The PDA's response to the GPhC's Consultation:

"Managing concerns about pharmacy professionals: Our strategy for change"

January 2021

| representing **your** interests | | defending **your** reputation |

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for profit defence association and trade union for pharmacists. It is the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy, currently with a membership of more than 32,000, the PDA is the largest representative membership body for pharmacists in the UK and this membership continues to grow.

Delivering more than 5,000 episodes of support provided to members who have found themselves in a critical incident situation in the last year alone, provides the PDA with a rich vein of up to date experiences which have informed policies and future strategy.

This experience has recently been informed by the very considerable number of Covid-19 related issues being faced by members. The practical experience gained in supporting member issues from the coal face is further enhanced by regular member surveys and focus group interactions. The information in this document is largely built upon the experience of our 32,000 members .

The primary aims of the PDA are to:

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

Summary :

The GPhC is consulting about its strategy for change for managing fitness to practise concerns.

The fundamental purpose of fitness to practise is to safeguard the public and not to provide redress for the complainant. **(1) (1a).** This was always the intent of the post Shipman reforms. However, these initial reforms, focused on individuals, have become overly adversarial.

The Government has recognised that the role of healthcare regulation needs reform to make it fit for modern purpose. Thus, these proposals by the GPhC must be viewed through that wider prism of background and context. Indeed, the Government will be consulting on these major changes in early 2021. **(2)**

These wider reforms will include a greater use of mediation, reflective learning, and a move away from a culture of blame and panel hearings. Given the imminent and extensive changes, it would be unwise for the GPhC to introduce measures that fail to fully reflect the Government desire for major change. For example, a greater role for employers or the introduction of mediation or changes to hearings or the introduction of complainant impact statements should await the Government consultation.

However, the GPhC could start the collection of robust data and recruiting of a wider, more diverse panel immediately. Similarly, it should focus its existing resource to ensure that current fitness to practise processes attain the required Professional Standards Authority standards. It has failed to meet these standards in each of the last 2 years. This has a huge impact on registrant and public confidence in the regulator.

A significant driver for the Government reforms has been a concern that healthcare regulation is neither fair nor proportionate. The Dr Bawa-Garba case and the subsequent Williams review highlighted many issues, not least the over-representation of BAME registrants in fitness to practise cases. Given the large proportion of BAME pharmacists (some 50% of the register) the requirement for the GPhC to be fair and unbiased is especially important. We discuss this in greater length in the following pages.

The GPhC consultation states that is seeking to learn from other regulators, and we will explore the lessons that the GPhC can especially learn from the NMC and the GMC. We look in greater detail at the systemic bias and prejudice faced by doctors and the role of employers in referrals.

Similarly, the Professional Standards Authority (the PSA) has consulted widely on what the public expects from Fitness to Practise of healthcare professionals. It has also subsequently published the views of the public garnered at these stakeholder events.

We propose a range of changes in our responses to the questions asked and we explain our reasoning. We will seek clarification on why the GPhC is consulting on remote hearings when it has already made certain decisions regarding this in its Council meeting of January 2021.

Overall, whilst we welcome the ethos of reform, we also see huge merit in the GPhC awaiting the wider more extensive Government proposals whilst at the same time putting in place measures to ensure that existing fitness to practise processes are free from bias, robust, timely, supportive and meet PSA standards. We present a summary of our key recommendations on the next page and discuss the points outlined above in greater depth in subsequent pages.

Summary of the PDA's recommendations

Considering forthcoming Government proposals around major reform to healthcare regulation, we believe that the General Pharmaceutical Council (GPhC) should consider delaying any of the wider proposed changes within the consultation until such time that the extent of the reforms are known.

The following PDA recommendations should be seen in context of this overarching recommendation.

Suggested interim measures

In the interim there are many things that the GPhC could do and include:

(1) The GPhC should consider putting into place enhanced support measures for both registrants and complainants.

(2) It should focus on improving the timeliness to case closure

(3) It should start the process of recruiting BAME Panellists so that when cases go to hearings (for the most serious cases) the diversity of the profession is reflected in the panel.

(4) It should ensure that all cases are fully documented and follow internal guidance.

(5) It should ensure that diversity data is captured and recorded at point of raising concern and all subsequent stages

(6) The GPhC should start to identify how it will meaningfully apply the same standards to premises owners as it does to individual registrants.

(7) It should have a full and meaningful EDI policy in place so that any reformed FtP fits into the overarching legal requirement of its statutory EDI obligations.

Public and Stakeholder Engagement

(8) The GPhC should focus on meeting the 6 areas identified by the public. It should also be more transparent and publish (with the help of independent experts) the full details of the feedback it has received from the public and stakeholder engagement.

PSA Standards

(9) The GPhC should consider how it will consistently meet the standards as set by the PSA for its Fitness to Practice processes before it embarks on any other major changes.

(10) The GPhC should agree with the PSA the extent of any changes before they are implemented to ensure that the problems following the introduction of the threshold standards are not repeated.

Equalities and EDI

(11) The GPhC should commission the expert review as requested by Council at the meeting of the 6th July2017 to ascertain if its Fitness to Practise processes may have inherent unconscious bias.

Role of Employers

(12) The GPhC should await the outcome of the wider Government review of healthcare regulation before making any changes to the employer role. In the interim, it should seek to learn from the GMC and NMC reviews detailed within the body of our response.

The Wider Reform of Regulation Context

The Government has been consulting on healthcare regulation reform since October 2017.

> ***"This needs to be complemented by a culture that enables professionals to learn from their experiences, including from their mistakes. All too often professionals encounter a culture of blame rather than learning. "(3)***

Similarly, the PSA has published a whole series of discussion documents around this. **(4)**

On the 2nd of December 2019 the Government took the opportunity to put into place their desire to create modern fit for purpose regulators with the creation of the new regulator, Social Work England. The extension of these reforms to the other existing regulators was noted by the PSA:

> ***"As part of wider reforms to the legislative framework for professional regulation, the Government is proposing to extend powers to all of the health and care professions' regulators, allowing them to dispose of any fitness to practise cases – including the most serious – at the end of the investigation without a hearing" (5) (6)***

As we can see, the Government has clearly stated its intent to introduce major reforms. In a paper published in November 2020 the Government outlined how it proposes to proceed:

> ***Improvements in fitness to practise: DHSC will make it easier for regulators to resolve complaints about a registrant's conduct or competence more quickly and in a less adversarial way. This will support a culture where professionals can learn and improve from their mistakes, while ensuring that the necessary steps are taken to protect the public from professionals who are not safe to practise (2)***

The aims listed in the GPhC consultation are a little light in detail and context. They seem not to fully engage in the ethos of what the Government seeks. By not fully acknowledging the wider context this GPhC consultation is struggling to meaningfully propose reforms which can demonstrate that they will be fair, equitable and free of bias.

The GPhC has yet to demonstrate that its existing FtP processes are free from bias (conscious or unconscious). Given that some 50% of pharmacists are BAME this is particularly important.

The GPhC will fail to gain public confidence if it continues not to meet the standards set by the PSA having already not met these FtP performance standards in both 2018-2019 and 2019-2020. Of note is the persistent documented lack of thorough record keeping and lack of consistency and timeliness in its decision making for FtP decisions.

Our focus is not merely on answering the pre-set questions of the GPhC which can never capture the full picture, nor the essence of what healthcare regulation is all about, but to set these responses within the proper context and enable a holistic understanding of current issues.

At the very core of all healthcare regulation is public protection and maintaining public confidence whilst being fair to registrants.

The Bawa-Garba case, which resulted in a manslaughter charge against a doctor following the death of a child so concerned the Government that it asked for a rapid policy review on some of the issues raised by this case.

This case is as seminal as Shipman but for different reasons. Shipman set out to murder his patients. Dr Bawa-Garba was caught up in a structure that utterly failed to support her (and thousands of other young BAME doctors) and led to the death of a patient.

The Government webpage states the reason why the review was commissioned as:

> ***The review was set up to look at the wider patient safety impact of concerns among healthcare professionals that simple errors could result in prosecution for gross negligence manslaughter, even if they happen in the context of broader organisation and system failings. (7)***

The Government asked Professor Sir Norman Williams to conduct this review and he made several recommendations for reform including:

> ***3.5 … development of a "just culture" in healthcare, which recognises both systemic factors and individual accountability.***
>
> ***7.2 …. seek to determine the extent and reasons for different fitness to practise outcomes in similar cases and, if appropriate, recommend changes to ensure greater consistency.***
>
> ***8.1 We support the PSA's intention to introduce, as part of its Standards of Good Regulation, equality and diversity standards for professional regulators.***
>
> ***9.1 The PSA should review whether the outcome of fitness to practise procedures is affected by the availability of legal representation of registrants. This needs to be considered alongside broader proposals for the reform of professional regulation which seek to establish a less adversarial approach to fitness to practise issues through the use of undertakings and consensual disposal. (8)***

Interestingly, the GPhC already has wide ranging powers to use undertakings. However, the table below (from GPhC data) shows the limited use of undertakings year on year:

	2020	2019	2018	2017	2016	2015	2014	2013	2012
Cases Closed	3148	2653	2303	1964	1882	1108	704	647	668
Undertakings	8	9	3	3	2	7	5	3	3

Why is this so important? The Williams review is one of the four specifically mentioned documents which the GPhC considered in this consultation.

Williams repeatedly mentioned a "just culture" which must recognise systemic factors as well as individual accountability. It is clear what this means and what it is supposed to mean.

In the present GPhC consultation, the term "just culture" is used only once:

> ***"We know that when professionals are open and honest, and demonstrate that they have learnt from mistakes, it helps to promote a professional, just culture that will contribute to improving patient safety".***

The disparity of context of what is a "just culture" as intended by the Williams Review and how it has been presented by the GPhC is clear. The failure to acknowledge and put into context systemic factors has been a long-standing concern with the GPhC fitness to practise process.

