



July 2017

## **Pharmacists' Defence Association Response to the General Pharmaceutical Council's Consultation on Revalidation for Pharmacy Professionals**

| representing **your** interests |

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## About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 26,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

### **The primary aims of the PDA are to:**

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

## Summary of GPhC proposals

The GPhC is consulting from 24 April 2017 until 17 July 2017 on proposals to change the existing Continuing Professional Development (CPD) requirements for pharmacists. It is calling the new framework "revalidation".

It is proposed that the current requirement for 9 CPD records to be completed each year will be reduced to 4 simplified CPD records (two of which must cover planned learning activities), plus a reflective account and a peer discussion.

## The PDA's recommendations are:

- The proposed revalidation framework and processes should be renamed to “continuing professional development” (CPD). The framework and process do not constitute revalidation or an assessment of fitness to practise; they do not include any formal appraisal, by a senior pharmacist, of a registrant's practise, will not detect impaired performance at an early stage and are otherwise not sufficiently rigorous. They do not meet the definitions of revalidation given by the Council for Healthcare Regulatory Excellence, the Professional Standards Authority or the Department of Health and are different in *principle* to the legal definition in the Medical Act 1983 (though the Act itself does not apply to pharmacists).
- Before changing the CPD process applicable to pharmacy technicians, the GPhC must undertake a detailed root cause analysis to understand why only a small number of pharmacy technicians joined the CFtP pilot process and the apparent lack of engagement / capability in completing all required records. It must then publish its findings.
- The review of CPD, peer discussion and reflective account records submitted by GPhC registrants should be conducted by pharmacists. Review by those who are not pharmacy professionals, including pharmacy technicians and lay persons, should be discouraged.
- We would like to see the ability to transfer records easily from a Royal Pharmaceutical Society faculty portfolio to the GPhC's online CPD, peer discussion and reflective account recording system.
- In respect of the proposed automated annual checks, we would like to see an alert given to pharmacists who are completing their annual declaration of fitness to practise, if it appears that they have not completed a full set of CPD, peer discussion and reflective account records. Such an alert would need to appear **before** they were able to complete the declaration. This should help avoid any minor errors leading to remedial action (for example a field mistakenly not completed on the online recording system).
- The list of potentially valid reasons for not submitting records, set out in the consultation document, is vague (it is limited to ill health and maternity leave). This must be expanded upon to aid fairness and standardisation of approach.
- The GPhC must clarify when and how it will communicate to registrants which standard of the Standards for Pharmacy Professionals it expects them to reflect upon for the reflective account.
- Employers must not be able to designate with whom pharmacists are to hold their peer discussions.
- Regardless of the nature of the framework introduced by the GPhC, it should include more stringent controls in relation to who may act as a peer for the peer discussion. For example, it may specify that the individual must have been qualified as a pharmacist for five years and have worked for at least two years in the same area of practice as the registrant. The General Medical Council's requirements of appraisers may provide a useful indication of what controls could be put in place.<sup>[1]</sup>
- In our view, the GPhC has not proposed a framework which constitutes revalidation. The GPhC should re-establish the CFtP advisory group with a view to considering whether a revalidation framework should be introduced, the practical aspects of what would be required, proportionality and the evidence for improvements in the safety or quality of patient care it would bring.
- The GPhC should develop and consult upon a separate revalidation framework for chief pharmacists, superintendent pharmacists and pharmacy owners, to assess whether or not they are (and remain) fit and proper persons to hold their positions of responsibility.
- The GPhC should impose a mandatory requirement on employers to provide protected time to complete the activities involved in meeting its proposed “revalidation” requirements.
- The GPhC should provide an explanation as to how any cost savings arising from the introduction of the proposed revalidation framework in its totality (including a saving of £200,000 associated with the lower rate of sampling and review) have been or will be invested in improving the protection it provides to the public. This would provide reassurances that the proposed framework will not simply reduce its own workload.

- The GPhC proposes to require pharmacists to collect and input the names, contact details and roles of those involved in peer discussion so that it may contact them to confirm the discussion took place. It proposes that this may include expert patients. The GPhC must evaluate the implications of the General Data Protection Regulation. It must provide advice to registrants on how appropriate consent will be obtained and by whom and consider, amongst other things, how it would deal with the withdrawal of consent to process data.
- The GPhC must ensure it does enough to avoid putting at a disadvantage those pharmacists who work part-time or in remote or isolated roles through the requirement to hold a peer discussion.

