Board of Examiners Newsletter Winter 2019

Dear Examiners, Educational Supervisors & Specialty Advisors

Welcome to the Winter 2019 newsletter for the Board of Examiners, from the Officers of the Board of Examiners (OBoE).

Diploma in Pharmaceutical Medicine Exam 2019

The results of the DPM for 2019 were ratified at the Board of Examiners (BoE) annual general meeting on 6th December. This year's results were:

* Part 1 (the MCQ paper) – 79.5% (31 out of 39 candidates) passed and were awarded the Certificate of Pharmaceutical Medicine
* Part 2 (the Short Answer Questions and Critical Appraisal Paper) – 74% (32 out of 43 candidates) passed and therefore passed the DPM; this is the best pass rate in over 10 years
* Distinctions were awarded to 3 candidates. Congratulations to candidates 15, 57 and 66 for your outstanding performances.

Changes to the DPM from this year:

Some changes have been made to the DPM, implemented for the 2019 examination onwards:

- Once passed, Part 1 (the MCQ) leads to the award of the Certificate in Pharmaceutical Medicine and does not have to be retaken even if a candidate fails the Part 2 multiple times
- For Part 2, candidates have to attempt both the SAQ and the CAP together the first time; However, if they pass one of the papers and fail the other, they do not have to retake the paper they passed and would need to retake only the paper they failed at the following year's sitting. (NB, this will not be applied retrospectively to previous years' exams).
- There's a caveat to this: validity of a pass in one of the Part 2 papers is time-limited, in order to maintain the expected standard for current knowledge across the curriculum:
    - Candidates have 3 opportunities to pass the previously failed paper (generally 3 years) before having to re-sit the paper they already passed.
    - Example: If a candidate takes the Part 2 in 2019, and passes the SAQ but fails the CAP, they then have the yearly sitting in 2020, 2021 and 2022 to pass the CAP separately. If they don't pass the CAP in 2022, they then have to start again with the Part 2 and take both the SAQ and CAP together.
    - The FPM can allow an extension to the validity of an individual's pass in one of the Part 2 papers if there are extenuating circumstances (such as illness, pregnancy) that prevent them taking the exam in a particular year.

Part 1 results

- The MCQ paper was held on 18th September 2019. This year the pass mark was 73% and 31 out of 39 passed (79.5%).
- 3 candidates applied to take Part 1 only and 39 applied for both Parts 1 & 2. Candidates should be aware that nothing is lost in applying for both Parts 1 and 2 upfront, as the Part 2 fee is refunded in case of failure in Part 1. However, a successful candidate in Part 1 who did not apply for Part 2 cannot then change their mind and sit Part 2 that year.

Part 2 results

- The Critical Appraisal Paper (CAP) was generally well done this year. Overall, 36 out of 43 candidates (84%) passed the paper, with quite a few people performing very well. The individual marks ranged from 26 to 44 out of 50 (median 35.25).
- The Short Answer Question paper (SAQ) was also well done; 35 out of 43 (81%) of candidates passed. The individual marks ranged from 45.25% to 85.75% (median 60.5%). Several candidates scored over 80% which is a really fantastic performance.
- Overall, 32 out of 43 candidates passed Part 2 (74%) and therefore passed the DPM overall, 4 failed both CAP and SAQ, 3 failed CAP only and 4 failed SAQ only.

Feedback from this year's examination

SAQ paper

Candidates are reminded that they can answer the questions in any order they like, and candidates might want to start with a couple of questions they know well to give them a bit of confidence. Overall, the time allowed is 15 minutes per question and candidates should manage their time and not go overboard on the questions they know, whilst not leaving enough time for those they might find more challenging.

A good example of how to do an SAQ well was a candidate who put a very full answer on one page of text by using carefully worded bullets and achieved a high mark. It was also legible, which is a substantial advantage when it comes to marking. A few minutes spent thinking and planning their answer would help many candidates.

It was pleasing to see that the statistics question (which included drawing a Forest plot) was generally well done this year, as was the question on the Code of Practice which was about Advanced Budgetary Notification and Joint Working. Although the scores ranged widely, the median was 7 or 7.5 (out of 10) showing that these two questions exceeded our expectations!

As ever, candidates are encouraged to read the question carefully, as marks are not given for an answer which doesn't address the question. We found that some candidates seem to take the approach of writing all they know about a topic without really addressing the question.

As an example, Question 1 asked this:

> You are the pharmaceutical physician responsible for reviewing the non-clinical data package to decide if a candidate drug should be taken into first in human studies. The data from the repeat dose in vivo dog study show a significant reduction in renal function.
> Briefly describe 10 important factors/considerations that will help to decide whether to take this candidate drug into first in human studies.

A good answer would have mentioned things like the NOAEL for renal function reduction, exposures at the toxic doses, exposure window, reversibility, histological correlate, mechanism, class effect, monitorability in man, risks in target population (con meds, concomitant disease etc), planned duration of dosing in man, potential benefit to patients etc etc.