The PDA has through freedom of information requests found that no premises owner has ever been subjected to a fitness to practise process by the GPhC since its inception in 2010. **(9)**

One pharmacy Inspection report is of particular note. In this report the GPhC inspector noted:

- ***staff had been in tears telling the inspector about the problems with staffing levels.***
- ***in recent dispensing error reports, staff shortages had been highlighted.***
- ***staff had attempted to raise concerns, but this was not always successful, and they felt their concerns weren't always listened to or acted upon, which deterred raising concerns in the future.***
- ***the inspector had tried personally during the visit to raise the staffing concerns within the company but could not get hold of the relevant people, (10)***

That pharmacy attained a satisfactory rating and was given an action plan for improvements by the GPhC. Will this reluctance to treat systemic factors with the same rigour as individual accountability continue with the GPhC interpretation of "just culture" as proposed in the consultation?

In his seminal work, "Good doctors, safer patients" following the Shipman Inquiry, Sir Liam Donaldson (the then Chief Medical Officer) specifically noted:

> ***Current concepts of patient safety place the prime responsibility for most adverse events on deficiencies in system design, organisation and operation rather than on the negligence or poor performance of individual providers ... (11)***

The focus of the GPhC fitness to practise since its inception in 2010 has always been on the individual. Wider systemic problems have never been subjected to the same process as individual registrants despite the potential of systems posing a far greater risk to the public than any single individual.

As the pharmacy landscape is dominated by large multinational corporate owners, the proper meaningful regulation of these premises becomes even more important.

The most recent example of these poor unprofessional behaviours by certain large corporate pharmacy owners was seen with the National Flu Service. In 2020, with the background of Covid-19 it was especially important that all at risk patients received a flu jab. This huge increase was well predicted but large corporate owners exhibited such poor behaviours (this putting at risk the safe provision of a vital service of National Importance) that the PDA had to issue an urgent guidance note for its 32,000 pharmacist members.

> ***Early and widespread feedback from members is now being received and this gives much cause for concern. Some pharmacists are being asked to provide vaccination services in premises that are wholly unacceptable. (12)***

Overarching Recommendation

The Government in 2021 will propose major reforms to healthcare regulation.

The GPhC should consider delaying any of the wider proposed changes within the consultation until such time as the extent of the Government proposals and the specific measures therein are clear.

All the other PDA recommendations should be seen in context of this overarching recommendation.

Recommendations for Interim Measures

However, in the interim and until the full Government proposals are detailed there are many things that the GPhC could do and include:

(1) The GPhC should consider putting into place enhanced support measures for both registrants and complainants.

(2) It should focus on improving the timeliness to case closure

(3) It should start the process of recruiting BAME Panellists so that when cases go to hearings (for the most serious cases) the diversity of the profession is reflected in the panel.

(4) It should ensure that all cases are fully documented and follow internal guidance.

(5) It should ensure that diversity data is captured and recorded at point of raising concern and all subsequent stages

(6) The GPhC should start to identify how it will meaningfully apply the same standards to premises owners as it does to individual registrants.

(7) It should have a full and meaningful EDI policy in place so that any reformed FtP fits into the overarching legal requirement of its statutory EDI obligations.

What does the public want and expect from Fitness to Practise?

The PSA, to test public appetite for reforming healthcare regulation, and how these reforms could maintain public confidence and as part of its engagement work commissioned research into this. A number of stakeholder events were held. It has, unlike the GPhC published the findings from the stakeholder events it held.

Persons who took part included those who had been complainants to one of the 10 regulators, but the majority were ordinary members of the public. It is really interesting that the report of these stakeholder events particularly emphasised the concept of an "informed public"

> ***The findings outlined in this report are based on the views of people who have considered the issues in greater depth, for more time, and with more information than members of the public who consider the issues in the course of their day-to-day lives. The feedback is, therefore, pertinent when considering the potential impact of the changes on an 'informed public'. (6)***

These informed and reasonable members of the public wanted any changes from fitness to practise procedures to improve the process for both registrants and claimants, so that it was:

- Timely
- Robust/Rigorous
- Transparent
- Fair/Independent
- Accessible/Inclusive
- Supportive

How do the standards which the GPhC did not meet link in with what an informed and reasonable public expects as detailed above? For this we need to look into greater detail at the PSA reports.

Recommendation - Public and Stakeholder Engagement

(8) The GPhC should focus on meeting the 6 areas identified by the public above. It should also be more transparent and publish (with the help of independent experts) the full details of the feedback it has received from the public and stakeholder engagement.

The Standards expected of Healthcare Regulators.

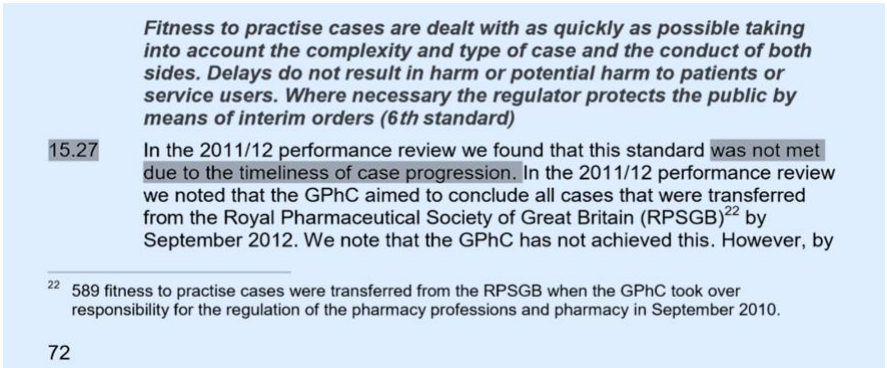
Dame Janet Smith, in the Shipman Inquiry, the 5th Report also noted:

> • ***Everything a regulator does must (subject to confidentiality) be capable of scrutiny, ie it must be transparent***
>
> • ***The work of the regulator must be thorough, careful and of high quality, meaning that every aspect of the fitness to practise procedures must be properly resourced, with each process being undertaken by persons who are suitably qualified and properly trained to carry it out***
>
> • ***In the interests of fairness and of the proper maintenance of standards, procedures must be followed and decisions made in a consistent, transparent manner. (1)***

It is obvious that the principles that regulators should apply in how they deal with FtP concerns align with expectations from members of the public. The two most recent reports on the GPhC performance in relation to how it manages Fitness to Practise concerns had room for improvement.

The PSA reviews of the GPhC scored it 6/10 (60%) for meeting the PSA fitness to practise standards in 2018-2019. The GPhC in 2019-2020 barely managed to meet 2/5 (40%) of the revised PSA fitness to practise standards. (The PSA revised 10 FtP standards to 5 FtP standards between the review years of 2018-2019 and 2019-2020)

A notable omission from the consultation is that the GPhC has since 2011-2012 failed to meet the PSA standard for the timely resolution of fitness to practise cases. The PSA in its Annual Review of 2012-2013, quoted below **(13),** referred back to identification of timeliness issues in its 2011-2012 review.



Fitness to practise cases are dealt with as quickly as possible taking into account the complexity and type of case and the conduct of both sides. Delays do not result in harm or potential harm to patients or service users. Where necessary the regulator protects the public by means of interim orders (6th standard)

15.27 In the 2011/12 performance review we found that this standard was not met due to the timeliness of case progression. In the 2011/12 performance review we noted that the GPhC aimed to conclude all cases that were transferred from the Royal Pharmaceutical Society of Great Britain (RPSGB)[22] by September 2012. We note that the GPhC has not achieved this. However, by

[22] 589 fitness to practise cases were transferred from the RPSGB when the GPhC took over responsibility for the regulation of the pharmacy professions and pharmacy in September 2010.

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The 2018-2019 PSA performance review of the GPhC:

By not meeting these 4 (from 10) PSA Standards the GPhC cannot meet the expectations of the public requirements identified during the PSA public stakeholder events

> ***PSA Standard 5:*** *"The fitness to practise process is transparent, fair, and proportionate and focused on public protection"*
>
> ***PSA Standard 6:*** *"Fitness to practise cases are dealt with as quickly as possible taking into account the complexity and type of case and the conduct of both sides. Delays do not result in harm or potential harm to patients and service users. Where necessary the regulator protects the public by means of interim orders"*
>
> ***PSA Standard 7:*** *All parties to a fitness to practise case are kept updated on the progress of their case and supported to participate effectively in the process*
>
> ***PSA Standard 8:*** *All fitness to practise decisions made at the initial and final stages of the process are well reasoned, consistent, protect the public and maintain confidence in the profession*

In 2017, the GPhC proposed a new set of threshold standards. This was put to consultation and even at this stage the PSA had doubts. It warned the GPhC that it had concerns about the proposed revised 2018 GPhC Threshold Criteria.

> ***When we responded to the GPhC's consultation on its new threshold criteria, we had concerns about:***
>
> - ***The clarity of the revised criteria and how transparently they would be applied***
> - ***A risk that cases which may meet the realistic prospect test are closed prematurely, potentially resulting in risks to the protection of the public***
> - ***A lack of scrutiny and transparent oversight of decisions being made. (14)***

Despite these concerns specifically being identified by the PSA the GPhC pressed ahead with the new Threshold Criteria without putting into place adequate safeguards to address the concerns detailed by the PSA.

