Faculty of Pharmaceutical Medicine

Advancing the science and practice of pharmaceutical medicine for the benefit of the public

Exam Specification

Certificate and Diploma in Pharmaceutical Medicine

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Version 6	10 January 2022 - Reviewed Feb 2024	Dr Penny Ward MBBS FFPM Chair, Education and Standards Committee Dr Ruth Dixon BSc, MB ChB, MRCP, DPM, DCPSA, FFPM Chair, Board of Examiners

Contents

1 Background

This document outlines the format and content of the Diploma in Pharmaceutical Medicine (DPM) examination and forms the basis of both the setting of the examination, with respect to the types of papers, the number and range of questions asked, and the provision of feedback to candidates.

Candidates for the Certificate in Pharmaceutical Medicine (CPM) should note that the DPM Part 1 multiple choice question paper referenced in this document is also the Certificate in Pharmaceutical Medicine question paper.

2 Syllabus

With effect from 2012, the DPM exam uses the IMI PharmaTrain Syllabus (the Syllabus) for Pharmaceutical Medicine/Drug development Science. Version 2.0 (dated 1 January 2018) will be used until further notice. A copy of the Syllabus is included as Appendix 1 to this document.

The Syllabus is divided into 13 sections are shown in Table 1:

Table 1 Syllabus Sections

Section No	Section name
SECTION 1	Discovery of Medicines
SECTION 2	Development of Medicines: Planning
SECTION 3	Non-Clinical Testing
SECTION 4	Pharmaceutical Development
SECTION 5	Exploratory Development (Molecule to Proof-of-Concept)
SECTION 6	Confirmatory Development
SECTION 7	Clinical Trials
SECTION 8	Ethics and Legal Issues
SECTION 9	Data Management and Statistics
SECTION 10	Regulatory Affairs
SECTION 11	Drug Safety, Pharmacovigilance and Pharmacoepidemiology
SECTION 12	Information, Promotion and Education
SECTION 13	Economics of Healthcare, Health Economics and Pharmacoeconomics

Within each major Section are sub-sections which list in greater detail the knowledge items appropriate to that section.

3 Examination Structure

The Diploma is a two-part examination. Part 1* consists of a Multiple-Choice Question (MCQ) paper and Part 2 comprises a Short Answer Question (SAQ) paper and a Critical Appraisal Paper (CAP). The two parts of the exam are set on separate days approximately 4 weeks apart. Candidates must have passed Part 1 before they are eligible to sit Part 2.

3.1 Part 1 Multiple Choice Questions

The MCQ paper* comprises 75 questions (stems) each with five completions such that a total of 375 discrete questions are asked. The completions relate directly to the stem and may be either true or false. Any number may be true and any number may be false. Candidates are required to indicate which are true and which false and are awarded 1 mark for each correct answer. Incorrect or missing answers score 0. There is no negative marking. Candidates have 2.5 hours to complete the paper.

Each of the 75 stems will be assigned one of the 13 categories shown in Table 1. The assignment will be made initially by the author of the question and will be verified by the examination review group (which is typically the Officers and Paper Conveners) before the use of the question in a sitting. If a question is re-used the category assignment will be confirmed prior to re-use.

Where the question tests knowledge that is drawn from more than one section of the syllabus, it will be assigned to the section which has the majority of completions.

The ***minimum*** number of questions per section of the syllabus for the MCQ paper is shown in Table 2. As this is the minimum number it does not add up to 75. The balance will be made up with questions from any section.

*The Diploma Part 1 multiple choice question paper is also the Certificate in Pharmaceutical Medicine question paper.

Table 2 Allocation of questions within the MCQ paper according to syllabus sections

Section Number	Section Title	Minimum Number of Questions
SECTION 1	Discovery of Medicines	2
SECTION 2	Development of Medicines: Planning	1
SECTION 3	Non-Clinical Testing	5
SECTION 4	Pharmaceutical Development	2
SECTION 5	Exploratory Development (Molecule to Proof-of Concept)	6

SECTION 6	Confirmatory Development	1
SECTION 7	Clinical Trials	9
SECTION 8	Ethics and Legal Issues	4
SECTION 9	Data Management and Statistics	5
SECTION 10	Regulatory Affairs	7
SECTION 11	Drug Safety, Pharmacovigilance and Pharmacoepidemiology	7
SECTION 12	Information, Promotion and Education	3
SECTION 13	Economics of Healthcare, Health Economics and Pharmacoeconomics	3

3.2 Part 2 Short Answer Question Paper

The SAQ paper will consist of 10 separate compulsory questions. Candidates are given 2.5 hours (average 15 minutes per question) to complete the paper and are expected to answer in note form.

