocols and investigator brochures, and the planning and correlation with the clinical evaluation of potential and observed toxicity in patients.	2	3.9
BCM 2.6	Safety pharmacology; hypersensitivity	5, 6	3.10
BCM 2.7	*In vitro* & *in vivo* study of metabolism; Absorption, Distribution, Metabolism, Elimination (ADME); Toxicokinetics.	7	3.11
BCM 2.8	Pharmaceutical development of *drug substance* (small chemical molecules or biological macromolecules) and up-scaling: manufacture & supply of materials; stability and storage; purity; compatibility; disposal.	3	4.1
BCM 2.9	Pharmaceutical development of *drug product* and up-scaling: formulation(s); manufacture and supply of materials; labelling & presentation; stability & storage; purity; compatibility; disposal.	3	4.1, 4.2
BCM 2.10	Choice of formulations and delivery systems depending on characteristics of compound and intended uses; testing formulations leading to a final specification, including bioequivalence.	3	4.3, 4.4
BCM 2.11	Safety specification; pharmacopoeias.	3	10.20, 10.22

BCM 2	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 2.12	The concept of blinding: preparing matching placebo and comparator products. Planning clinical trials supply requirements; packaging and labelling of clinical trial supplies (including stability and storage requirements); distributing supplies and disposing of remaining stocks.	4	4.5, 4.6, 7.14
BCM 2.13	Assessment of non-clinical data and risk as prerequisites before administration to man: description of intended therapeutic indications, biomarkers, surrogate endpoints and criteria for 'go' 'no-go' decisions.	5, 7	5.1, 5.2
BCM 2.14	The early clinical development plan: objectives, design, conduct and analysis; tolerability, metabolism, pharmacokinetics, pharmacodynamics and safety in man; risk mitigation strategies; first-into-man studies, including exploratory strategies (Phase 0).	8	5.3, 5.4
BCM 2.15	Clinical pharmacodynamics & pharmacokinetics: ADME; determinants of PK parameters; bioavailability & bioequivalence; extrinsic & intrinsic factors affecting drug metabolism (e.g. drug-drug, drug-food, drug-disease interactions).	9	5.5, 5.6, 5.7, 5.8
BCM 2.16	Pharmacogenetics, pharmacogenomics, population pharmacokinetics, genetic factors influencing PK, PD and response to therapy. Personalised medicine.	3, 10	5.9, 5.10
BCM 2.17	Applicability of pharmacokinetics to dosage regimen and study design. Pharmacokinetic / pharmacodynamic modelling and simulation.	9	5.11
BCM 2.18	Therapeutic Topic 3		14.1 – 14.10
BCM 2.19	Therapeutic Topic 4		14.1 – 14.10

PHARMATRAIN BASE COURSE **MODULE BCM 3: EXPLORATORY AND CONFIRMATORY CLINICAL DEVELOPMENT**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Describe the early studies in patients: dose-finding / proof of concept studies and their impact on drug development plan.
2. Outline the design of clinical trials, including legal, regulatory, ethical & practical aspects and Good Clinical Practice (GCP).
3. Discuss the principles and application of statistics in clinical trials.
4. Describe the procedures for clinical trial data collection (paper & electronic) and data management (including validation processes) to ensure optimal quality data.
5. Identify the key strategic and operational issues in the clinical trial process, in terms of legislative requirements and Good Clinical Practice (GCP).
6. Describe the role of the Investigator Drug Brochure (IDB).
7. Discuss the principles and practical relevance of ethical issues in biomedical research.
8. Outline the legal and ethical provisions for protection of clinical trial subjects.