This 2018-2019 PSA review also noted that any concern reported to the GPhC will undergo an initial 3 step process:

> ***There are three main decision-making stages at the initial stages of the GPhC's fitness to practise process:***
>
> - ***Triage – where the GPhC reviews the information available and decides whether further investigation is needed***
> - ***Investigation – at the conclusion of the investigation the GPhC considers whether a case meets the criteria for referral to the IC (with a recommendation for disposal) or can be closed with no further action or with informal advice to the registrant***
> - ***Investigating committee***

As promised, the PSA considered the impact of the changes in its 2018-2019 audit of a sample of cases and noted:

> ***"Under Standard 5 below, we have reported that our audit of closed cases established that the GPhC is departing from its internal triage guidance as it is considering factors beyond whether a complaint is within its jurisdiction when triaging cases."***

Of equally worrying concern was the failure of all 3 decision-making stages listed above. The PSA noted:

> ***Our audit identified concerns about other aspects of all three decision-making stages where we thought that reasoning was flawed, lacking or unclear or the outcome appeared contrary to the GPhC's current guidance.***

The PSA also noted poor practise in risk assessment of complaints:

> ***"The GPhC told us that…risk assessments are not documented at the triage stage,"***

This lack of clarity means that reliable information about unfair practises cannot be determined as the full factors underlying decision making cannot be assessed, the PSA noted:

> ***"Our findings about the transparency of these processes meant that we could not be assured that the processes in place were fair …."***
>
> ***"Our audit found examples of flawed or unclear reasoning at all three of the initial decision-making points. The GPhC had already identified for itself that its IC decisions require improvement."***

In response, the GPhC disputed some of the PSA findings:

> ***"The GPhC did not agree with our audit findings about inconsistent decisions."***

What would an informed member of the public think about a regulator which failed to accept the findings of an independent performance review by the Professional Standards Authority?

Why is this threshold and triage process so important and why are we looking at this so closely? Well, this is the critical first step in managing concerns. The stratification of concerns starts here and it is at this stage where critical decisions are made.

In a follow up document, the PSA again stresses the importance of the threshold criteria as this is the gateway to the whole fitness to practise process:

> ***We have identified two key areas where the current system could be improved and which will also benefit any future, more radical reform. These are:***
>
> ***how regulators decide which cases to investigate and which to reject (known as 'thresholds')***
>
> ***how regulators can deal with cases safely and transparently without taking them all the way to a hearing (also known as 'consensual disposal') (15)***

The importance of having proper threshold standards, properly triaged, properly documented and properly and fairly resolved is an absolute pre-requisite if a regulator is to manage concerns in the manner the public and registrants expect.

The 2019-2020 PSA performance review of the GPhC:

There was a small change in the PSA standards from 2018 into 2019. However, the concerns from the 2018-2019 review regarding investigation of concerns had still not been addressed adequately by the time of its 2019-2020 review. **(16)**

It is important to understand that the failure to meet PSA standards has impact on both complainants and registrants. A regulator that fails to meet 3 out of 5 standards and barely meets the other 2 is failing both registrants and the public.

These are 3 PSA standards which are still NOT met in the 2019-2020 review:

> ***Standard 15:*** *The regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case and ensures that appropriate evidence is available to support decision-makers to reach a fair decision that protects the public at each stage of the process.*
>
> ***Standard 16:*** *The regulator ensures that all decisions are made in accordance with its processes, are proportionate, consistent and fair, take account of the statutory objectives, the regulator's standards and the relevant case law and prioritise patient and service user safety.*
>
> ***Standard 18:*** *All parties to a complaint are supported to participate effectively in the process.*

Why is the failure of the GPhC to meet the above standards so important? We need to revisit what the CHRE (predecessor of the PSA) said in 2011: **(1)**

> 3.4 The need for fairness in the process is also reflected in the requirement that regulators' fitness to practise proceedings must comply with the Human Rights Act 1998. Under the Act it is unlawful for a 'public authority' to act in a way that is incompatible with a European Convention right. The health professional regulators' fitness to practise panels are 'tribunals' and therefore 'public authorities' for the purposes of the Act and it would be unlawful for them to act in a way that is incompatible with the European Convention.

Any failure to follow a fair and equitable process undermines the integrity of the whole of fitness to practise process and would also be unlawful.

A tribunal case illustrated the risk to the GPhC of having process which may be discriminatory against any protected characteristic. **(16a)**

The current consultation by the GPhC lists one of its aims as having a FtP process that is free of bias. However, lack of robust process makes it difficult to make sure that the GPhC processes are not free of bias.

Recommendation – PSA Standards

(9) The GPhC should consider how it will consistently meet the standards as set by the PSA for its Fitness to Practise processes before it embarks on any other major changes.

(10) The GPhC should agree with the PSA the extent of any changes before they are implemented to ensure that the problems following the introduction of the threshold standards are not repeated.

The EDI Impact of not meeting PSA Standards.

The GPhC Executive put to Council in its September 2020 meeting that it had taken heed of Councils specific wish expressed in July 2020 and:

> ***" .. separated the issue of eliminating bias in decision making (under aim 2) from the systemic issue of disproportionate representation of Black and minority ethnic registrants in referrals (under aim 4)…."*** ***(17)***

Looking at these 2 aims, aim 2 and aim 4 we cannot see how this can fully address the separation requested by Council:

- ***take a person-centred approach that is fair, inclusive and free from discrimination and bias***
- ***take account of context and work with others to deal with problems in the wider pharmacy and healthcare systems***

The GPhC has specifically mentioned the disproportionality in the cases it investigates. We will discuss this in context of the other regulators later, but the separation required by Council is crucial in ensuring that the GPhC processes are free from bias.

Given the problems identified by the PSA in triage, investigations, documentation, and consistency how can assurance be given that the process is free from bias?

We begin by welcoming the decision by the GPhC to finally re-introduce blind reviews with registrant information data redacted, but without proper initial triaging, bias in the system could remain.

> ***The pharmacy regulator is to introduce blind reviews during its fitness-to-practise (FTP) investigations in an attempt to remove bias from the system. The General Pharmaceutical Council (GPhC) will trial redacting any information that might identify a pharmacist's race and/or ethnicity from documents that are seen by FTP investigating committees. The GPhC pilot will begin in September 2020 and run until March 2021.*** ***(18)***

This is what a past member of the Investigating Committee, Mohammed Hussain said in an interview with the Pharmaceutical Journal published 14 July 2020 stated on learning about this pilot:

> ***"This is long overdue and something I had pushed for following my own experiences of sitting as a panel member for the investigating committee. There were rare, but clear, examples of a panellist airing assumptions about an individual based on their presumed belonging to a certain group."*** ***(18)***

Issues regarding potential bias in Investigating committee and fitness to practise procedures are not new and were recognised over 20 years ago. It is disappointing that GPhC is still struggling to deal with this given that on 21.01.2000 the predecessor of the GPhC (the RPSGB) had stated to the Pharmaceutical Journal:

> ***Mrs Sharpe said that the profession had for many years included high numbers of pharmacists from ethnic minorities. A commitment to ensure equal treatment of all pharmacists was reflected in the Society's decision in 1997 to undertake ethnic monitoring. Implementation of the decision had had to await the installation of new computer systems, but ethnic monitoring had begun in 1999 and the Society continued to give it active attention.***

> ***Mrs Sharpe added that the Society was satisfied that it had measures in place to minimise racial or other bias. All cases examined by the Council for possible referral to the Statutory Committee were considered anonymously to eliminate risk of bias. The identities of pharmacists were not known until a decision had been taken. (19)***

In its submission to Government in January 2018 the GPhC clearly understood the relevance of data and its importance especially the impact on ensuring bias free FtP. It stated:

> ***"There is also an opportunity for data driven regulation to provide us with a greater understanding of equality, diversity and inclusion issues and the effect of regulation on these." (20)***

The need to collect data is well known and documented. Similarly, the GPhC in its Equality and Diversity Report of January 2016 **(21)** presented to Council noted:

Use qualitative EDI analysis to better understand FtP outcomes	We understand and mitigate the effects of unconscious bias			

Why is the GPhC now only "considering" collecting data rather than focusing on it?

> ***We are considering collecting more data about the sources of concerns, to help us take the appropriate action to deal with any bias that we discover.***

It is of even greater concern that this GPhC consultation states:

> ***We are not the only regulator facing challenges in developing good practise in how we consider equality, diversity and inclusion. Other regulators are facing similar challenges.***

The other regulators are ahead of the GPhC in this matter as we will evidence below.

The GPhC EDI Strategy - Context

We have already discussed the concerns about the disproportional number of BAME registrants being sent for full hearings which has been ongoing for over 20 years.

We have already evidenced the failure of the GPhC processes identified by the PSA reviews. This has real and material impact on the fairness and equity of the whole FtP process. We are especially concerned that the GPhC consultation intertwines 2 other separate and distinct issues:

> ***We are also developing our equality, diversity and inclusion (EDI) strategy alongside this fitness to practise strategy. We are committed to demonstrating how our approach to fitness to practise will support our EDI work.***

Firstly, the GPhC has had some form of EDI strategy as legally required under the Equalities Act 2010 since 2010. This is what was presented to the GPhC Council on 15th September 2010:

> ***"The Equality Scheme will be supplemented with action plans. These will be introduced gradually through a detailed timetable until the end of the year, to be in place for the beginning of 2011." (22)***

Secondly, if the existing EDI strategy was fit-for-purpose and complied with the Equalities Legislation then it would already be supporting a fair and equitable fitness to practise approach.

It is legitimate to ask what exactly needs updating in the existing EDI action plan pertaining to the work of the Fitness to Practise Directorate. What is failing and what needs reform and are the proposed changes likely to achieve the required outcomes?

The GPhC states in the consultation:

> ***"We need to improve our understanding of why we get a disproportionately high number of concerns about BAME professionals, and the context in which these are made.***
>
> ***We want to learn and adopt the best practises for dealing with this disproportionate representation, both when concerns are raised and throughout the process."***

Given the poor documentation and decision-making processes noted by the PSA how can the public and registrants be assured that there is no systemic bias within the GPhC processes and especially at the triage stage? The NMC, as we will discuss later, found exactly this type of bias in its triage process.

We urge the GPhC to ensure that it takes major steps to ensure meaningful data collection for FtP. The registrant survey demonstrates that it is possible to collect better quality data. **(23)**

The Equalities and BAME issue – How the GPhC could learn from the GMC.

If the GPhC genuinely wants to learn from other regulators then should it be suggesting an enhanced role for employers in light of the research findings of a review commissioned by the GMC?

The GMC, unlike the GPhC has met ***ALL*** the standards set by the PSA for each of the last 7 performance reviews.

The GMC is generally not well regarded by doctors of BAME origin and this distrust was only heightened by its decision to appeal the Bawa-Garba case. Having identified that this was a potential issue which had been simmering beneath the surface for many years, the GMC did the right thing by commissioning an independent review.