Each of the 10 questions will be assigned to one of the 13 categories shown in Table 1. The assignment will be made initially by the author of the question and will be verified by the examination review group (which is typically the Officers and Paper Conveners) before the use of the question in a sitting. If a question is re-used the category assignment will be confirmed prior to re-use. For questions which require knowledge of more than one section of the syllabus, a primary section will be assigned according to the predominant theme of the question.

The SAQ paper will consist of at least one question from the following sections of the syllabus:

Section 1 or Section 3	Discovery of Medicines / Non-Clinical Testing
Section 5	Exploratory Development
Section 7 or Section 8	Clinical Trials / Ethics and Legal Issues
Section 9	Data Management & Statistics
Section 10	Regulatory Affairs
Section 11	Drug Safety, Pharmacovigilance and Pharmacoepidemiology

Section 12 or Section 13	Information, Promotion and Education / Economics of Healthcare, Health Economics and Pharmacoeconomics

The balance of the 10 questions will be drawn from all sections of the syllabus, including from the compulsory sections listed above. There will be no more than two primary questions from any one section.

3.3 Part 2 Critical Appraisal Paper

The CAP will require candidates to read a published manuscript and answer questions on the article. Two and a half hours are allowed for this paper. The questions will be of three broad types:

1. Descriptive questions. These require the candidate to summarise information or data that is given within the manuscript.

2. Comment/critique questions. These questions will require the candidate to comment in a critical way on information within the paper. A comment question will typically follow a descriptive question and will relate directly to it.

3. Questions relating to next steps, trial redesign etc. These questions will require the candidate to think beyond the paper they have in front of them and suggest alternative or follow-up study designs etc.

The total number of questions asked will vary from year to year according to the content of the manuscript but will typically be around 12. There will be a ***minimum*** of four questions from category 1, three questions from category 2 and one question from category 3. The remainder of the questions can be drawn from any category provided the split allows for the allocation of marks described below.

Approximately 40% (permitted range 35-45%) of the marks available for the paper will be assigned to descriptive (category 1) questions and the remainder of the marks will be awarded to questions from categories 2 and 3.

The questions in the CAP will be designed to broadly assess a candidate's competence with respect to the following Speciality Capabilities in Practice (CiPs) sections of the *2021 PMST Curriculum*:

Speciality CiP	**Objective**
1	Enables and supports patients' timely access to medicines appropriate for their clinical need
2	Operates within ethical, regulatory and good practice frameworks

3	Participates in data generation, analysis and communication
4	Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices
5	Conducts clinical research for the development of medical products.
6	Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation
8	Supports business decision-making and progression in medical product innovation and development

Questions asked in the CAP may come from any part of the *Syllabus*, and the mix of questions will vary from sitting to sitting according to the constraints of the particular manuscript chosen. However, at a ***minimum***, the manuscript chosen must allow at least one question from the following sections of the Syllabus to be asked:

Section 7	Clinical Trials
Section 8	Ethics & Legal Issues
Section 9	Data Management & Statistics

Ideally, the manuscript will also allow at least one question from Section 11, Drug Safety, Pharmacovigilance and Pharmacoepidemiology.

4 Feedback to Candidates

4.1 Passing Candidates

Candidates who pass either Part of the DPM examination will be informed by email that they have passed and will be provided with their overall marks for each of the sections that they sat.

4.2 Failing Candidates

Candidates who fail either Part of the DPM examination will be informed by email that they have failed and will be provided with their overall marks for each of the sections which they sat. In addition, to assist these candidates with preparation for future examinations, more detailed feedback will be provided on their performance in each of the sections of the syllabus.