MODULE BCM3: EXPLORATORY AND CONFIRMATORY CLINICAL DEVELOPMENT

BCM 3	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 3.1	First administration to patients; principles of proof of concept and dose-finding studies.	1	5.12
BCM 3.2	Concept of blinding.	2	4.5
BCM 3.3	Trial design: pre-trial decisions and specifications; literature review; incidence & prevalence of the disease; risk factors; confounding variables; dealing with confounding factors and bias; review of literature.	2	9.8, 9.25, 9.11, 9.20, 9.24
BCM 3.4	Clinical trials regulations; EU Directives & Guidances and their diversity in national implementation; CTA including IMPD, substantial amendments. Clinical trial regulations in other regions e.g. the US IND process.	2, 5	10.10

BCM 3	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 3.5	Protocol writing: detailing choice of location(s), trial design, blinding, placebo or other comparators, end-points, patient population, informed consent, sample size, randomisation, statistical methods, interim analysis.	2, 3	7.6
BCM 3.6	Analysis of efficacy endpoints and of safety (intention to treat principles, handling of missing data etc.); interim analysis; statistical tests (sensitivity & specificity of tests; paired & non-paired tests, parametric & non-parametric tests, confidence limits).	3	9.14, 9.15, 9.16, 9.18, 9.19
BCM 3.7	Options for data collection (manual & electronic) and standardisation; creation, maintenance and security of databases, software validation and archiving.	4	9.1, 9.3
BCM 3.8	Case report form (CRF) design and review.	4	9.2
BCM 3.9	The purpose and fundamentals of statistics. The role & responsibilities of the statistician. Statistical considerations of study design: hypothesis testing (the Null hypothesis, type I & type II error, significance, power), randomisation, sample size. The Statistical Analysis Plan (SAP), including interim analysis.	3	9.5, 9.6, 9.7, 9.9, 9.10, 9.11, 9.15
BCM 3.10	Principles of Good Clinical Practice (GCP) and procedures applied in all stages of the clinical trial process to ensure subject protection, scientific validity and safety. Clinical trial registries.	5	7.4, 7.11
BCM 3.11	Investigator Brochure: content, review and maintenance.	6	7.5
BCM 3.12	Ethics: principles, history including Declaration of Helsinki, EU Directive 2001/20/EC, ethical review process, informed consent, safety & human dignity of research subjects. Ethical issues in biomedical research and pharmaceutical medicine.	7	8.1, 8.2
BCM 3.13	Protection of research subjects. Risks, benefits and burden of study participation. Minimising risk including site qualification assessment; ethical aspects of subject contact and recruitment, and of reimbursement, compensation and inducement; indemnity and insurance for participants, investigators, institutions; complaint procedures.	7, 8	8.3, 8.6, 8.7, 8.8, 8.11
BCM 3.14	Ethical aspects of research questions and study designs for first-in-human to post-marketing and epidemiological studies, including post-study follow-up procedures, placebo and comparator choice.	7, 8	8.4, 8.12

BCM 3	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 3.15	Conflict of interest and equipoise.	8	8.5
BCM 3.16	The informed consent process. Privacy, confidentiality and data protection.	7, 8	8.9, 8.10
BCM 3.17	Ethical aspects of taking trial samples for genomic and related analyses.	8	8.13
BCM 3.18	Ethical aspects of clinical trials in vulnerable populations.	8	8.14
BCM 3.19	Ethical aspects of advanced therapy medicinal products.	8	8.15
BCM 3.20	Ethical aspects of international clinical trials, considering socio-cultural differences.	7, 8	8.16
BCM 3.21	Therapeutic Topic 5		14.1-14.10
BCM 3.22	Therapeutic Topic 6		14.1-14.10

PHARMATRAIN BASE COURSE **MODULE BCM 4: CLINICAL TRIALS**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Describe the various types of clinical studies and the methods used to choose the appropriate design.
2. Describe the main statistical methods used in clinical research.
3. Identify the key issues involved in the conduct of a clinical study including investigator and site recruitment, investigative site management and conflict resolution.
4. Discuss the collection, evaluation and reporting of adverse event data in clinical trials.
5. Outline the various quality management issues in clinical trials.
6. Describe the impact of emerging results on the drug development plan.
7. Outline the key operational and strategic issues in the clinical development plan.
8. Explain the evaluation of the outcome of drug development: final therapeutic profile / usage of a medicine.
9. Describe the role of the Target Product Profile (TPP) and Target Product Claims (TPC).
10. Explain the role of the Drug Safety Monitoring Board (DSMB) and other relevant study committees.
11. Discuss the statistical issues in statistical report writing.
12. Describe the evaluation and interpretation of clinical trial results.
13. Illustrate the principles and practical application of critical appraisal.