The 2018 GMC review **(24)** wanted to identify:

- Why some groups of doctors were referred to the GMC by their employers more than others
- Why some groups of doctors were subjected to more formal disciplinary processes by employers and other healthcare providers
- Why the rate of referral by employers for BAME doctors was double that of white doctors

The GPhC is considering an enhanced role for employers in managing concerns and thus the FtP process. It is vital that the GPhC takes into account the GMC research findings before it considers an enhanced role for employers.

The GPhC proposes in this consultation:

> ***"Employers may often be best placed to recognise and manage some concerns. We will work with employers to help them identify the types of concerns that can be managed locally for faster, more focused and fairer resolutions."***

However, it seems that the GPhC is already involving employers and allowing them to close cases. How does the GPhC monitor these for EDI? This is what the GPhC told the PSA during its 2019-2020 performance review:

> ***The Terms of Reference also state that where an employer is undertaking an investigation and there is no immediate public safety or public interest risk, the GPhC may decide to close the case and ask the employer to contact them again and provide a copy of the investigation report once the investigation has concluded. (16)***

The "Terms of Reference" is the document that the Concerns Oversight Panel is guided by.

The GPhC needs to be clear and forthright in spelling out exactly how it is seeking to widen the role of employers in FtP. Why is this so important? We have already seen instances where pharmacists are being threatened with referral to the regulator for refusing to undertake excessive workloads (for example 50 flu jabs in addition to usual workload)

This could apply to employees and locum pharmacists. The GPhC proposals fail to identify how locums would be supported as they have no employer. In fact, locum agencies have recently started to refer locums to the GPhC for having the temerity to set their own rate at which to offer their services.

There is a real risk that BAME pharmacists, often herded into community pharmacy, as employees or locums and unsupported by large global corporations will face bullying from these employers to undertake work which may expose the public to risk.

The disproportional number of complaints made against BAME doctors is not unique. The GMC review seems to identify underlying societal and structural issues which:

> ***Across all healthcare professional regulators, the rates at which registrants are referred into the Fitness to Practise processes are higher for BAME registrants than they are for white registrants.***
>
> ***"What is clear is that significant opportunity for addressing the risk of bias in the referral process is beyond the scope of doctors from the over-represented group, and rather lies with the leadership within each organisation" (24)***

A number of issues are identified including poor support, isolated working, poor employment practises, stratification from University into worse pre-reg placements and so on.

This GMC commissioned review is an independent credible report which goes to root cause analysis. It offers good insight into how systems and processes and prejudices can impact the reporting of concerns. The first issue is the "why" there is a disproportionate number of referrals and the second issue is the potential bias in the FtP process. As discussed earlier, the GPhC needs to fully separate these 2 issues **(17).**

Interestingly, the GMC report clearly identified stereotyping and bias as an underlying issue in the referral process:

> ***This suggests that bias and stereotypes regarding some groups' competence is compounded by a fear of challenge by these groups (because they have less power).***
>
> ***This is likely to contribute ultimately to the over-referral of certain types of doctors in the FtP process.***
>
> ***Further, data suggest that hesitation to name racism as a form of outgroup bias was seen as pervasive across the NHS systems: (24)***

In fact, there was a BAME doctor who noted a distinct propensity to over-report BAME doctors:

> ***…if there is a mistake made by a white doctor these wider factors then come into play …whereas with an IMG the moment there is a mistake made there is no context to it, the only thing that is visible to the white manager or the white senior person is the mistake and it's really white and black. (24)***

Another BAME GP noted:

> ***On the whole Asian doctors kept their heads down because they could see no point in openly challenging the racism they met. They did not feel they would be supported. (UK trained) (24)***

This racism, whether from colleagues or from patients was accepted to be embedded, just part of the job:

> ***A quarter of BAME GPs surveyed reported experiencing discrimination from patients at least monthly, with three quarters saying they faced racial discrimination from their patients at some point. One quarter said that they felt discriminated against by a practise they had applied to join (24)***

There is no reason to doubt that the experiences faced by doctors do not mirror those that are faced by BAME pharmacists.

The GPhC needs to take heed of the findings from the GMC and this may be best achieved by having an independent review from the same persons that carried out the GMC review.

The Equalities and BAME issue – How the GPhC could learn from the NMC.

We have already discussed that BAME registrants across all professions face a disproportionate FtP process. The NMC faced a similar situation and commissioned an independent report which was published in January 2017:

> ***"Cases brought against nurses and midwives of white, other or unknown ethnicities are more likely to be closed at screening than are cases brought against Asian or black nurses and midwives, whose cases are more likely to be closed at the investigation stage," it said. (25)***

We have also already seen from the PSA reviews that the GPhC has a very poor record for adequately documenting the initial stages of investigation following the reporting of a concern. There is therefore no way of ascertaining whether in the case of the GPhC there is a systemic bias or not.

The GPhC as part of the strategy proposes that the role of the employer in increased in the FtP process. This may well be a retrograde step as both the GMC and NMC reports have identified what appears to be bias on the part of employers.

The NMC data showed that employers were more likely to refer BAME registrants to the regulator.

> ***"This suggests that the FtP process does not discriminate against BME nurses and midwives, but that there is some evidence of discrimination in terms of the disproportionate number of referrals by employers," concluded the report.***

The Equalities and BAME issue - The Wider NHS Context

The issue surrounding disproportionality of BAME referrals to FtP processes is not new. Within pharmacy we have already evidenced that this was recognised over 20 years ago.

Similarly, within the wider NHS this has also been a long simmering issue. A report commissioned by NHS Employers and NHS Institute for Innovation and Improvement and published in 2010 noted:

> ***"It was thought that inconsistent management practises in relation to disciplinaries reflected a lack of confidence amongst managers in dealing with issues relating to staff from different ethnic backgrounds.***
>
> ***In some cases it masked underlying racism that was not always challenged by human resources departments, but unless BME staff could identify comparable cases in which there was differential treatment of white staff, it was difficult to establish whether discrimination was at play." (26)***

We return to the case of Dr Bawa-Garba, a junior doctor who prior to one incident had an unblemished record and no concerns about her clinical competency had ever been raised. Dr Bawa-Garba was convicted of gross negligence manslaughter.

The Court of Appeal, which removed the GMC striking-off judgement noted:

> ***"..that whilst your actions fell far short of the standards expected and were a causative factor in the early death of Patient A, they took place in the context of wider failings." (27)***

The Court of Appeal also noted the comments of the PSA:

> ***As the Professional Standards Authority has emphasised, the present case is unusual. No concerns have ever been raised about the clinical competency of Dr Bawa-Garba, other than in relation to Jack's death. This is so even though she continued to be employed by the Trust until her conviction and for a significant part of that time carried out clinical work as a doctor. (27)***

The GPhC states that it took into account the Williams review when drafting this consultation. Clearly it has failed to understand the much wider issues surrounding this case.

In the letter to the Secretary of State for Health as a foreword in his review, Professor Sir Norman Williams stated:

> ***Testimony to our panel also raised concerns about the regulatory system which had wider implications than those limited to gross negligence manslaughter.***

> ***....There was evidence also to suggest that in both criminal and regulatory investigations there was a disproportionate number of Black, Asian and Minority Ethnic professionals involved. Although the causes were by no means certain, there was enough unease from panel members to ensure that we made recommendations to address any perceived injustice. (7)***

One of the recommendations made by Professor Williams asked regulators to address:

> ***"Concerns about the over representation of Black, Asian and Minority Ethnic healthcare professionals in fitness to practise cases to be investigated, understood and addressed." (7)***

It is particularly interesting to note that future performance reviews of the GPhC (and other regulators) will now include their ability to demonstrate that they are fulfilling the EDI requirements expected of them.

The Williams report especially noted how some regulators have embraced change and the impact this can have:

> ***"Regulators have taken steps to ensure that fitness to practise processes are fair. For example, the panel heard that the GMC has improved BAME representation on fitness to practise panels.***
>
> ***In 2000 there was BAME representation on just two per cent of panels, whereas by the time the role was transferred to the MPTS in 2015 this had increased to 80 per cent."***

The PSA report of 2019-2020 noted that the GPhC had not carried out recruitment for panellists:

> ***The GPhC reported that its last recruitment campaign for associates and partners, which took place in Spring of 2018, was designed to attract applicants from as diverse a range of backgrounds and sections of the community as possible.***
>
> ***The AAC reported that in 2017/18 the proportion of non-white panellists had risen since 2015, from 21 per cent to 25.9%. There has been no recruitment since the 2017/18 report, so the report for 2018/19 contains largely similar data. (16)***

However, even if the GPhC were to recruit BAME panellists there is no guarantee that they would actually sit on any convened panels. Why do we say this? The clue is in the Gender Pay Report prepared by the GPhC and reported in the June 2020 Council Meeting

> ***7.3 Fee rates were the same for male and female members, so there were no 'equal pay' issues in that sense. However, the overall amounts of fees paid to men and women in the same group over the year showed some significant differences, because men were being empanelled more than women. (28)***

Thus, the GPhC not only needs to widen the net of panellists it also needs to ensure that they actually sit on convened panels.