The candidate's performance in the MCQ paper will be fed back by means of completion of the following table (Table 3) for each candidate individually:

Table 3 Feedback table for MCQ paper

Syllabus Section Number	Syllabus Section	Number of Questions from this Section	Total possible score for questions in this section (= no. of qu x 5)	Candidate's score for this Section
1	Discovery of Medicines			
2	Development of Medicines: Planning			
3	Non-Clinical Testing			
4	Pharmaceutical Development			
5	Exploratory Development (Molecule to POC)			
6	Confirmatory Development			
7	Clinical Trials			
8	Ethics and Legal Issues			
9	Data Management and Statistics			
10	Regulatory Affairs			
11	Drug Safety, PV and Pharmacoepidemiology			
12	Information, Promotion and Education			
13	Economics of Healthcare, Health Economics and Pharmacoeconomics			

The candidate's performance in the SAQ paper will be fed back by means of completion of the following table (Table 4) for each candidate individually:

Table 4 Feedback table for SAQ paper

Question Number	Syllabus Section^	Candidate's Score (Out of 10)
1		
2		
3		

4		
5		
6		
7		
8		
9		
10		
^Section of the Syllabus to which the question primarily relates		

For the CAP, candidates will be notified of their marks for each of the questions individually, as shown in Table 5.

Table 5 Feedback table for CAP paper

Question Number	Number of marks available	Candidate's Score
1		
2		
3		
4		
5		
6		
etc		

5. Review

The examination specification will be kept under informal review on a continual basis by the Officers of the Board of Examiners and Paper Conveners group. In addition, it will undergo a formal review at any time that there is a change in the Syllabus or a change in structure or conduct of the examination. Changes may be made to the specification following either type of review.

6. Approval

The Examination Specification will be approved by the Chairs of the Board of Examiners and the Education and Standards Committee who will sign off the document on behalf of the two bodies following appropriate review and approval by those two bodies.

Appendix 1: PharmaTrain Syllabus

PharmaTrain MASTERING MEDICINES DEVELOPMENT *Syllabus 2018*

PharmaTrain Syllabus for Pharmaceutical Medicine / Medicines Development Science

Section Overview

1. **SECTION Discovery of Medicines**
2. **SECTION Development of Medicines: Planning**
3. **SECTION Non-Clinical Testing**
4. **SECTION Pharmaceutical Development**
5. **SECTION Exploratory Development (Molecule to Proof of Concept)**
6. **SECTION Confirmatory Development**
7. **SECTION Clinical Trials**
8. **SECTION Ethics and Legal Issues**
9. **SECTION Data Management and Statistics**
10. **SECTION Regulatory Affairs**
11. **SECTION Drug Safety, Pharmacovigilance and Pharmacoepidemiology**
12. **SECTION Information, Promotion and Education**
13. **SECTION Economics of Healthcare, Health Economics and Pharmacoeconomics**

1. Discovery of Medicines

1.1 Strategy and organisation of research including collaborative approaches with academia and small- and medium-sized enterprises; in- and out-licensing, medical due diligence; intellectual property

1.2 Unmet medical need; target identification and validation

1.3 Receptor-based approaches (agonists and antagonists), enzyme inhibitors; genomics, proteomics, metabolomics

1.4 Other therapeutic approaches: natural products, drug-coupled devices, advanced therapies e.g., gene therapy, cell therapies, tissue engineering

1.5 Hit-to-lead, lead optimisation and candidate compound selection for further development

1.6 *In silico*, *in vitro* and *in vivo* testing of new compounds

1.7 Principles of translational medicine

1.8 Relationship between animal and human pharmacology, molecular biology and physiology e.g., biomarkers, functional imaging, modelling and simulation

2. Development of Medicines: Planning

2.1 The elements and functions necessary in the integrated development of a new medicine at a corporate and international level

2.2 Quality management planning

2.3 Project management techniques: drug development plan, project teams, tools and decision-making from target product profile (TPP) and target product claims (TPC) to registration dossier submission and life-cycle management

2.4 Programme-planning in special populations e.g., elderly, children, people with rare diseases, incapacitated people

2.5 Programmes in developing countries

2.6 R&D portfolio planning including in- and out-licensing of medicines (business development)

2.7 Resource planning: budgeting and cost control

2.8 Corporate finance relevant to medicines development: financial control, return on investment, fixed assets, budgeting, accounting, profitability

