



Medicines & Healthcare products Regulatory Agency

Board Meeting

A Framework of Quality Assurance for Responsible Officers and Revalidation

16 September 2019

<p><u>Issue/ Purpose:</u></p> <p>To provide the required assurance that the Responsible Officer and the Designated Body are discharging their statutory responsibilities as defined in the Responsible Officer Regulations.</p>
<p><u>Summary:</u></p> <p>A revalidation Framework of Quality Assurance (FQA) was introduced in order to provide the assurance required that the Responsible Officer and Designated Body are discharging their respective statutory responsibilities.</p> <p>The following three documents are attached:</p> <ul style="list-style-type: none"> the sixth Revalidation Annual Report covering the period April 2018 to March 2019 which includes a statement of compliance to be signed off by the Chairman before 27 September and then submitted to the higher-level responsible officer the Annual Organisational Audit (AOA) (an end of year questionnaire submitted to NHS England/Department of Health in early June 2019) a self-assessment using the effective clinical governance for the medical profession toolkit <p>Areas for highlighting to the Board are in the covering paper.</p>
<p><u>Resource implications:</u> None</p>
<p><u>Timings:</u></p> <p>The statement of internal compliance needs to be submitted to DHSC by 27 September 2019</p>
<p><u>Action required by the Board:</u></p> <p>The Board is asked to:</p> <ul style="list-style-type: none"> note and comment on the Annual Report and agree that the statement of compliance can be signed provide any comments on the clinical guidance handbook self-assessment note and make any comments on the AOA agree to the Responsible Officer plans following the retirement of the current Responsible Officer
<p><u>Links:</u> N/A</p>

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<u>FOI/publication issues:</u> None
<u>Which of the five themes in the Corporate Plan 2018/2023 does the paper support?</u> Theme 5
<u>If relevant, which Business Plan strategic activity does it support?</u>
<u>CET Sponsor:</u> Dr Ian Hudson

Background

1. The Framework of Quality Assurance (FQA) provides an overview of the elements defined in the Responsible Officer Regulations, along with a series of processes to support Responsible Officers and their Designated Bodies in providing the required assurance that they are discharging their respective statutory responsibilities. Designated Bodies are to receive annual board reports on the implementation of revalidation and submit an annual statement of compliance to their higher-level responsible officers.
2. The FQA assists responsible officers in providing assurance to their organisation's board or equivalent governance/executive group that doctors working in the designated body remain up to date and fit to practise. The process supports responsible officers in the preparation of their own appraisal portfolios, giving an overview of their performance. It also provides a formal record of compliance, which may be helpful should a designated body's systems and processes become subject to challenge at any stage.

Overview of documentation provided

3. The standardised FQA templates have been updated with a redesign of the key documents; the Annual Organisational Audit, the Board Report and the Statement of Compliance.
 - **Annual Organisational Audit**
4. The MHRA submitted the mandatory 2018/19 Annual Organisational Audit (please see attached – Annex A) in June 19. The MHRA appraiser network has considered the statistics and the comparisons with other organisations and against last years results.
 - **Annual Report and Statement of Compliance**
5. The Annual Board Report on medical revalidation covers the period April 2018 to March 2019 (please see attached – labelled as Annex D). The Board is asked to review the report and agree that the Chairman should sign the Statement of Compliance.
 - **Effective clinical governance for the medical profession: a self-assessment tool**
6. The General Medical Council has published a handbook, '[Effective clinical governance for the medical profession](#)' aimed at those who play an important leadership role in delivering and assuring the quality of clinical governance processes for doctors. We used the handbook's accompanying self-assessment tool to identify areas for improvement and the MHRA appraiser network has discussed (please see Annex B).

Particular areas to highlight to the Board

7. Areas for drawing to the Board's attention, including those identified through using the toolkit are highlighted below.

- **Responsible Officer succession plans**

8. The Board is asked to agree that Dr June Raine is appointed as the Responsible Officer following Dr Ian Hudson's retirement. Dr Raine will complete the required Responsible Officer training and attend the NHS England and DHSC Responsible Officer meetings.

- **Peer Review**

9. A reciprocal peer review has been agreed with Public Health England to look at each other's revalidation systems, to identify whether any improvements can be made and to learn from each other. Public Health England is part of the DHSC Responsible Officer network and share similarities with having doctors who do not engage in direct patient-facing clinical work. PHE will be carrying out the MHRA review on 4th September and MHRA will conduct the PHE review on 3rd October. A report will be prepared by PHE and this will be considered at an MHRA appraiser network meeting and an action plan developed as necessary, such as reviewing the Revalidation policy and providing additional training.

- **Missed appraisals and liaison with the General Medical Council**

10. The reasons for the missed appraisals (category 2 and 3, i.e. approved (e.g. for maternity/sick leave) and unapproved) are documented in the AOA. The missed appraisal that has been referred to the GMC is still under active review and has not yet been completed; we will continue to work with the GMC in terms of recommended next steps. The other incomplete appraisals were all associated with a single appraiser who has since left the MHRA (the appraiser had received good feedback from appraisees about their appraisal meetings, but unfortunately the appraisal documentation was not finalised within the required timeframes and the appraiser did not have their own appraisal before they left).

- **Lay involvement**

11. We have been considering how to increase lay involvement in revalidation and discussing the benefits this can bring. Lay representatives can provide a degree of independent scrutiny and challenge to revalidation processes. Mrs Madeleine Wang, who is a Commission on Human Medicines Expert Advisory Group lay representative has agreed to be involved with our revalidation activities and will contribute non-medical professional expertise and provide constructive challenge and provide support to the Responsible Officer as required. Mrs Wang has previous external revalidation experience with involvement with the introduction of revalidation. The Revalidation

Annual Report will also be considered at Board meetings open to the public and can be shared through the Patient Group Consultative Forum.

- **Board involvement**

12. Dr Barbara Bannister (Agency Board Non-Executive Director) has agreed to become the medical appraiser for some of the more senior doctors and will act as the Board 'Revalidation Champion'.

13. Revalidation should be built into the induction for new Board members, with additional revalidation training as required.

Actions

14. The Board is asked to:

- note and comment on the Annual Report and agree that the statement of compliance can be signed
- provide any comments on the clinical guidance handbook self-assessment and areas highlighted to the Board
- note and make any comments on the AOA
- agree to the Responsible Officer plans following the retirement of the current RO