It is particularly interesting that increasing the number of BAME panellists and also ensuring that the panels are balanced is not part of the EDI emerging strategy document that was presented to Council in June 2020 **(29)**

The issue surrounding the composition of panels is also relevant. In an appeal against a decision made by the GPhC, a woman BAME pharmacist made an appeal to the Court of Appeal. The Court of Appeal CoA) judgement noted:

> ***"The fact that a differently-constituted Committee might possibly have opted for suspension rather than removal from the Register does not mean that this Committee's decision was "wrong"." (30)***

However, the CoA also noted that the GPhC guide *"Good decision making: fitness to practise hearings and sanctions guidance"* specifically notes:

> ***The committee should be aware that there may be cultural differences in the way that insight is expressed, for example, whether or how an apology or expression of regret is framed and delivered. Sensitivity to these issues is important in deciding how a registrant frames their 'insight' and in judging their behaviour and attitude during the hearing." (30)***

As Peter Herbert, a prominent Judge of BAME origin has often observed:

> ***"Justice is not colour blind, nor is it equal…. (31)***

> ***"Over the last 20 years the situation has deteriorated under successive governments as the culture has proved resistant to change. Training has become focused on tick-box exercises, more concerned with the sensitivities of judges and magistrates than the outcomes and consequences of those on the receiving end of differential treatment." (32)***

Why is this so important – the juxtaposition of the criminal sanctions and the subsequent regulatory sanction? We have already seen that there is some PSA concern around GPhC FtP outcomes and the PSA specifically noted:

> ***We also found a number of cases which appeared to us to be factually similar but were managed differently and different recommendations for their disposal were made. From the documented information, we could not establish why differing approaches had been taken so these outcomes appeared to us to be inconsistent(14)***

The PSA commissioned research into how dishonest behaviour would be viewed by the public or how this could undermine confidence. It noted the following:

> ***" … there was a small minority that saw an issue in black and white and judged any instance of dishonesty as being grounds for exclusion from the profession. In the case study that involved an immigrant, these individuals tended also to think in terms of deportation. This group were generally much more punitive in their approach, regardless of context." (33)***

Recommendation – Equalities and EDI

(11) The GPhC should commission the expert review as requested by Council at the meeting of the 6th July2017 to ascertain if its FtP processes may have inherent unconscious bias.

The Role of Employers:

Throughout the consultation, the GPhC seeks to introduce an extended sharing of information and an extended role for employers to investigate and manage concerns.

> ***We will develop and publish guidance, referral tools, templates and case studies for employers. This will help them:***

• understand which cases they should refer to us, and
• decide when they are better placed to manage and resolve concerns quickly at local level when there is no immediate risk to patient or public safety
We will develop a web-based tool to share with employers the things we learn from the concerns we see, and how these are successfully resolved

However, the GPhC in 2016 has published a guide for employers and locum agencies who wish to make a referral which clearly states:

> ***Most concerns we receive about pharmacy professionals come from patients or members of the public. Some of these people are not happy with the way their complaint was managed locally, or they just want an apology for what went wrong. Many of these concerns can be resolved locally.***
>
> ***You should have an efficient process in place for resolving concerns locally.***
>
> ***It is important that you encourage an environment and culture where individuals are supported in raising concerns about standards of care and risks to patient safety (34)***

We need to see what further role is envisaged for employers and the GPhC should clearly detail and link with this existing document so that we can identify the extent of the changes.

The General Optical Council, which regulates optometrists and optician premises specifically states in their guidance note for employers :

> ***Fitness to practise investigations are private and we do not publicise the fact that a registrant is under investigation. However, we are required to write to employers and notify you of the investigation. If you ask for more information about the investigation we have to decide whether it is in the public interest to provide it. You must make that request to us in writing, explaining why it is in the public interest for you to receive more information, and we will consider your request accordingly. (35)***

We know that the PSA performance review of 2019-2020 identified that the GPhC was closing cases following employer investigations. The GPhC needs to specify the exact role that it is now considering for employers.

The PDA has received feedback from members that large corporate owners often reward complaints with gift vouchers rather than investigate why the complaint was made. The focus is on retail “customer service” rather than support and understanding that “the customer/patient may not always be right”. We are aware of complaints against pharmacists working in corporate pharmacies who have refused to make an illegal switch of a product on a prescription or who have been unable to supply an item due to shortages etc and were unsupported by their line managers.

Our preceding pages have discussed the Bawa-Garba case where a whole range of systemic failings by her employing Trust were exposed.

A recent research paper specifically relating to pharmacy fitness to practise found that:

> ***"The findings suggest that, in general terms, situational factors should be considered alongside personal factors when assessing, judging or remediating fitness to practise."*** ***(36)***

This is an important finding. Pharmacists work in hugely diverse settings. Some may work in large pharmacies within NHS Trusts, some in independent GP surgeries, many in large corporately owned community pharmacies and many in small local community pharmacies. This diversity of employer is challenging.

In 2018, the NMC commissioned independent qualitative research with key stakeholders including employers, registrants and members of the public to explore the future of the NMC fitness to practise process. This report was published. Whilst it is beyond the scope for this submission to analyse in detail this comprehensive 173 page report the concerns expressed by NMC stakeholders would probably also resonate with GPhC stakeholders. We list just a few of the concerns noted in the report: **(37)**

- Employers stated they would be dissatisfied if the NMC provided feedback of context if it was the employer that made the original referral.
- Nurses were concerned about how low staffing would be taken into account at a time of an incident, especially if this had already been flagged to the employer
- Concerns surrounding employer willingness to oversee mediation
- Concerns around employer truthfulness if it implicated the employer
- How the NMC would monitor that employers were managing a registrant's FtP

We have already evidenced that the GPhC has to date never issued a sanction against employers and their registered premises even though the systemic risk from poor systems in premises will be higher than the risk from any individual practitioner.

A Salient Example of a failed Employer Investigation and its consequences:

It is beyond the scope of this submission to discuss in great detail the following case. However, the case raises some relevant issues in context of the current GPhC proposal.

A patient at a NHS Trust hospital sent an email complaint on 06.09.2015 about the care he had received from Nurse Abdullah and another nurse. The complaints about Nurse Abdullah, a Malaysian immigrant nurse, was regarding 2 non-clinical matters but the complaint about Nurse X was about a serious clinical matter.

An investigation was carried out by Nurse Abdullah's employer, the NHS Trust. On 24.09.2015 the patient sent a further email including raising a concern about the Investigating Officer.

A hearing was subsequently convened and following that hearing Nurse Abdullah was dismissed and subsequently committed suicide. The Trust was now asked to review the case and commissioned The Independent Veritas Report

This review was damning of the initial investigation. It is important to understand the context of this.

A failed investigation, where for unknown motivation an investigating officer raised questions about honesty with no evidence, and the subsequent cover up happened in an NHS Trust with huge resources and a public duty of care.

The large corporations that own the majority of community pharmacies are commercial concerns and we have repeatedly seen that they are not fit persons to conduct impartial investigations especially when relating to non-clinical complaints (like the one Nurse Abdullah) faced. The failures identified in this report could easily happen in many community pharmacy situations.

Key points in the report include :

- The poor application of the written policies of the Trust in this investigation
- Weight given to certain negative perceptions by the constituted panel
- Serious inaccuracies in the summary report following Nurse Abdullah's case which exonerate the Trust
- The blunt description of the summary report as "a whitewash" **(38)**

Recommendation – Role of Employers

(12) The GPhC should await the outcome of the wider Government review of healthcare regulation before making any changes to the employer role. In the interim, it should seek to learn from the GMC and NMC reviews detailed above.

Timeliness of the process, support and communication:

We have seen that the GPhC, pretty much since its inception in 2010 has failed to manage the concerns caseload in a timely manner.

This has real and material impact on all parties including registrants and members of the public. The PSA review of the GPhC 2019-2020 stated:

> ***"... we noted that in a number of decisions the IC explicitly commented on significant delays in the GPhC's investigation ….. Two cases were rescinded, in part because of the length of time that had passed ... However, we were concerned by this evidence of delays affecting the viability of allegations, and potentially the continued engagement of witnesses, and the impact this could have on public protection." (16)***

The PSA stakeholder engagement report also noted:

> ***"Participants also called for clear information on the expected timescales throughout the process." (6)***

The PDA has numerous examples of cases where it has helped members and our legal teams faced:

- Having to chase the GPhC for updates on case progression
- Case workers staff turnover and impact on process
- New case workers having inadequate notes in case files – poor continuity of process.

One recent case the PDA is aware of took 26 months to resolve with the outcome that following the initial investigation the concern was closed. During that period the registrant was not kept informed of progress and sadly the registrant's spouse passed away during that 26-month period without knowing the outcome of the concern.

Following the rising incidence of suicide amongst doctors, the GMC in 2014 conducted an internal review which recommended:

> ***"The GMC needs to create an environment where doctors undergoing a fitness to practise investigation feel they are treated as 'innocent until proven guilty' – as with any judicial process. Investigations need to be conducted in a compassionate manner and as quickly and effectively as possible ...***
>
> ***Any doctor referred to the GMC should be considered to be vulnerable and therefore supported and assisted in a compassionate manner" (39)***

There are a whole number of guidance notes that the GMC has in place for ensuring that the communications and interactions especially with vulnerable doctors are managed well. **(40) (41)**

Whilst the GPhC notes in this consultation that:

> ***"Investigations into concerns about professionals take a long time and can be frustrating for everyone involved. How we contact people, and the method and tone of our communications, can lead to unintended consequences such as an adverse impact on the mental health of the people we are investigating. Vulnerable people can find it hard to get support.***
>
> ***We need to make more progress on cutting down the time it takes to conclude cases."***

We are concerned that to date we have no evidence to show that it found any approaches to address this. It has failed to spell out exactly how it will improve the tone, timeliness and method of communication. It has also been promising the PSA to reduce the time to conclude cases for the last 8 years without success.

We welcome the promise by the GPhC to offer an "Information Pack" for registrants with health issues. But we believe that this is not sufficient and fails in its duty of care towards registrants.

The GPhC could learn from the GMC which in 2017 identified the stress that a GMC investigation caused to doctors. We also welcome the promise to conduct an "assessment of needs" but ask why it has not been doing so as a matter of course and duty already.

As an example of how the GPhC can learn from other regulators we can compare the web landing page for the GDC, NMC and GMC who explain in detail the FtP process and the support on offer. The lack of support offered by the GPhC when compared to the other regulators is notable.

The Need for representation:

We welcome the pledge by the GPhC in this consultation to:

> ***We will also see if there is more we can do for professionals who aren't legally represented. For example, we could provide support through guidance on the***

> ***importance of being represented, information on sources of support or partnerships with organisations that provide representation services.***

However, it has not provided any data to reveal the extent to which registrants have not been represented nor the impact of this lack of representation.