3. Non-Clinical Testing

3.1 Use of *in silico*, animal- and cell-based models of disease mechanisms to study the pharmacology of a new drug

3.2 Differences in non-clinical safety and toxicity packages between small molecules, biological medicines, advanced therapies

3.3 The differences and similarities between the pharmacology and toxicology of compounds and their metabolites in animals, humans and cell preparations that provide qualitative and quantitative assessment through: genotoxicity, general toxicity, toxicokinetics, pharmacokinetics, drug metabolism, safety pharmacology, immunotoxicity, reproductive toxicity, carcinogenicity; duration of studies to support clinical trials and marketing approval

3.4 The purpose of descriptive and quantitative *in silico, in vitro* and *in vivo* toxicity testing; the choice of appropriate tests for acute and chronic drug administration

3.5 The common mechanisms of drug-induced organ damage and dysfunction; detection and elucidation; pathological assessment e.g., structural staining and immune-histochemistry; functional assessment e.g., QTc interval testing, liver and lung function tests

3.6 The scheduling of toxicity tests linked to product development plans, regulatory needs, human and animal pharmacology, intended clinical use and route(s) of administration

3.7 The size, cost and administration of the toxicology programme, its data management, quality assurance and reporting

3.8 The regular review of toxicity, its inclusion into clinical trial protocols and investigator brochures, and the appropriate planning and correlation with the clinical evaluation of potential and observed toxicity in patients

3.9 Safety pharmacology including drug hypersensitivity of both small and large molecules

3.10 Toxicokinetics; *in vitro* and *in vivo* study of metabolism; administration, distribution, metabolism, elimination (ADME)

3.11 The non-clinical study of biological medicines, vaccines, advanced therapies e.g., gene therapy, cell therapies, tissue engineering

3.12 The non-clinical study of biopharmaceutical formulations

4. Pharmaceutical Development

4.1 Pharmaceutical development of drug substance and drug product, including biological medicines and advanced therapies: formulations; manufacture and supply of materials; labelling and presentation; stability and storage; purity; compatibility; disposal

4.2 The economic primary production of new compounds and secondary production of research and market formulations

4.3 The choice of formulations depending upon the characteristics of the compound and the intended uses of the product

4.4 The principles of *in vitro* and *in vivo* testing of formulations for bioequivalence, stability, impurity and incompatibility leading to a final specification, including formulations of follow-on drugs - generics, biosimilars

4.5 Planning clinical trial supply requirements; packaging and labelling of clinical trial supplies; stability and storage requirements; supply distribution; disposal of remaining stocks

4.6 Clinical trial supplies: preparing matching placebo and competitor products

4.7 Pharmacopoeias: role, use and hierarchy

5 Exploratory Development (Molecule to Proof of Concept)

5.1 Intended therapeutic indications, biomarkers for target engagement, efficacy and safety requirements, efficacy and safety end-points and criteria for 'go' / 'no-go' decisions for entry into humans and progression to Proof of Concept trials

5.2 Assessment of non-clinical data and the risk of hazards as prerequisites before administration to humans

5.3 Phase 0 studies: exploratory microdose and sub-therapeutic dose studies; the importance, limitations and uses of microdoses (ICH M3)

5.4 The early clinical development plan: exploratory development studies:
- from First in Human to Proof of Concept
- modelling and simulation
- tolerability, metabolism, pharmacokinetics, pharmacodynamics, safety in humans
- safety assessment in patient and healthy volunteer populations
- dose escalating safety committees (membership and role)
- special considerations for advanced therapies and drug-coupled devices

5.5 Pharmacokinetics, ADME, pharmacokinetic / pharmacodynamic models, including concepts of half-life, volume of distribution, clearance; intrinsic and extrinsic factors which affect the pharmacokinetics of an innovative medicinal product; dosage and accumulation, bioavailability, bioequivalence and population pharmacokinetics

5.6 Pharmacogenetics / pharmacogenomics

5.7 Starting dose and dose escalation plan for First in Human and early clinical studies, including applicability of pharmacokinetics to dosage regimen and study design in First in Human studies and subsequent Phase II and Phase III clinical trials