## Definitions and genesis of revalidation

The concept of revalidation originated in the 1970s.<sup>[2]</sup> It may be regarded as a very specific means of assuring Continuing Fitness to Practise (CFtP).<sup>[3]</sup> The two UK healthcare regulators to introduce it thus far (the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC)) have taken markedly different approaches. The GMC's approach was made more robust, such that it might detect both poor and grossly dysfunctional performance, following severe criticisms of the organisation in the Shipman Inquiry Report.

- The Medical Act 1983 defines revalidation as “the evaluation of a medical practitioner’s fitness to practise” and it is on this basis that the GMC carries out revalidation.<sup>[4]</sup>
  - Dame Janet Smith, in the fifth Shipman Inquiry Report, concluded that this required the individual evaluation of every doctor, and that the GMC must make the final decision as to whether to revalidate. She concluded that an annual appraisal by another person was insufficient on its own; Professor Sir Liam Donaldson made the same conclusion in the ‘Good doctors, safer patients’ report (2006).<sup>[5] [2]</sup>
- The GMC provides the following definition: “Revalidation is the process by which all licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise in their chosen field and able to provide a good level of care. This means that holding a licence to practise is becoming an indicator that the doctor continues to meet the professional standards set by the GMC. Revalidation aims to give extra confidence to patients that their doctor is being regularly checked by their employer and the GMC.”<sup>[6]</sup>
- The NMC provides a different definition (emphasis added): “Revalidation is the new process that all nurses and midwives in the UK will need to follow to maintain their registration with the NMC... [it] will help you as a nurse or midwife demonstrate that you practise safely and effectively... It is important to know that revalidation is **not about making an assessment of your fitness to practise**; it is about promoting good practice across the whole population of nurses and midwives, as well as strengthening public confidence in the nursing and midwifery professions.”<sup>[7]</sup> This approach is not entirely congruent with some of the other definitions set out here.
- The Council for Healthcare Regulatory Excellence, which was replaced by the Professional Standards Authority in 2012, stated: “Revalidation is the process by which a regulator can regularly and objectively check that their registrants are up to date and remain fit to practise after registration.”<sup>[8]</sup>
- The Professional Standards Authority stated: “Revalidation is often referred to, as it was in Trust, Assurance and Safety, as a means of ensuring that professionals are both fit to practise and up-to-date” and “the outcome of revalidation or equivalent schemes should be that registrants could demonstrate they were safe and fit to practise.” It defined revalidation as “a periodic assessment of fitness to practise.”<sup>[9]</sup>
- The Department of Health (DoH) stated: “The appraisal process, which will be a central component of revalidation, should be both formative and summative, to ensure objectively that required standards are met.”<sup>[10]</sup> It also confirmed, broadly, that the purpose of revalidation was to confirm the fitness to practise of registrants and to identify poor practice for further investigation and remediation.<sup>[9] [11]</sup>
- Newcastle University research, commissioned by the DoH, was published in March 2017. It found that: “Over time, references to ‘revalidation’ have generally become specific to the appraisal-based requirements introduced by the General Medical Council (GMC) for doctors, and supported through funding and legislation, in 2012. (Although the Nursing and Midwifery Council (NMC) has recently started using this term.)”<sup>[12]</sup>

## Consultation Response

### 1. Do you have any comments on any of the steps in the process covered in the framework?

**The framework aims to provide further assurance to the public that pharmacy professionals keep their knowledge and skills up to date and remain fit to practise throughout their careers.**

**The changes we are proposing are:**

- **a simplified approach to CPD recording**
- **introducing a peer discussion, and**
- **introducing a reflective account based on the standards for pharmacy professionals**

#### YES

In principle, we support the annual check on pharmacists' continuing professional development (CPD). We also support the introduction of a peer discussion and reflective account, as alternative forms of CPD which enhance the breadth and nature of the activities involved.

We would welcome further discussions about the introduction of revalidation for pharmacists, but we do not believe that the proposed framework constitutes revalidation and should instead be called "Continuing Professional Development". Our reasoning is explained in response to other questions.

### 2. Do you think the changes above will help to support registrants in their practice and provide assurance that pharmacy professionals remain fit to practise?

#### NO

The activity of undertaking professional development and learning, prompted by the proposed framework, could be of benefit to pharmacists' practice. However, the public might reasonably expect the term "revalidation" to mean that the GPhC is validating once again, on a proposed annual basis, that its registrants have been formally assessed as fit to practise in a modern context and have up-to-date knowledge which is relevant to their sphere of practise. Our view is that the term may provide assurances to the public and to government ministers and officials beyond those justified by closer examination of the framework.

