ART. 1 A "Diploma in Pharmaceutical Medicine" will be awarded to physicians who succeed an examination composed of three parts:

- four written assignments;
- multiple choice questionnaire;
- an oral examination.

ART. 2 Examinations, both written and oral, are held in English.

ART. 3 The written assignments include the following tests:

1. case study in drug discovery and development;
2. analysis of pharmacokinetic data;
3. drafting a protocol for a clinical study;
4. health economics case study.

ART. 4 The written examination consists of a series of multiple choice questions (MCQ), taken from any part of the material taught in the 8 modules of the course. For each question 4 or 5 answers are provided: each of them can be true or false. No response or an incorrect one receives a zero mark.

ART. 5 The written examination and the written assignments can be performed according to two distinct pathways (see Art. 10,11, 12 and 13):

PATHWAY A: the written examination is split in 3 parts administered in January, April and June of each year; the written assignments are integrated into the courses with the subjects of assignments 1, 2, 3 and 4 provided in October, January, February and May respectively, the assignments being submitted 3 weeks later.

PATHWAY B: candidates will receive their tasks for the written assignments 12 weeks before the examination session and will submit their work ten weeks later i.e. two weeks before the session; written and oral examinations will take place on the same day or on two consecutive days.

ART. 6 During the oral examination, the candidate will choose in a random way among 5 questions proposed by each examiner. The jury will give a mark based on a checklist established by the examiner for each question. The duration of an oral examination is between 30 and 45 minutes.

ART. 7 The oral examination is held once a year in November or December. The date will be announced at least 3 months in advance.

ART. 8 It is desirable that candidates by the time of the examination have not only theoretical knowledge, but also some practical experience in pharmaceutical medicine. Those who are not yet employed by the pharmaceutical industry, a CRO or a hospital
performing clinical trials, are advised to work as a trainee for a period of 3 to 6 months in a pharmaceutical company, a CRO or an academic research laboratory before sitting the oral examination.

**Art. 9** The examination is organized by the Board of Examiners. Permanent members of the Board of Examiners and their area of special competence are as follows:

Jean-Marie BOEYNAEMS (Drug discovery and development), Chairman
Dominique DUBOIS (Pharmacoeconomics)
Roger VERBEECK (Pharmacokinetics)
Jean-Pierre TASSIGNON (Clinical Research)

At least 3 ordinary members should be present at each oral examination.

**Sequence of events**

**Pathway A**

**Art. 10** Pathway A is available to those participants who follow the modules in a sequential way over 1 or several years. The sequence of events is as follows:

**October**: The subject of the assignment "drug discovery and development" is submitted and briefly explained at the end of the week

**November**: Participants send their assignments a few days before the module; they are analyzed and discussed during the module

**January**: MCQ on preclinical research and development; the subject of the assignment "pharmacokinetic analysis " is submitted and briefly explained at the end of the week

**February**: Participants send their assignments a few days before the module; they are analyzed and discussed during the module

**February**: The subject of the assignment "clinical trial protocol " is submitted and briefly explained at the end of the week

**March**: Participants send their assignments a few days before the module; they are analyzed and discussed during the module

**April**: MCQ on pharmacokinetics, biostatistics and clinical trials

**May**: The subject of the assignment "health economics " is submitted and briefly explained at the end of the week

**June**: MCQ on drug safety evaluation, pharmacoepidemiology, pharmacoeconomics, regulatory affairs and medical information; participants send their assignments a few days before the module; they are analyzed and discussed during the module

Written assignments are prepared by groups of 3 participants. Depending on the total number of participants, there might be groups of 2 or 4 participants. Composition of the groups must be changed for each homework.

**Art. 11** The participants who follow the course over more than one year establish a
calendar according to which they intend to fulfill the various requirements. This calendar must be approved by the PHARMED Board of Examiners. It can be amended.

**Pathway B**

**Art. 12** Pathway B is available to candidates who do not attend the course, or who have attended the courses before academic year 2008-2009, or who do not follow the courses in the sequential way requested to comply with the calendar described in Art. 10. Candidates will receive their tasks for the written assignments 12 weeks before the examination session and will submit their work ten weeks later i.e. two weeks before the session. Written and oral examinations will take place on the same day or on two consecutive days.

**Art. 13** Candidates who follow the course in more than 1 year may choose to perform the assignments as described in Art. 10 but to present the MCQ according to Art. 12.

**Registration**

**Art. 14** Candidates intending to sit the oral examination should require a registration form from the PHARMED secretariat (Mrs B. Jellouli). After completion, registration forms should be submitted to the secretariat at least three months before the examination session together with a certified copy of the candidate’s diploma in medicine.

**Art. 15** To be eligible to sit the examination, candidates have to bear a University degree in human medicine awarded by a University recognised by the Free University of Brussels. In addition, they should have attended the 8 modules of the PHARMED course or have acquired equivalent theoretical and practical experience. Eligibility will be determined by the Chairman of the Board of Examiners on a case by case basis.

**Art. 16** Candidates found eligible to sit the oral examination will be informed in writing within one week after receipt of their completed registration form.

**Art. 17** Each candidate will receive a copy of the present "Examination Regulations and Procedures" as an attachment to the letter of acceptance of their application.

**Art. 18** Candidates are advised to look for assistance in the preparation of their examination from senior pharmaceutical physicians.

**Marks**

**Art. 19** Allocation of marks is as follows: 30/100 for the written assignments, 30/100 for the written examination and 40/100 for the oral examination. When the written examination is split, each part will be allocated 10/100.

**Art. 20** To pass the examination, candidates need to obtain:

- a 50% global mark for the assignments, with no more than one mark less than 50% for the individual assignments

- a 65% mark for each MCQ

- a 50% global mark for the oral examination, with no more than one mark less than 50% for the 4 individual parts of this oral examination
· a 60 % mark for the total.

If the candidate has demonstrated a severe weakness in one part of the oral examination, the jury may decide that, despite reaching a 50% global mark and a 60% mark for the total, the candidate has failed and needs to sit again only that part of the oral examination.

Art. 21 Candidates passing the examination will be awarded a "Diploma in Pharmaceutical Medicine".

Adjudication

Art. 22 The Board of Examiners meets soon after the oral examination, adjudicates and awards the degree to the successful candidates.

Art. 23 The Board of Examiners will award the degree with distinction to a candidate who achieves a high standard in all parts of the written and oral examinations.

Art. 24 The secretariat of PHARMED will inform the candidates in writing of the outcome of their examination.

Art. 25 A degree certificate signed by the members of the Board of Examiners will be delivered by mail.

Art. 26 Unsuccessful candidates will be advised, if they so request in writing, in which part(s) of the examination they failed.

Art. 27 An unsuccessful candidate may resit later the parts(s) of the examination that he/she failed, but normally can only sit three times.

Compliance with the regulations

Art. 28 The Board of Examiners may refuse to register a candidate or withdraw such registration at any time if the candidate’s behaviour is prejudicial before or during the examination by not complying with examination regulations and instructions.

Art. 29 The Board of Examiners may investigate any suspected dishonesty or misconduct by a candidate in relation to the examination and may later decide to revoke the degree.

Art. 30 Any representations or formal appeals by candidates on the conduct of the examination must be made in writing to the Chairman of the Board of Examiners. Formal appeals will be transmitted to the board of the Belgian College of Pharmaceutical Medicine, that will make a final decision.

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