In 2016 a GPhC adjudication was taken to the Appeal Court. We mentioned this case earlier. The GPhC outcome was upheld by the Court of Appeal but a firm of solicitors made the following observation:

> ***The case highlights two key factors: firstly, the importance of a fitness to practise panel discharging its duty to unrepresented registrants by explaining the procedure and any relevant legal concepts. If fitness to practise panels fail to discharge this burden, it may be considered that the registrant in question did not have receive a fair hearing, and that had they been represented, the outcome may have been more favourable. (42)***

The importance of having legal representation and its impact on outcomes cannot be overstated. This is especially important early in the process.

In an inhouse recent data review of the impact of unrepresented defendants the Ministry of Justice was informed of the following:

> ***In addition, unrepresented defendants were seen as a barrier to achieving early guilty pleas. (43)***

However, in the case of healthcare regulation involving registered professionals this should not be the goal. The goal is to encourage the registrant an opportunity to reflect as appropriate according to the circumstance of the allegation.

Section one: Strategic aims and outcomes

On page 12, we identify four strategic aims that will guide our work and help us to evaluate the impact of the strategy. We want your views on whether we have identified the right strategic aims.

1. Considering all four strategic aims, to what extent do you agree or disagree that these are appropriate?

- Strongly agree
- Agree
- Neither agree nor disagree ☑
- Disagree
- Strongly disagree
- Don't know

We neither agree nor disagree as all strategic aims are incumbent for any regulator. The strategic aims for any organisation should be relevant, aspirational, and deliverable and within the scope of the organisation's role.

2. Is there anything missing from the strategic aims, or anything that should be changed?

- Yes ☑
- No
- Don't know

Yes. Please also read in context of the introduction and our answers to 2a and 2b below.

There needs to be a specific section that addresses how concerns about the fitness of premises and any concerns which are reported would be addressed. The focus in this consultation has been on individuals.

2a. If yes, which of the following strategic aims need additions and/or amendments? (Please tick all that apply)

- keep patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns
- take a person-centred approach that is fair, inclusive and free from discrimination and bias ☑
- shift the perception from blame and punishment to openness, learning and improvement ☑
- take account of context and work with others to deal with problems in the wider pharmacy and healthcare systems ☑
- additional aims are needed ☑

We make the following suggestions for the wording of the four aims and the additional aim:

Strategic aims:

- *keep patients and the public safe by using our full range of regulatory tools to prevent, anticipate and resolve concerns*
- *to ensure that our systems and processes take a person-centred approach that is fair, inclusive, and free from discrimination and bias and to monitor this by using robust data collection and analysis*
- *to create a culture which promotes openness, learning and improvement rather than focus on blame and punishment*
- *take account of context and work with others to deal with problems in the wider pharmacy and healthcare systems particularly considering that systemic failures pose a greater risk to the public than the failure of any individual registrant.*

- *to ensure that pharmacy education, including any foundation training inculcates professionalism and good professional practise*

2b.	Please give a brief description of the amendments, additions, or additional aims you think are needed.

The only way to ensure that the GPhC processes are free of bias is by the collection of full and robust data. Otherwise, the aim as stated becomes a mere tick-box exercise.

We suggest that creating a "culture" rather than a "perception" is more relevant and useful in promoting and demonstrating real meaningful change rather than papering over underlying issues.

In the introduction we discussed the role of employers in fitness to practise referrals and the greater risk to patients caused by systems. Poor working practises, coupled with high stress environments can culminate in complaints about pharmacists to the regulator. There is thus a conflict of interest in that the GPhC not only regulate pharmacists, but also the pharmacies in which they are working. In one specific example, a pharmacy owned by a large multinational owner has still failed to meet a GPhC standard 12 months after an "action plan" was put in place by the GPhC.

The aims need to reflect that there is much more which needs to be done to ensure that the sector and the people governing it are equipped with the skills necessary to work in a time of unprecedented change. New registrants need to be equipped with a robust post-graduate training programme to better prepare them to work on the front line and especially in the newly emerging roles within GP practises. This would result in safer practise and should help to prevent FtP referrals from growing in this sector of pharmacy practise.

3.	Considering the full set of strategic outcomes on page 12, to what extent do you agree or disagree that these are appropriate?

- Strongly agree
- Agree
- Neither agree nor disagree ☑
- Disagree
- Strongly disagree
- Don't know

The reply to question 3 should be read in context of and together with question 4, 4a and 4b.

4.	Is there anything missing from the strategic outcomes, or anything that should be changed?

- Yes ☑
- No
- Don't know

4a.	If yes, which of the following strategic outcomes need additions and/or amendments? (Please tick all that apply)

- Patients and the public receive safe and effective care because pharmacy professionals are safe to practise and can get any support they may need to help them meet our standards.☑
- Professionals understand the importance of being open and honest, and that if they acknowledge any mistakes quickly this will minimise the need for a fitness to practise investigation. ☑
- It is easy to raise a concern, and understand the process and what it means to everyone involved. ☑
- Our decisions are clear, timely, free of bias, proportionate and deal with the cause of the regulatory concern. ☑

- Professionals, patients, the public and any witnesses feel confident and supported to take part in the process. ☑
- Our stakeholders are confident we are taking appropriate action to deal with concerns, even if we do not start a formal fitness to practise investigation. ☑
- More concerns are resolved safely at an earlier stage through support, reflection and learning, without the need for a hearing. ☑
- Only the most serious concerns reach a hearing. ☑
- Additional outcomes are needed. ☑

4b. Please give a brief description of the amendments, additions, or additional outcomes you think are needed.

• Patients and the public receive safe and effective care because pharmacy professionals are safe to practise and can get any support they may need to help them meet our standards:
Further clarity would be welcomed in terms of what kind of support is being referred to. There is significant disparity between pharmacy sectors and within sectors. For example, NHS employers may be better equipped in terms of a willingness and ability to offer support compared to target driven multinational pharmacy chains. Also, will this support be from the regulator or if from the employers will it be delivered within a regulatory framework? If pharmacists receive mental health support will there be systems in place to ensure confidentiality and ensure that this does not disadvantage or discriminate against them.

• Professionals understand the importance of being open and honest, and that if they acknowledge any mistakes quickly this will minimise the need for a fitness to practise investigation:
The tone of this point, particularly the use of the word quickly, goes against the purported new approach towards fitness to practise. There is a real risk here that pharmacists, faced with the threat of a stressful fitness to practise process may be coerced into falsely admitting to improper conduct to spare themselves an ordeal, rather than follow a fair and proper process. The Dental Complaints Service encourage the use of an apology, should that suffice, negating the need for a referral to the fitness to practise committee. However, there must not be any undue pressure on pharmacists to make false admissions. An early apology is not without its benefits as it may be all that a complainant wants. However, we would caution any registrant to seek legal advice before taking up this option in case an apology is misconstrued as an admission of any sort.

• It is easy to raise a concern and understand the process and what it means to everyone involved.
Whilst it is important to ensure the process for raising a concern is straightforward, it is equally important that the process doesn't encourage vexatious or spurious complaints and become a tool for disgruntled patients to punish healthcare professionals for carrying out actions with which they disagree. The PSA research published in 2020 noted feedback from informed patients was that:

> ***"some participants indicated that they felt the new process may encourage patients or service users to raise complaints because they were less likely to have to face a daunting hearing." (6)***

Considering this, we suggest a more robust, standardised approach during the initial stages of an investigation to ensure spurious complaints are weeded out.

• Our decisions are clear, timely, free of bias, proportionate and deal with the cause of the regulatory concern.
This should be routine practise for any regulator. The outcome needs to go further and state that all steps in the process follow internal guidance and also follow a consistent and properly documented decision-making process.

Most participants in the PSA research felt that independent oversight should be retained, but the introduction of 'checks and balances' within the system was essential to maintain integrity of the system. By moving towards a reduction in numbers of hearings, there would be a corresponding reduction in scrutiny of decision-making processes. They go on to state:

> ***"Some wondered if regulators would be tempted to be more lenient with registrants in order to ensure that more cases are agreed and, therefore, avoid an expensive and lengthy hearing or if unconscious bias would come into play. Particular concerns were expressed about a small number of people (sitting on Investigating Committees or as Case Examiners) making decisions on cases in private with no further oversight. They felt that there was a need to retain greater scrutiny of consensual disposal cases by an independent organisation to ensure that the process is impartial (and is seen to be)". (6)***

The GMC and NMC collect ethnicity details at point of reporting a concern. There is no option to record such data when raising concerns to the GPhC. This is something the GPhC could learn from other regulators and we would suggest the GPhC does this to fall in line with other healthcare regulators.

• ***Professionals, patients, the public and any witnesses feel confident and supported to take part in the process.***

In order to make widespread changes to the FtP process, as stated by the PSA research, they would only be acceptable if the public have confidence in the process overall. With a government- led move towards more consensual disposal of cases, a robust triaging system would be more important than ever. In the 2019-20 report, the PSA stated:

> ***"We were concerned about the GPhC's triage process because we noted that factors that were not included in its guidance were being considered when decisions were being made. The GPhC did not update its guidance to address this point during the period under review. However, the GPhC has introduced additional oversight of cases closed at triage with no further action". (16)***

Unfortunately, the GPhC consultation paper does not make any specific reference to their triaging process. The triaging process, as we have already discussed has been particularly difficult for the GPhC to manage. PSA research indicated that members of the public expected there to be more than one person involved in the triaging process and for them to have received specialist training in this process. They should also look at the whole picture when dealing with cases and be trained to identify patterns in data received to identify systemic problems. We would also like to see more details about exactly how the GPhC will support all the parties mentioned in any fitness to practise process.

• ***Our stakeholders are confident we are taking appropriate action to deal with concerns, even if we do not start a formal fitness to practise investigation.***

As stated above, we share the same concerns as those raised by the survey conducted by the PSA research. The GPhC needs to follow a standardised approach to casework and all decisions and reasoning behind them is fully documented and following published Guidance. To ensure confidence in the process there must be a system of checks and balance, with decisions made by groups of people with specialised training.