### 3 Do you have any comments about the changes we have proposed?

#### Other healthcare regulators

If the proposals are accepted, the GPhC will become the third UK healthcare regulator to introduce a framework called "revalidation"; the first was the General Medical Council (GMC) and the second the Nursing and Midwifery Council (NMC). The GMC's model could be regarded as the most robust.

The majority of practising doctors have a connection to a designated body (such as those employed by an NHS trust or a GP practice), and as such have regular appraisals with their employer, typically on at least an annual basis. Matters which may be discussed at appraisal include whether the doctor is meeting the principles and values set out in 'Good Medical Practice' (professional standards for doctors); the doctor's personal details (such as evidence of continuing GMC registration); scope and nature of work; record of annual appraisals; personal development plans; probity, and personal health (fitness to practice, registration with a GP and immunisation status). A similarly robust process also exists for practising doctors who do not have a connection to a designated body, such as self-employed doctors who work in private practice. These doctors have to secure a similar annual appraisal from an independent trained appraiser, and submit evidence of it alongside the

other information and evidence required by the GMC as part of their annual return.

Practising doctors also undergo a full assessment once every 5 years from a trained Responsible Officer or Suitable Person, who must submit a recommendation to the GMC as to whether the doctor should be revalidated. The GMC provides a field team of Employer Liaison Advisers to support with the process. Evidence covering the following areas must be provided by the doctor and discussed during appraisals at least once every 5 years. Some of the information will be required more frequently depending on local practice. Evidence of CPD undertaken is required annually. The following areas are often covered during a doctor's regular appraisal process:

1. Continuing professional development
2. Quality improvement activity (e.g. participation in clinical audit)
3. Significant events (which could or did lead to patient harm)
4. Feedback from colleagues (collected independently of the doctor)
5. Feedback from patients (collected independently of the doctor)
6. Review of complaints and compliments <sup>[13]</sup> <sup>[14]</sup> <sup>[1]</sup> <sup>[15]</sup> <sup>[16]</sup>

The GMC makes the final decision as to whether to revalidate the doctor.

The NMC takes a less stringent approach than the GMC. Every three years, it requires registrants to declare and demonstrate:

- 450 practice hours, or 900 if renewing as both a nurse and midwife over a three-year period
- 35 hours of CPD including 20 hours of participatory learning
- Five pieces of practice-related feedback (verbal, formal or informal, but recorded in note form by the registrant)
- Five written reflective accounts
- A reflective discussion

As part of the process, a “confirmer” must evaluate whether the registrant has met the revalidation requirements, and submit a report to the NMC. The confirmer should ideally be a line manager, but may be a fellow nurse, midwife or other regulated health professional such as a doctor, dentist or pharmacist. <sup>[17]</sup>

## Nuances of the framework proposed by the GPhC

The GPhC has taken the same approach to revalidation for its professional and technical registrants (pharmacists and pharmacy technicians). The proposed framework features the following nuances:

- The GPhC will review at least 2.5% of registrants' records annually
  - in 2017, it made cost savings by reducing this from 20% annually
  - if it is resourced to review 2.5%, it will struggle to increase this by any substantial amount if systemic issues / themes are identified
  - systemic issues may not be apparent with such a small sample size
  - a registrant's records may only be called once every 40 years (and it may be less often than this)
  - annual automated checks will ensure registrants have entered the correct number and type of records, though the nature of the content will not be checked annually
- The GPhC is considering introducing an algorithm to make it more likely that a registrant's records will be called, the greater the length of time that has elapsed since the last call - or if the registrant's records have not previously been called. However, the proportion of registrants' records called may still be around 2.5%, so the usefulness of such an algorithm is questionable.
- When the GPhC does call records for review, it will only review the past 12 months' worth (at present it reviews records submitted since the last call – five years' worth).
- If the information provided is unsatisfactory, the registrant may be given two further chances to provide satisfactory records before the GPhC takes punitive action.
- The GPhC destroys the records submitted to it after 5 years.
- Only 301 pharmacy technicians of over 23,000 on the register signed up to participate in the Continuing Fitness to Practice (CFtP) pilot and only 85 completed the required pilot entries (c.f. 1045 pharmacists who signed up out of a cohort of circa 54,000, 495 of whom completed the required entries). <sup>[18]</sup> <sup>[19]</sup>