If the question had asked what data is required for FTIH, many candidates would have scored highly. However, omitting to make any mention of the renal findings severely hampered many of the candidates' ability to score good marks (and saying carcinogenicity studies scored no marks).

There were similar lessons in Question 2 which asked:

> For a healthy volunteer, single ascending dose, first in human study, dose escalation meetings are held.
>
> a. Briefly describe the data required to be reviewed during these meetings.
> b. Briefly describe 4 potential outcomes following review of data at these meetings.
> c. Briefly describe 3 important logistical considerations for the conduct of each meeting.

A good answer to part a would have mentioned safety data (AEs, labs, vitals, ECG etc), PK data, PD data, PK-PD relationship etc. A list of non-clinical studies required prior to FTIH, given by some candidates, did not score.

CAP paper

The manuscript provided for the CAP this year described a placebo-controlled, crossover study examining the effect of soy phytoestrogens on hot flushes. One of the main problems with the study was that there was no washout period in between the two treatment periods, so that the data from the second period was uninterpretable due to carryover. Although many candidates did very well in the paper, a significant number failed entirely to spot this flaw.

The "descriptive" questions (i.e., answers that can be found within the paper) were (inevitably) done much better than the "critique" questions (i.e., ones that need some interpretation and comment). Nineteen marks were available for the last 4 questions which were "critique". These questions were answered particularly poorly by the candidates who failed. One of the questions (worth 6 marks) required candidates to give design features with justification of a new study to give a robust go / no-go decision for soy in the treatment of hot flushes. Some candidates just gave design features without justifying them – so simply saying "double blind" would not have scored. The final question focussed on requirements for public disclosure of trial results and disclosure of conflicts of interest, which was

chosen as a question in light of the poor performance in the SAQ on this topic in 2018. Whilst some candidates had clearly revised this area, some still performed poorly on this question. Multiple candidates only referred to the registration of the protocol and did not mention the results. As we've already said, reading the question is important.

There was a question asking about how patients were randomised to treatment. Very few candidates included the comment that there were no details on how the randomisation was performed (e.g., IVRS etc.).

There was a question on how the study subjects were recruited and screened. Some candidates focused their answer on the results of the study which was not being asked for in this question and did not mention that all screened candidates were eligible (too good to be true?).

Like the last few years, candidates were not required to draw a CONSORT diagram. Candidates were asked to consider patient disposition and need to be clear what disposition is. Drawing a CONSORT diagram has not been removed as a category of question and may be used again when appropriate, although it has been noted that their construction can be a time-consuming activity.

There were questions asking candidates to comment on the way that side effects were assessed and reported and on how compliance with study medication was assessed. Some candidates focused their answer on the results of the study which were not being asked for in this question

Planned changes to the DPM

From 2021, it is planned that the MCQ exam will be an electronic examination taken on a computer. A provider is being engaged which runs test sites in a large number of locations (akin to driving test centres where prospective drivers do the theory test) which has the potential to give more flexibility to candidates in the location they attend and accommodate overseas candidates too.

DHP, CHP and DET examinations

At the BoE AGM on Dec 6th, updates on the Certificate and Diploma in Human Pharmacology (CHP and DHP) and the Diploma in Experimental Therapeutics (DET) were given. Details of these qualifications can be found on the FPM website.

Dates for 2020

Examiners' training day: Friday 6 March 2020
DPM Part 1: Wednesday 16 September 2020
DPM Part 2: Monday 12 October 2020
BOE AGM: Friday 11 Dec 2020

Officers of the Board of Examiners

Juliet Roberts (Chair)
Ruth Dixon (Secretary)
Sheuli Porkess (Critical appraisal paper convenor)
Jon Sisson (MCQ paper convenor)
Eric Teo (SAQ paper convenor)
Chris Brearley
Kate Owen
Darren Wilbraham
Sanjay Patel
Marianne Whitelam (Examinations and Standards Manager) is currently on maternity leave. Sarah Davis is covering temporarily.

Changes to the OBOE in 2020:

After 6 years at the helm, Juliet Roberts has served the maximum two terms as Chair of the BOE. I'm delighted that Juliet's tireless work on the BOE (amongst other achievements in the advancement of pharmaceutical medicine) was recognised by award of the President's Medal at the recent FPM Annual General Meeting.

Sheuli Porkess will also stepping down from the role of CAP Convenor during 2020.

I will be taking the reigns as Chair in the new year and I'm grateful to both Juliet and Sheuli for their fabulous work.

I also want to thank all the BoE members who in any way contribute to the exams. BoE members are welcome to submit MCQ or SAQ questions, or a paper you think would be good for the CAP at any time, to any member of OBOE or the FPM.

Ruth Dixon, Examinations Secretary