MODULE BCM 4: CLINICAL TRIALS

BCM 4	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 4.1	Choice of interventional clinical trial design, of placebo and other comparators, of patient populations, of locations. New trial designs e.g. adaptive design. Non-interventional / observational study design.	1	7.1, 7.2, 7.3

BCM 4	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 4.2	Types of data and standardisation of measurement e.g. handling of rating scales, including visual analogue scales and laboratory values. Statistical analysis of efficacy end-points and of safety. Patient-reported outcomes e.g. diaries; quality-of-life measures	2	9.12, 9.13, 9.14, 9.17
BCM 4.3	Feasibility testing and investigator recruitment; pre-study visits and investigator meetings; investigator training; contractual arrangements with investigators and contract research organisations, including matters such as publication rights and conflicts of interest.	3	7.7, 7.8, 7.10
BCM 4.4	Project management: EUDRACT, CTA and ethics opinion, resources and budget, timelines, conflict resolution (e.g. investigator discontinuation).	3	7.9
BCM 4.5	Clinical trial conduct / Investigative site management: Trial Master File (TMF), monitoring and source document verification, study medication handling and drug accountability. Within-trial decisions (e.g. code-breaking, premature termination); emergency coverage.	3	7.12, 7.13, 7.14, 7.15, 7.16, 7.17
BCM 4.6	Quality management: quality assurance and quality control; SOPs; audits; inspections.	5	7.18
BCM 4.7	Fraud & misconduct in biomedical research and clinical development.	3, 5	8.17
BCM 4.8	Assessment and classification of adverse events (AEs), adverse drug reactions (ADRs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs); evidence for association and causality.	3, 4	11.2
BCM 4.9	Collection of adverse events in clinical trials; role of sponsors and investigators in reporting; regulatory requirements.	3, 4	11.4, 11.5
BCM 4.10	Impact of results on the drug development plan (DDP) and possible need for further toxicology / pharmaceutical development data; regulatory review of existing and emerging research results.	6	5.13, 6.6
BCM 4.11	Final definition of therapeutic indications. Categories of patients, delivery system(s), dosage forms and dosage regimens.	8	6.1

BCM 4	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 4.12	Planning & global coordination / harmonisation of pre- and post-licensing clinical trial programmes; use of non-clinical and existing clinical trial data.	7	6.2
BCM 4.13	Decision points, schedules and resources required for confirmatory clinical development plan (CDP). Calculation of clinical trial supplies and costs up to registration.	7	6.3, 6.4
BCM 4.14	Review & maintenance of Target Product Profile (TPP) and Target Product Claims (TPC).	9	2.3
BCM 4.15	The role of the independent Drug Safety Monitoring Board (DSMB) and other relevant study committees.	10	7.13
BCM 4.16	Measurement and types of data; monitoring of clinical trials; source document verification, CRF review and correction, data entry, query generation and resolution, coding of adverse events, database lock.	2, 4	7.16, 9.4
BCM 4.17	Preparing the statistical report: interpretation of analyses; assessment of violations, withdrawals, errors, bias; data manipulation, transformation and merging.	11	9.21, 9.22
BCM 4.18	Clinical interpretation of study analyses and results. The Clinical Trial Report.	12	7.19, 9.23
BCM 4.19	Critical review of publications.	13	9.25
BCM 4.20	Therapeutic Topic 7		14.1-14.10
BCM 4.21	Therapeutic Topic 8		14.1-14.10