5.8 First in Human studies: patients and healthy volunteers; principles of Proof of Concept and dose-finding studies; biomarker qualification / validation for Proof of Concept studies

5.9 Impact of results on planned therapeutic indications, predicted dosage schedules and drug delivery concepts / formulations; additional animal toxicology requirements; reformulation studies; new pharmacology studies; risk prediction algorithms to assess safety risks and enable development of risk management approaches to be applied during continued development

6. Confirmatory Development

6.1 Options for the clinical development plan (CDP); asset risk assessment and mitigation; schedules and decision points for the confirmatory clinical development programme

6.2 Translation of the defined target product profile (TPP) into the confirmatory clinical development programme design; pivotal and other Phase III studies; selection of primary and secondary endpoints and comparators for Phase III clinical trials; final definition of therapeutic indications; risk minimisation measures for research participants

6.3 Choice of countries / regions to participate in confirmatory clinical trials; patient numbers and selection criteria; delivery systems; dosage forms; dosage regimens; clinical trial supplies - ensuring all these are appropriate for this stage of development

6.4 Planning and global coordination including alignment of pre-licensing and post-licensing clinical trial programmes; permitted use of competitor class data, non-clinical data and existing clinical trial data

6.5 Life-cycle management planning: label extension of therapeutic claims and new formulations

6.6 Obtaining and implementing feedback from regulatory agencies and / or health technology assessment bodies on emerging research results and development plans through scientific advice procedures; consulting with other external bodies on proposed development plans

7. Clinical Trials

7.1 Choice of trial design, considering: non-inferiority / superiority / other design; placebo / other comparators; patient populations; sample size; locations; randomisation; end-points; statistical analysis

7.2 New trial designs and required technologies

7.3 Post-authorisation clinical development: Phase IV clinical trials; non-interventional / observational studies; Real World Evidence (RWE) generation; post-authorisation studies; patient group registries

7.4 Investigator Brochure: content, review and maintenance

7.5 Protocol development and amendments

7.6 Clinical trial feasibility and investigator recruitment; pre-study visits; investigator meetings and investigator training

7.7 Trial management including investigational site management and site qualification assessment

7.8 Contractual arrangements with investigators, academic institutions / hospitals, contract research organisations, site management organisations; publication rights

7.9 Clinical trial registries

7.10 Within-trial decisions e.g., code-breaking, interim analysis, data and safety monitoring committee (DSMC), premature termination

7.11 Study medication handling and drug accountability

7.12 Adverse event assessment and reporting; emergency cover

7.13 Monitoring and source document verification; evolution of clinical trial monitoring

7.14 Trial master file (TMF)

7.15 Quality management system; quality manual; standard operating procedures; quality assurance and quality control; independent audits; inspections

7.16 Reporting of clinical trial data: data sharing and open data, transparency, aggregate clinical trial report reviews, annual clinical trial reports

7.17 Consideration for special populations in clinical trials e.g., elderly, children, extreme ages e.g.,prematures-neonates, incapacitated people; clinical trials in rare diseases

7.18 Medical device and drug-coupled device trials

8. Ethics and Legal Issues

8.1 Ethics: principles, history including Declaration of Helsinki, Directive 2001/20/EC, ethical review, informed consent, safety and human dignity of research participants, role of ICH GCP and other Good Practices (GxPs)

8.2 Ethical issues in biomedical research and pharmaceutical medicine

8.3 Protection of research participants; sponsor and investigator responsibilities, in particular, to avoid conflicts of interest

8.4 Ethical aspects in research questions and study designs for First in Human to post-marketing and epidemiological studies, including scientific rationale, statistical robustness, appropriate patient populations, comparators and choice of endpoints; ensuring equipoise in comparator clinical studies; consideration of conflicts of interest

8.5 Ethical aspects of methods of recruitment including database searches and advertising; participant contact; participant reimbursement

8.6 Informed consent process, including defining benefit-risk balance, requirements for study participation including for special populations e.g., elderly, children, emergency research, incapacitated people

8.7 Privacy, confidentiality, international standards for data protection and consensual dissemination of clinical trial data