- For three years, the proposals have been developed as a “CFtP” programme, not a revalidation programme. The GPhC decided to change the name to “revalidation” around 3 weeks before the launch of the consultation, after the CFtP advisory group had been disbanded, ostensibly due to concerns over the negative connotations associated with the term “fitness to practice” (which will not be ameliorated by the avoidance of its use). During the GPhC’s internal discussions which led to this change, a key senior official at the GPhC spoke in favour of calling it, simply, “CPD” (we are in agreement).
- The GPhC’s reasons for not calling the framework “revalidation” during the 3-year operation of the CFtP programme and pilot were explained to the advisory group. These were that its focus was on continuous improvement and unlike the GMC and NMC revalidation models, it did not include a formal assessment by another that a registrant was meeting regulatory requirements. The GPhC was taking a lighter-touch approach than the GMC, which it felt was proportionate.
- The words in bold below, taken from the CFtP Interim Evaluation Report shared with the advisory group [in December 2016], were removed and were not present in the final evaluation report published online by the GPhC. *“Given the PSA guidance on the CFtP model being proportionate to risk, **the GPhC’s focus on continuing improvement in practice as opposed to formal assessment for revalidation makes sense.**”*<sup>[19]</sup> This provides a clear indication that the focus of the GPhC’s model was not on revalidation – and that it did not constitute revalidation because it did not include a formal assessment.
- The CFtP pilot was conducted among willing volunteers, with the promise that volunteers’ records would not be subsequently called for review for at least two years. The framework was not piloted among the wider group of registrants, who may struggle to a greater degree with the new requirements.<sup>[20]</sup>

Concerningly, many of the above details are not included in the consultation documents and were not shared by the GPhC with the wider audience at its engagement event in London on 16 May 2017, which was attended by a representative of the PDA. In essence, a registrant could fill in poor-quality records annually, just to pass the automated test, in the knowledge that there will likely be only a 1 in 40 chance of his / her records being called for review and that if the records are deemed unsatisfactory, he/she could be given two further chances to put this right.

Due to, amongst other things, the low frequency of GPhC reviews of the records submitted and the absence of a formal registrant appraisal process being conducted by a senior pharmacist, this framework is not capable of the early detection of deficient practice. This was a key expectation of the GMC’s revalidation framework following the Shipman Inquiry.<sup>[2] [21] [22]</sup>

The PDA was delighted to be part of a panel of experts on the GPhC’s CFtP advisory group in the last six months of its operation. However, our view is that, given the history and complexity of the genesis of revalidation in healthcare, and its meaning as defined by the Department of Health, the Professional Standards Authority and other healthcare regulators, it was highly inappropriate to rename the framework from “Continuing Fitness to Practice” to “revalidation” after the CFtP advisory group had been disbanded. Though it would arise in different circumstances, the GPhC risks the same criticism as was directed at the GMC by the Chair of the Shipman Inquiry - that it has designed a rubber-stamping exercise that will mislead the public.<sup>a</sup>

Whilst we welcome the simplicity in terms of the regulatory burden involved, we are concerned that calling the framework “revalidation” may de-professionalize the pharmacy profession – if it is accepted that pharmacists can “revalidate” annually simply by creating six records with very little chance that they will be reviewed by anyone, let alone the GPhC. The GPhC’s approach in proposing the same framework for pharmacists and pharmacy technicians does not take in to account the practical and operational differences between the profession and the occupational group, such as the nature of the roles undertaken and the public expectations of each. We are concerned that this approach may have arisen for reasons of expediency, not of principle, resulting in a process which is insufficiently rigorous to be termed ‘revalidation’.

The revalidation process used by the NMC, whilst not as stringent as that used by the GMC, does at least include a formal assessment by another, within each revalidation period, that registrants have met the revalidation requirements. We are concerned that the term “revalidation” as used by the GPhC may overstate the degree of public protection actually afforded by the proposed framework. By extension, the level of assurance afforded by the term may be unwarranted. In the future, the use of the term in association with these frameworks may be regarded as a mistake – but one which at this stage it is not necessary for the GPhC to make.

**Recommendation**

The proposed revalidation framework and processes should be renamed to “continuing professional development” (CPD). The framework and process do not constitute revalidation or an assessment of fitness to practise; they do not include any formal appraisal, by a senior pharmacist, of a registrant’s practise, will not detect impaired performance at an early stage and are otherwise not sufficiently rigorous. They do not meet the definitions of revalidation given by the Council for Healthcare Regulatory Excellence, the Professional Standards Authority or the Department of Health and are different *in principle* to the legal definition in the Medical Act 1983 (though the Act itself does not apply to pharmacists).