PHARMATRAIN BASE COURSE **MODULE BCM 5: REGULATORY AFFAIRS; DRUG SAFETY AND PHARMACOVIGILANCE**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Describe the general principles of medicines regulation (both pre- & post-approval) at EU and global level.
2. Discuss the impact of medicines legislative requirements on regulatory activities within a pharmaceutical company.
3. Explain the role of national agencies and international bodies in medicines regulation.
4. Describe the national provisions for management of: (1) off-label / unlicensed use of medicines, and (2) controlled drugs.
5. Discuss the place of the International Conference on Harmonisation (ICH) in medicines regulation (including Common Technical Document [CTD]).
6. Explain the regulatory processes in the EU / EEA areas.
7. Describe the regulation & legal considerations of Product Information.
8. Outline the principles & practical application of medical devices regulation.
9. Discuss the roles of the various stakeholders (including pharmaceutical and other healthcare professionals, investigators, regulatory authorities) in drug safety and pharmacovigilance.
10. Outline the classification of adverse events / adverse drug reactions.
11. Describe the safety reporting requirements (according to the type of adverse event / reaction) pre- & post-approval.
12. Discuss the ongoing management of drug safety issues pre- & post-approval (including Risk Management Plans [RMPs], Periodic Safety Update Reports [PSURs]); ongoing benefit / risk assessment throughout the life-cycle of a medicine.
13. Discuss the role of pharmacoepidemiology in the life-cycle management of a medicine.
14. Describe the factors influencing medication safety from the perspective of each stakeholder.

MODULE BCM 5: REGULATORY AFFAIRS; DRUG SAFETY AND PHARMACOVIGILANCE

BCM 5	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 5.1	General principles of medicines regulation; philosophy of regulatory oversight; input of international bodies; evolution of control mechanisms; general differences between agencies; International Conference on Harmonisation (ICH).	1, 5	10.1, 10.2, 10.3, 10.4
BCM 5.2	Overview of relevant regulatory Directives; overview of Good Practices (e.g. GCP, GMP, GLP) including inspections.	1, 5	10.5
BCM 5.3	Integration of regulatory affairs in pre- & post-marketing company activities; planning and reviewing product strategy. Prescription-Only-Medicines (POM) & Over-The-Counter (OTC) medicines; OTC switching strategies. Generics and biosimilars. Parallel imports.	2	10.6, 10.16, 13.10
BCM 5.4	Common Technical Document (CTD & eCTD). Overviews; aggregate clinical trial report reviews, including annual reports and CTD summaries.	5	10.11, 10.12
BCM 5.5	Regulatory systems in Europe, US, Rest of the World (ROW), and local special regulatory requirements. The preparation and submissions of marketing authorisation applications in major countries.	1, 2, 3	10.9, 10.13
BCM 5.6	Approval, appeals and referral processes in Europe (Centralised Procedure, Mutual Recognition Procedure, Decentralised procedure, national procedures); updating and maintaining Marketing Authorisations (variations regulation); aspects of confidentiality and transparency.	6	10.7
BCM 5.7	Regulation of Product Information: Summary of Product Characteristics (SmPC), labelling, US Prescribing Information, EU Package Leaflet; EU readability testing.	7	10.14
BCM 5.8	National differences in regulations / procedures for using locally unlicensed medicines (e.g. compassionate use). Off-label use and misuse.	4	10.17, 10.26
BCM 5.9	Controlled drugs regulation.	4	10.25