8.8 Indemnity and insurance for participants, investigators and institutions; complaint procedures

8.9 Ethical aspects of clinical trial follow-on: continuation of study medication to study participants, pre-marketing authorisation, availability pre-reimbursement

8.10 Ethical aspects of trial samples for genomic and related analyses: scientific rationale, ethics and consequences of anonymisation; biobanks

8.11 Ethical aspects of clinical trials in special populations e.g., elderly, children, emergency research, incapacitated people

8.12 Ethical aspects of all stakeholders involved in research of advanced therapies e.g., gene therapy, cell therapies, tissue engineering

8.13 Ethical aspects of clinical trials in developing countries

8.14 Fraud and misconduct in biomedical research and clinical development

9. Data Management and Statistics

Statistical Aspects of Study Design

9.1 Fundamentals: randomisation, choice of endpoints, avoidance of bias, avoidance of missing data, sample size calculation

9.2 Interim analyses: efficacy, futility, harm

9.3 The design of dose-finding studies

9.4 Equivalence and non-inferiority trials: rationale, choice of margin

9.5 Adaptive designs: basic ideas including advantages, concerns, avoidance of statistical and operational bias

Data Management

9.6 Data collection: options, to include manual and electronic, including diaries

9.7 Case report form (CRF) design and completion; source data verification, query generation and resolution

9.8 Data processing: data entry, coding of adverse events, medical history and concomitant medications; identification of protocol violations and deviations

9.9 Databases: maintenance, security, standardisation, streamlining the processes; Clinical Data Interchange Standards Consortium (CDISC)

Statistical Methods for Analysis

9.10 Fundamentals: Null and alternative hypotheses, type I and type II errors, p-values, confidence intervals, power, analysis sets

9.11 Endpoints: endpoint types (continuous, binary / categorical, time-to-event, rating scales), data transformation, primary and secondary endpoints, dealing with multiplicity, evaluating equivalence and non-inferiority

9.12 Specific methodologies: simple statistical tests (parametric and non-parametric), Odds Ratios, Risk Ratios, Hazard Ratios, Kaplan-Meier curves, modelling to correct for baseline imbalances and to reduce variation

9.13 Evaluating homogeneity: Forest plots and subgroup evaluation, testing for interaction

9.14 Dealing with missing data through imputation

9.15 Bayesian statistics; basic ideas

9.16 Safety data: tables and graphs for the evaluation of adverse events, laboratory data and other data relating to safety

9.17 Diagnosis: sensitivity, specificity and introduction to Receiver Operating Characteristic (ROC) curves

9.18 Meta-analysis: distinction versus pooling, fixed and random effects models

9.19 Observational studies: matching to minimise bias

The Statistics Process

9.20 Content for the protocol statistical methods section and the Statistical Analysis Plan

9.21 Writing the Statistical Study Report and contributing to the Clinical Study Report and clinical publications; to include the clinical interpretation of statistical analyses

9.22 Critical review of publications

10. Regulatory Affairs

10.1 Background to and general principles of medicines regulation; evolution of control mechanisms; differences between agencies

10.2 Philosophy of regulatory oversight; practical input of international bodies e.g., World Health Organisation (WHO), World Medical Association (WMA), Council for International Organisations of Medical Sciences (CIOMS), and national agencies

10.3 Activities and contribution of International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

10.4 Good Practices relevant to medicines development e.g., Good Manufacturing Practice, Good Laboratory Practice, Good Clinical Practice, Good Clinical Laboratory Practice, Good Pharmacovigilance Practice

10.5 Integration of regulatory affairs into pre- and post-marketing; planning and review of product strategy

10.6 Regulatory processes in Europe for the evaluation and approval of new medicinal products; scientific advice; appeal and arbitration procedures; procedures for maintaining, varying and cancelling European Marketing Authorisations; referrals processes; confidentiality and transparency

10.7 Regulatory processes: rare diseases, children, advanced therapies

10.8 Regulatory processes: generics and biosimilars

10.9 Comparison of international regulatory systems: Europe, US, Japan, and the Rest of the World; local special regulatory requirements

10.10 European regulations and guidance for Clinical Trial Application (CTA), maintenance and completion; EU single submission portal; substantial protocol modifications; transparency; clinical trial regulations in Europe, US, Japan and the Rest of the World