• ***More concerns are resolved safely at an earlier stage through support, reflection and learning, without the need for a hearing.***

We support this approach but greater detail needs to be provided as to how it will work. The GPhC should confirm that reflective accounts will remain confidential. The Dr Bawa-Garba case highlighted the concerns surrounding how true reflective account by a registrant being used against that registrant. Furthermore, we would urge any registrants to seek legal advice before accepting an early resolution.

• ***Only the most serious concerns reach a hearing.***
We agree that this is the correct approach provided that decisions are fully documented and transparent. The GPhC should consult on specific criteria for concerns that should go to hearings.

Section two: Our proposals and how we will achieve them

We are proposing to make more enquiries when we first receive a concern, to help us gather enough evidence to make an informed decision on the most suitable action to take. We set out the areas of enquiry on page 14.

5. Have we identified the appropriate areas of enquiry?

• Yes ☑ • No • Don't know

After our enquiries conclude, we also propose to apply the following test to decide if a concern should be referred for investigation or an alternative is appropriate in the circumstances: Does the information suggest potential grounds for investigating whether a pharmacy professional's fitness to practise may be impaired?

6. To what extent do you agree or disagree that the proposed test is appropriate?

• Strongly agree
• Agree
• Neither agree nor disagree ☑
• Disagree
• Strongly disagree
• Don't know

7. Please explain your responses to the two questions above.

We discussed in the introduction the comments by The Professional Standards Authority in their annual performance review of the GPhC for 2018/ 19 which noted:

> ***"Through our audit of closed cases we established that the GPhC is <u>not</u> complying with its own guidance…"***

They go on to add:

> ***"At investigation, we saw examples of cases where:***
>
> ***• further enquiries could reasonably have been made to enable a more informed decision to be taken***
> ***• the reasoning for the threshold criteria decision was inaccurate or inappropriate. In these cases, we did not think that the flawed reasoning had led to an incorrect decision being made***
> ***• the reasons for the GPhC's recommendation to the IC for disposal of the case were***

unclear or flawed ..
• the outcomes were contrary to the GPhC's internal guidance." (10)

We would encourage more specific enquiries to be made early on in the process to weed out spurious complaints, and in particular to safeguard those with protected characteristics.

We agree that the test is appropriate, however, more must be done to remove the apparent bias in the FtP process because we do not accept that ethnicity is linked to a registrant's fitness to practise. We have already evidenced in the introduction the independent research conducted by the GMC and the NMC and the GPhC should base their processes to robustly collect data in case a disproportionate number of BAME registrants are being referred to it.

When the GPhC are making enquiries about a registrant, we agree that it is wholly appropriate to consider the outcome of any investigations by another body such as an employer or the police. However, it must be stressed that these outcomes must not carry an overt amount of influence into the GPhC's decision about whether to proceed with FtP or not, as these investigations by third parties may well have been compromised by their own inherent biased processes. The GPhC must approach each case with a clean pair of hands and look at all the evidence placed before it.

During the course of initial enquiries into the concern raised, investigations may be made into whether the registrant has a history of fitness to practise concerns. This is entirely understandable as it must be considered whether a registrant is showing a lack of reflection and is entering into a cycle of repeat behaviour which puts the public and profession at risk. Similarly, when behaviours of contractors with multiple premises show repeated breaches of premises standards then this too must be enforced.

Irrespective of the decision made following the triage process, it is imperative that all decision-making processes are thoroughly documented and standardised.

We are proposing to invite pharmacy professionals in certain cases to produce a reflective piece as a way of managing some concerns outside the formal processes. This proposal is set out on page 14.

8. To what extent do you agree or disagree that this is an appropriate and effective outcome for some concerns?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree ☑
- Strongly disagree
- Don't know

9. Please explain your response.

We recommend earlier that, like the PSA, the GMC, the NMC and others, the GPhC publishes full details about the discussions with stakeholders. This would then provide meaningful background at how the current GPhC proposals have been arrived at.

A reflective account is a useful and powerful tool, often used by professionals to reflect upon their personal practise. However, to maintain its' integrity, the individuals' right to protect their reflective

account from unnecessary publication should be sacrosanct. Also, the decision-making process when deciding to resolve a concern by writing a reflective piece as opposed to proceeding to a full FtP inquiry must be documented to minimise the risk of subconscious or conscious bias against a registrant.

High profile cases, particularly that of Dr Bawa- Garba have created a climate in which professionals fear reprisals from their honest accounts, which threatens to undermine the sole purpose of the reflective account.

The William's report into gross negligence manslaughter in healthcare addressed this issue by stating:

> ***"The General Medical Council and General Optical Council will no longer be able to require registrants to provide reflective material when investigating fitness to practise cases. This change will help ensure healthcare professionals are not afraid to use their notes for open, honest reflection which supports improvements in patient care" (7)***

In response to this, the BMA proposed an amendment to section 35A (1A) of the Medical Act 1983 which allowed the GMC to compel disclosure, recommending that:

> ***"Legal protection is provided to reflections in all education and training documents, such as e-portfolios and all annual appraisals, training forms and the Annual Review of Competence Progression." (44)***

Therefore, the proposal by the GPhC must be approached with much caution. If used correctly, it can be used to allow the registrant to reflect upon their practise and identify areas of weakness which they can then proceed to address. If used incorrectly, there is a real risk that registrants will find that if they record their honest thoughts and feelings in a reflective account, they will prejudice the outcome of any future GPhC referrals. Therefore, they would be less inclined to fully embrace the principle of the reflective outcome.

The involvement of the employer in this process is also an issue of concern for us. All too often we see reports of target- driven behaviour by contractors against employees. This is a highly stressed environment which many registrants find themselves.

Systemic flaws may be missed, and the reflective account may risk becoming tick box exercises if registrants are forced to write them under duress.

The GPhC must not create a culture in which the registrant is reluctant to speak out against their current (or previous employer) for fear of reprisals.

Our discussions with stakeholders, including our work looking at other regulators, showed that mediation could play a role in resolving concerns.

10. To what extent do you agree or disagree that mediation can play a role in resolving concerns about pharmacy professionals?

- Strongly agree
- Agree
- Neither agree nor disagree ☑
- Disagree
- Strongly disagree
- Don't know

11. Please explain your response including, if it is appropriate, what form you think the mediation should take. To make sure we put people at the heart of what we do, we are proposing a number of service promises that set out what you should expect from us. These are included in the table on pages 17 and 18.

In 2012, the Law Commission conducted a review of the UK law relating to the regulation of healthcare professionals. The review considered many issues including:

- The investigation and adjudication of fitness to practise case.
- The regulation of business premises and activities
- The systems through which the regulators can be held to account, including the roles of the Privy Council, Government and Parliament, and duties to consult the public.

With regards the introduction of mediation as a means of settling disputes where the registrant has been found to be at fault but is still fit to practise, the Law Commission were not convinced of its benefits, stating:

> ***"Despite the widespread support for mediation, we remain unconvinced that it is an appropriate process for dealing with allegations of impaired fitness to practise. Mediation tends to be used in disputes involving individuals, and outcomes are negotiated rather than imposed. In contrast, a regulatory body is charged with investigation and taking action in order to protect the public; sanctions are imposed on this basis and are not properly the subject of negotiation. Mediation would only be appropriate early in the process and perhaps only where there is no question of an allegation amounting to impaired fitness to practise being raised." (45)***

We agree with the view that this would be analogous to being given further powers of disposal but, left unchecked, could undermine confidence in the regulator.

The PSA audit identified several cases at the GPhC which demonstrated questionable decision- making processes with flawed reasoning. Furthermore, without knowing the ethnicity data or protected characteristic details for registrants referred to FtP and the outcomes they faced (subject to an FOI request) we cannot say for certain that the process would be free of bias.

We are also concerned that there is no detail of who would be responsible for administering the process of mediation. If it is the GPhC, will there be specially trained individuals to deal with the issues that may be presented? Or, if left to employers to administer, there a real risk that they will simply use it as a chance to pass blame onto the employee and a systemic problem may be covered up ?

For this reason, we agree that mediation should be a means to resolving concerns about a registrant provided all the concerns around documentation and recording of the process are clear and fully transparent. However, the GPhC should await the Government consultation before introducing this measure.

12.	Do you think our service promises give you clear expectations of the service you will receive from us? • Yes ☑ • No • Don't know
13.	Please explain your response.

The six "promises" should be a given for any modern organisation. Overall, the six promises as laid out are clear and relevant to the service provided by the GPhC. However, the very fact that the GPhC feels that it has to now list these to move forward may be indicative of a systemic culture resulting in outcomes already discussed within the PSA reports of 2018-2019 and 2019-2020.

Promise	Our view
Communicate with you clearly and tailor our communications to your needs	The experience of the PDA indicates poor communication processes in general. Staffing needs to fully reflect the diversity of the registrant population. We welcome the commitment made by the GPhC to assign a dedicated member of staff to deal with each concern.
Explain what you can expect from us	In certain cases where the GPhC is unable to deal with a concern directly, our view is that these cases must be documented fully using internal procedures. An example would be a registrant raising concerns about a contractors' premises. In this way, these concerns are logged and can be scrutinised accordingly. The annual Fitness to Practise report should contain more data to reduce the need to extract information using FOI requests.
Handle your information with care	It is suggested that registrants' health- related matters may be shared with other organisations. This should strictly only ever be done with the full consent of the registrant. We have already highlighted the way other regulators have guaranteed confidentiality.
Act with professionalism, kindness and respect at all times	This should be a given for any regulator
Provide an accessible service to everyone involved	This should be a given for any regulator
Listen and respond to feedback and use this to learn and improve our services	This should be a given for any regulator

We want to improve our understanding about the potential barriers that may prevent groups and individuals being able to engage effectively with us because of one or more protected characteristics. This will help us develop effective measures to remove these barriers. In particular, we want to understand whether people who share one or more protected characteristics encounter specific barriers in our fitness to practise processes, because of those characteristics, once a concern has been raised. Under the Equality Act 2010, there are nine protected characteristics:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race/ethnicity
- religion or belief
- sex
- sexual orientation

14. Do you think people who share one or more protected characteristics encounter specific barriers in our fitness to practise processes because of that characteristic?