BCM 5	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 5.10	Medical device regulation.	8	10.19
BCM 5.11	Risk management; EU Detailed Description of Pharmacovigilance System (DDPS); EU Risk Management Plan (RMP); Risk Evaluation and Mitigation Strategies (REMS) in the USA.	12	10.21
BCM 5.12	The role of the pharmaceutical professional in drug safety and pharmacovigilance.	9	11.1
BCM 5.13	The concept of benefit / risk assessment. Assessment and classification of adverse events (AEs), adverse drug reactions (ADRs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs); evidence for association and causality.	10, 12	11.2, 11.3
BCM 5.14	Risk factors for adverse events.	14	11.6
BCM 5.15	Spontaneous reporting of suspected adverse drug reactions in the post-licensing phase.	11	11.7
BCM 5.16	Dosage, drug accumulation, medication errors and interactions.	14	11.8
BCM 5.17	Drug adherence / compliance.	14	11.9
BCM 5.18	Periodic Safety Update Reports (PSURs).	11, 12	11.10
BCM 5.19	Pharmacoepidemiology; main sources of epidemiological pharmacovigilance information.	13	11.11, 11.12
BCM 5.20	Signal detection, interpretation and management.	12	11.13
BCM 5.21	Post-Authorisation Safety Studies (PASS).	12, 13	11.14
BCM 5.22	Post-authorisation risk management including issue and crisis management, risk communication with all the stakeholders; Direct Healthcare Professional Communication (DHPC).	12	11.15. 11.16
BCM 5.23	Product withdrawal procedures; product defects and recall.	12	10.18, 10.24
BCM 5.24	Therapeutic Topic 9		14.1-14.10
BCM 5.25	Therapeutic Topic 10		14.1-14.10

PHARMATRAIN BASE COURSE **MODULE BCM 6: HEALTHCARE MARKETPLACE; ECONOMICS OF HEALTHCARE**
LEARNING OUTCOMES
On successful completion of this Module the student should be able to:
1. Illustrate the life-cycle management (clinical, regulatory and marketing) of medicines.
2. Describe the processes of production and review of product information to ensure adherence to ethical and legal principles pertaining to marketing activities (Good Promotional Practice).
3. Discuss the role of patient organisations.
4. Discuss the principles & practical application of health economics and patient-reported outcomes within the pharmaceutical industry.
5. Outline the principles of health technology assessment (HTA) and its role in the supply of medicines to the marketplace.
6. Discuss the principles and practice of marketing within the pharmaceutical industry.
7. Discuss drug budget control; pricing mechanisms.

MODULE BCM 6: HEALTHCARE MARKETPLACE; ECONOMICS OF HEALTHCARE

BCM 6	**CURRICULUM CONTENT**	**LEARNING OUTCOMES MAPPING**	**SYLLABUS MAPPING**
BCM 6.1	Life-cycle management planning: extension of therapeutic claims, new formulations, new dosage schedules by peri-marketing trials, post-marketing (surveillance) studies, OTC studies and quality of life measures.	1	6.5, 13.4, 13.10
BCM 6.2	Information, promotion and education; information to patients, prescribing and patient compliance. Direct Healthcare Professional Communication (DHPC).	2	10.23, 12.1
BCM 6.3	Advertising and promotion regulations; advertising claims: ethics, control and approval; promotional materials; Codes of Practice; promotional policy & procedures; Good Promotional Practice; promotional material and product support on the basis of the Marketing Authorisation.	2	10.5, 12.2, 12.3, 12.4, 12.5

BCM 6	CURRICULUM CONTENT	LEARNING OUTCOMES MAPPING	SYLLABUS MAPPING
BCM 6.4	Role of patient organisations.	3	12.1
BCM 6.5	Overview of healthcare economics, health economic evaluation studies. Principles of pharmacoeconomics and evidence-based medicine. Measurement of healthcare efficiency. Governmental policy and third party reimbursement.	4	13.1, 13.2, 13.3, 13.7, 13.11
BCM 6.6	Evidence Based Medicine (EBM), Health Technology Assessment (HTA), Treatment Guidelines.	5	13.11
BCM 6.7	Quality of Life, concept and measurement instruments.	4, 5	13.4
BCM 6.8	Principles & practice of marketing; market structure and competition; market analysis; medical marketing and market access. Economics of industry: competition, licensing, co-marketing.	6	13.5, 13.6, 13.8
BCM 6.9	Publication strategy; educational meetings; sponsored meetings and publications.	2, 6	12.6, 12.8
BCM 6.10	Sales representative training; material and aids.	2, 6	12.7
BCM 6.11	Drug budget control; pricing mechanisms; methods of reimbursement.	7	13.1, 13.5
BCM 6.12	Therapeutic Topic 11		14.1-14.10
BCM 6.13	Therapeutic Topic 12		14.1-14.10