10.11 Common Technical Document (CTD and eCTD); Clinical Overviews; Clinical Summaries

10.12 The preparation and submission of marketing applications in major countries e.g. Marketing Authorisation Application (MAA), New Drug Application (NDA), Japanese NDA, Canadian NDA

10.13 Product Information regulation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets

10.14 Prescription-only and over-the-counter medicines; switches

10.15 Regulatory provisions for the use of unlicensed medicines

10.16 Product restriction, suspension and withdrawal procedures; product defects and recall

10.17 Medical device regulations

10.18 Regulation of natural products e.g., herbals, synbiotics, traditional remedies, Chinese medicines

10.19 Risk management: Risk Management Plan (EU); Risk Evaluation and Mitigation Strategies (USA); additional monitoring of authorised medicines e.g., inverted black triangle (EU), black box warning (USA)

10.20 Periodic Benefit Risk Evaluation Report (PBRER); Periodic Safety Update Report (PSUR); Development Safety Update Report (DSUR)

10.21 Regulation and procedures for early access to medicines

10.22 Falsified and counterfeit medicines

10.23 Post-authorisation safety studies; post-authorisation efficacy studies; investigator-initiated studies

11. Drug Safety, Pharmacovigilance and Pharmacoepidemiology

11.1 The role of the pharmaceutical professional in drug safety and pharmacovigilance

11.2 Assessment and classification of Adverse Events, Adverse Drug Reactions, Serious Adverse Events and Suspected Unexpected Serious Adverse Reactions (SUSARs); evidence for association and causality

11.3 The concept of benefit-risk balance assessment

11.4 Collection of adverse events in clinical trials

11.5 The role of investigators, clinicians, study monitors, sponsors and manufacturers in the pre- and post-marketing phases to detect, assess and report adverse events and suspected adverse drug reactions; regulatory reporting requirements in the pre- and post-marketing phases; medical literature reports

11.6 Predisposing factors and the impact of pre-existing disease on the susceptibility for and severity of adverse events and how to minimise risk

11.7 Post-marketing spontaneous reporting

11.8 Reportable events: overdose, medication errors, off-label use, misuse and abuse, experience during pregnancy

11.9 Drug interactions

11.10 Pharmacoepidemiology

11.11 Main sources of epidemiological pharmacovigilance information

11.12 Signal detection, interpretation and management

11.13 Post-authorisation risk management including issue and crisis management

11.14 Risk communication

12. Information, Promotion and Education

12.1 Information and disclosure to patients and patient organizations; compliance in patient engagement activities

12.2 Non-promotional product support, medical information, direct healthcare professional communication (DHPC) and other non-promotional activities; pre-licence activities

12.3 Codes of conduct: promotional policy and procedures; Good Promotional Practice; preapproval and post-approval activities; disclosure of transfers of value

12.4 Advertising: claims, prescribing information, media and digital methods, audiences, compliance, ethics, control and approval

12.5 Publication strategy for clinical trials and clinical research studies

12.6 Support of the development of clinical guidelines

12.7 Post-marketing studies

12.8 Educational meetings; sponsored meetings and sponsored publications

12.9 Characterising patient preferences used in health technology assessment dossiers or research e.g., discrete choice experiments (DCE), focus groups

12.10 Principles and practice of marketing; market structure and competition; market analysis

13 Economics of Healthcare, Health Economics and Pharmacoeconomics

13.1 Principles and methods of the economics of healthcare, health economics and pharmacoeconomics

13.2 Evidence-based medicine (EBM)

13.3 Health-related quality of life / patient-reported outcomes: concepts and methods of measurement.

13.4 Pricing and reimbursement strategies e.g., value-based pricing, reference pricing, risk-sharing schemes, advance budgetary notifications

13.5 Market access, national and local formularies

13.6 Measurement of healthcare efficiency: principles of international governmental policy and third-party reimbursement

13.7 Economics of industry: competition, licensing, co-marketing and life-cycle management to include generics, biosimilars, parallel imports and switching strategies

13.8 The appraisal of health-economic evidence, systematic reviews and meta-analyses, health technology assessment

13.9 Patient access to medicines: alternative funding routes for non-reimbursed products; preparing a simple economic impact model