**Pharmacy technicians**

Given the apparent poor engagement and / or capability of pharmacy technicians to get involved in and complete all required records during the pilot, we make the following recommendation.

**Recommendation**

Before changing the CPD process applicable to pharmacy technicians, the GPhC must undertake a detailed root cause analysis to understand why only a small number of pharmacy technicians joined the CFtP pilot process and the apparent lack of engagement / capability in completing all required records. It must then publish its findings.

**Personalised feedback and lay reviewers**

We welcome the introduction of personalised developmental feedback following review of the CPD records, to replace the percentage score given under the existing framework. However, whilst it is important that the profession and the GPhC are transparent to the public, we regard the use of a lay reviewer as tokenistic. Without professional knowledge, the individual will likely struggle to give meaningful developmental feedback relevant to the safe and effective practise of pharmacy. As was pointed out by a delegate to the wider audience at the GPhC’s consultation engagement event on 16th May in London, a lay reviewer may be more lenient than a professional

reviewer. This may potentially reduce the robustness of the review process and in doing so, undermine its purpose. A trained lay reviewer who is regularly involved in the process may cease to be regarded as truly representative of a member of the public, in any case.

We note that lay reviewers are currently involved in the review process, but for some years they have simply been checking whether all the necessary fields have been completed in the GPhC’s online CPD recording system, not the content (and even if the content has been poor or unrelated to pharmacy, the reviewers have had to award the registrant full marks for their submission). Whilst a lay reviewer may reasonably be engaged in a quantitative process such as this, the GPhC’s intention is that reviewers will begin providing qualitative developmental feedback to pharmacists; it is unlikely that there will be many situations in which a lay reviewer could provide meaningful feedback of this nature.

For similar reasons, we take the view that to avoid reducing the robustness and value of the review process and undermining its purpose, pharmacy technicians as a group should not be permitted to conduct the reviews.

**Recommendation**

The review of CPD, peer discussion and reflective account records submitted by GPhC registrants should be conducted by pharmacists. Review by those who are not pharmacy professionals, including pharmacy technicians and lay persons, should be discouraged.

**Additional comments and recommendations**

We welcome the reduced need for ‘dual recording’ mentioned in the consultation document – so that it will be possible to import records from learning and development portfolios held with other organisations into the GPhC’s online recording tool. Little detail was provided in this regard, but it could be a positive development.

In addition to our broader points, we make the following additional recommendations.

**Recommendation**

We would like to see the ability to transfer records easily from a Royal Pharmaceutical Society faculty portfolio to the GPhC’s online CPD, peer discussion and reflective account recording system.

**Recommendation**

In respect of the proposed automated annual checks, we would like to see an alert given to pharmacists who are completing their annual declaration of fitness to practise, if it appears that they have not completed a full set of CPD, peer discussion and reflective account records. Such an alert would need to appear **before** they were able to complete the declaration. This should help avoid any minor errors leading to remedial action (for example a field mistakenly not completed on the online recording system).

**Recommendation**

The list of potentially valid reasons for not submitting records, set out in the consultation document, is vague (it is limited to ill health and maternity leave). This must be expanded upon to aid fairness and standardisation of approach.

**Recommendation**

The GPhC must clarify when and how it will communicate to registrants which standard of the Standards for Pharmacy Professionals it expects them to reflect upon for the reflective account.

**Recommendation**

Employers must not be able to designate with whom pharmacists are to hold their peer discussions.

**Recommendation**

Regardless of the nature of the framework introduced by the GPhC, it should include more stringent controls in relation to who may act as a peer for the peer discussion. For example, it may specify that the individual must have been qualified as a pharmacist for five years and have worked for at least two years in the same area of practice as the registrant. The General Medical Council’s requirements of appraisers may provide a useful indication of what controls could be put in place.<sup>[1]</sup>

**Recommendation**

In our view, the GPhC has not proposed a framework which constitutes revalidation. The GPhC should re-establish the CFtP advisory group with a view to considering whether a revalidation framework should be introduced, the practical aspects of what would be required, proportionality and the evidence for improvements in the safety or quality of patient care it would bring.