- Yes ☑
- No
- Don't know

14a. If yes, please explain including any measures to remove these barriers.

We welcome the proposed introduction of an assessment of needs to address any specific needs of a registrant or complainant so that the concern is appropriately and fairly managed.

We have already detailed in the introduction concerns dating back from year 2000 surrounding bias, and the announcement by the GPhC in 2020 to re-introduce anonymised case information to reduce the risk of bias.

However, the GPhC have also stated that:

> *"Any characteristic which provides essential context to the background of the allegations such as gender in a sexual misconduct case or their religion in an allegation of antisemitism, Islamophobia, etc, would need to remain in the documents provided to the investigating committee".*

This is understandable, but, whilst it is important to capture this information in relation to the registrant during an investigation, it would be equally, if not more important, to ensure such information is available about the complainant.

Taking all the protected characteristics as a whole, we feel there is much more that the GPhC can do to fully represent and understand the broad range of protected characteristics seen in its registrants. For example, in response to a 2019 independent review into sexism and sexual harassment at the BMA, they set out a clear charter and action plan to implement 31 recommendations put forward by Daphne Romney QC. Committee members are subject to feedback and 360 appraisals and every committee member must undergo training in diversity, equality, anti-bullying, active-bystander and collegiate working.

In addition to this they have:

- Set up a network of elected women representatives who will champion and strengthen female leadership and advance diversity for the benefit of our Association.
- Introduced an equality, diversity and inclusion advisory group provide expert advice and guidance on all matters relating to equality, diversity and inclusion work at the BMA.

- Set up a national BAME forum to strengthen our commitment to diversity and inclusion.

In comparison with the steps taken at the BMA to include registrants with different protected characteristics, the GPhC proposals need additional detail especially on panel composition.

During the pandemic we have learnt that remote hearings can be effective, but we know they shouldn't replace our usual ones. We want to understand more about when they could be used and what impact they may have.

15. Do you think that to continue with remote hearings would:

a. disadvantage anyone?
• Yes • No • Don't know ☑

b. present any risks to a fair hearing?
• Yes ☑ • No • Don't know

c. have benefits for those involved?
• Yes • No • Don't know ☑

16. Please explain your response.

It is beyond the scope of this submission to detail a huge analysis on this complex area. We would caution the GPhC not to use a percentage (in form said yes 90% said they agree to this question) to justify any proposals that may follow this consultation.

There are several evaluative research papers detailing the complex issues around this and the GPhC must use this independent research to inform any further steps it proposes (and consults on).

A recent paper discussed many issues surrounding remote hearings, and this also contains a significant bibliography.

2 Key points from this recent paper are:

- ***The journey to a video hearing involves a suitability assessment, including assessing whether parties ….***
- ***Judges reported that access to video hearings should be increased but not as a substitute to physical hearings …. (46)***

Our experience has shown that there is a risk to fair hearing, particularly where evidence from witnesses is disputed. Also, since not all registrants will be familiar and comfortable with using remote hearing technology this may have a negative impact.

We note with disappointment that at the GPhC Council meeting of 8th January 2021 a number of matters surrounding remote hearings were agreed and accepted. A full equality impact analysis was also published. Most respondents to this consultation will not be aware of the processes used presently and the impact of these. For example, the GPhC now has the power to send documents by email without the consent of the registrant and there is no requirement to seek such consent.

Any temporary measures the GPhC proposes to make permanent must be consulted on separately at the end of the pandemic period and at that stage the GPhC must share the experience of how these processes

have worked. It must also at that stage detail how the processes proposed fit in with currently recognised best practise and how they also align with other regulators especially on public access and consent to service of documents by electronic means.

We want to get a better understanding of the wider implications and appropriateness of using personal experience statements (see page 19) – from the people affected by the concern – in the fitness to practise process. The statements could be taken into account at any stage, including during an investigation, at an investigating committee, or at a fitness to practise hearing.

17. Do you think that we should take personal experience statements into account when deciding what regulatory action is suitable?

• Yes • No ☑ • Don't know

18. Please explain your response.

We have already discussed in the introduction the purpose and ethos for professional regulation and its purpose.

> ***However, the sanctions imposed by fitness to practise panels may have a punitive effect. .... the fitness to practise process is not a 'complaints process' as such, and its purpose is not to provide redress to the person who raised the concern (1)***

The ethos and purpose of FtP hearings would be seriously undermined were personal experience statements taken into account.

The NMC has considered the use of personal experience statements and is conducting a wider review to inform the next steps it takes before it decides to publicly consult on this specific matter. There is considerable unease within the nursing profession and some of the comments reported include:

> ***"…the statements could give service users 'undue weight' in the fitness-to-practise process by 'stacking the odds' in favour of patients and 'unfairly biasing' the process against registrants." (47)***

We cannot support the use of personal experience statements and it would be incumbent on the GPhC to demonstrate that such statements will be free from undue weight, bias and disproportionality against registrants.

We are committed to improving and learning from people's experiences of being involved in a concern. We know we can improve how we communicate with people throughout our process to get feedback from everyone involved.

19. What methods would be effective in getting feedback from, and understanding the experience of, people that have raised a concern or had a concern raised against them?

The GPhC should proactively seek anonymised feedback using forms which capture data on protected characteristics so that the information can be scrutinised, and the process thoroughly audited by an independent entity competent to do so. The proactive measures the GPhC takes to obtain feedback should be fully documented for each concern.

We will consider the wider context within which a professional is working when we assess concerns and decide on the most appropriate way of managing the concern. We think that if we can better understand the context, then we can better identify whether there is a fitness to practise concern at all, or whether the issue would be better dealt with in another way, for example through our inspections.

20. To what extent do you agree or disagree that the wider context within which a professional is working should be a significant factor when assessing a concern?

- Strongly agree ☑
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know

21. Please explain your response.

Workplace issues have long been cited as a key factor in patient incidents. In a survey conducted by the Royal Pharmaceutical Society and Pharmacist Support, 80% of respondents said they were at a 'high' or 'very high' risk of burnout through exhaustion.

Almost half of pharmacists who responded to the survey on workforce wellbeing said they worry about making mistakes or providing a poor-quality service to their patients. One in five respondents to the survey cited a lack of pharmacy support staff as a factor in their poor mental health and wellbeing. The same proportion of respondents cited unrealistic expectations from their manager or organisation as a major factor in their mental wellbeing.

We have already discussed the failure of the GPhC in regulating pharmacy premises. This failure not only affects individual registrants, it also has the potential to harm patients. We agree that context is important but effective and measurable sanction against pharmacy premises that pose a systemic risk is more important.

We plan to improve our website, website materials (guidance about what we deal with and guidance for witnesses) and online form for raising a concern. This is to improve the support we give to patients and the public involved in the fitness to practise process.

22. Are there any other ways, not identified in our proposals, we could provide support to patients and the public involved in the fitness to practise process?

We have already discussed the expectations of an "informed public". This indicates that the focus for the GPhC should be to ensure that the processes it employs are fit for purpose and meet PSA standards as this would be the best way to support patients and the public.

The substantial year on year increases in number of concerns received (by 28% between 2017 to 2019) does not seem to indicate that there are any barriers to the raising of a concern. The percentage of

concerns which failed to meet the threshold standards has increased from 21% in 2018-2019 to 34% in 2019-2020.

There should be greater clarity on what constitutes a concern as a larger proportion of concerns are not meeting the threshold standard.

We want to understand whether our proposals may have a positive or negative impact on any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. The protected characteristics are:

- age
- disability
- gender reassignment
- marriage and civil partnership
- pregnancy and maternity
- race/ethnicity
- religion or belief
- sex
- sexual orientation

23. Do you think our proposals will have a positive or negative impact on individuals or groups who share any of the protected characteristics?
- Yes - positive impact
- Yes - negative impact
- Yes - both positive and negative impact ☑
- No impact
- Don't know

We also want to know if our proposals will have any other impact on any other individuals or groups (not related to protected characteristics), for example: patients, pharmacy owners or pharmacy staff.

24. Do you think our proposals would have a positive or negative impact on any other individuals or groups?
- Yes - positive impact
- Yes - negative impact
- Yes - positive and negative impact ☑
- No impact
- Don't know

25. Please give comments explaining your answers to the two impact questions above. Please describe the individuals or groups concerned and the impact you think our proposals would have.

In the Lammy Review, David Lammy identified that persons of BAME origin were disproportionately represented in prisons. For example, black people make up around 3% of the general population but accounted for more than 12% of the adult population in prison in 2015/16. In an article following the publication of the review he stated:

> ***… my judgment is that we have a significant problem in the criminal justice system itself … (48)***

Given the inadequate documentation identified by the PSA reviews, it is difficult to know if the GPhC system is biased as the adjudication data clearly indicates a disproportionate number of BAME pharmacists facing sanctions.

Without knowing whether the current existing system is biased or not, we cannot comment on the impact of changes.

The focus for the GPhC should be on ensuring that its existing systems are fit for purpose in both collecting and recording not only protected characteristic but especially ethnicity data for both the registrant and the complainant for the purposes of checks and balances, whilst ensuring this data is not visible to the FtP committee to minimise any subconscious bias during the process.

However, currently, the GPhC offer an anonymising facility for complainants which hasn't been mentioned during the course of this consultation. This can mean that complainants are free to lodge complaints against registrants, whether consciously or subconsciously biased, safe in the knowledge that they can maintain complete anonymity while the potentially totally innocent registrant becomes embroiled in a long, stressful investigation into their work.

In order to weed out subconscious bias, the right kind of data must be anonymised and at the appropriate stages. If data relating to patient name and ethnicity is to be anonymised, then in the interests of fairness all such data relating to the registrant must also be anonymised so that the investigating committee can focus solely on the facts without any element of bias creeping in from anybody in relation to any of the protected characteristics.

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