**4. Do you think the revalidation framework overall will achieve its aim of providing further assurance to users of pharmacy services?**

**NO**

The public is generally not very well versed on the details of the revalidation framework. Where it enters the public conscience, individuals may take some reassurance from the fact that a framework exists, but typically will not examine the details. Were they to do so, they may take less assurance from the proposed framework than the term “revalidation” would suggest they ought.

**5. Is there anything else, not covered in the framework, that you would find useful? Please give details.**

Though the online CPD recording system and framework did need to be reviewed and updated, these proposals are an example of the GPhC's incessant focus, at an organisational level, on the regulation of individual pharmacists, in the context of insufficient focus on serious systemic issues affecting patient and public safety (such as workplace pressure and corporate profiteering). The GPhC could have focused on the responsibilities of pharmacy owners, chief pharmacists and superintendents to help address some of these issues.

**Recommendation**

The GPhC should develop and consult upon a separate revalidation framework for chief pharmacists, superintendent pharmacists and pharmacy owners, to assess whether or not they are (and remain) fit and proper persons to hold their positions of responsibility.

**6. What kind of impact do you think the proposals will have on people using pharmacy services?**

**PLEASE REFER TO OUR RESPONSE TO QUESTION 4.**

**7. What kind of impact do you think the proposals will have on pharmacy professionals?**

We expect that pharmacists will find it easier to complete their records on the whole, though it will require a change in self-discipline for some to ensure that the records are completed annually.

**8. What kind of impact do you think the proposals will have on pharmacy employers?**

The proposals may have no impact on employers at all; many do not provide any dedicated time to pharmacists to allow them to carry out CPD activities. Some pharmacies may run CPD events, but these may be focused on commercial or organisational objectives rather than simply giving time to the pharmacist to carry out the activities of his / her choosing. Peer reviews, in particular, will most likely need to be completed during working hours.

**Recommendation**

The GPhC should impose a mandatory requirement on employers to provide protected time to complete the activities involved in meeting its proposed "revalidation" requirements.

**9. Please give any further comments you have on the possible impact of the proposals on any of the above groups.**

Although not related to the aforementioned groups, we are concerned about the impact of the proposals on pharmacy technicians. During the pilot process, there was an apparent lack of engagement and/or capability among pharmacy technicians to get involved and meet the proposed requirements. Please refer to our response to question 4 for further details.

In addition, it appears that the framework, in its totality, would significantly reduce the GPhC's workload and costs and affect how it operates as a public authority, with a resource saving of £200,000 per year arising from the changes to CPD sampling consulted upon in 2016.<sup>[23]</sup> The GPhC sustains itself from the fees collected from registrants and pharmacy business owners. Despite the apparent reduction in costs, no corresponding reduction in fees has been proposed, which would be expected unless the GPhC's operating costs increased by the same amount in some other respect. The resource implications associated with the changes proposed in this consultation have not been outlined in the consultation document.

**Recommendation**

The GPhC should provide an explanation as to how any cost savings arising from the introduction of the proposed revalidation framework in its totality (including a saving of £200,000 associated with the lower rate of sampling and review) have been or will be invested in improving the protection it provides to the public. This would provide reassurances that the proposed framework will not simply reduce its own workload.

**10. Do you think the proposal might have an impact on certain individuals or groups who share any of the protected characteristics? If ‘Yes’, please explain and give examples.**

The proposals might disadvantage part-time workers and those in remote or isolated roles, due to the reduced number of opportunities they may have to complete a peer discussion. This may disadvantage certain groups who are statistically more likely to carry out part-time work, such as women. <sup>[26]</sup>

The UK is in the process of implementing the EU General Data Protection Regulation (GDPR), which will come in to force on 25 May 2018. The GDPR includes a new definition of the consent required for data processing: *“any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”*. <sup>[24]</sup>

Though the implications are currently being considered, it may mean that consent must specifically cover the data controller’s name, the purposes of the processing and the way in which it will be processed. Consent will require a positive action to opt in. Written records of consent may be advisable. The GDPR also stipulates that people must have genuine ongoing choice and control over how their data are used. <sup>[25]</sup>

**Recommendation**

The GPhC proposes to require pharmacists to collect and input the names, contact details and roles of those involved in peer discussion so that it may contact them to confirm the discussion took place. It proposes that this may include expert patients. The GPhC must evaluate the implications of the General Data Protection Regulation. It must provide advice to registrants on how appropriate consent will be obtained and by whom and consider, amongst other things, how it would deal with the withdrawal of consent to process data.

## References

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