Protecting Registering Regulating

Department of Health and Social Care

Regulating healthcare professionals, protecting the public

Consultation Response from the Council of the Pharmaceutical Society NI

22 June 2021

Duty to Cooperate.

1. **Do you agree or disagree that regulators should be under a duty to co-operate with the organisations set out above? Please give a reason for your answer.**

We **agree** that regulators should be under a duty to co-operate with the organisations set out and welcome this duty. The Healthcare landscape is complex and multifaceted, covering multidisciplinary teams, systems and continually evolving service delivery. It is appropriate that in such circumstances regulators cooperate with each other to protect the public. This duty will have to be appropriately aligned with data handling, sharing and collection requirements.

In addition, we consider this an opportunity to better integrate the regulation of healthcare professionals with systems regulators at a devolved level and would welcome additional focus in this area, to further build understanding and relationships across the regions of the UK.

Objective of transparency and related duties

2. **Do you agree or disagree that regulators should have an objective to be transparent when carrying out their functions and these related duties? Please give a reason for your answer.**

We **agree** that regulators should have an objective to be transparent when carrying out their functions and related duties. We support transparency and consider it very important for public confidence. To operate effectively and to deliver on regulators' overarching goal of public protection, issues like commercial sensitivity and policy making will require the ability to conduct appropriate elements of our business in camera.

Duty to assess the proportionality of changes

3. **Do you agree or disagree that regulators should be required to assess the impact of proposed changes to their rules, processes and systems before they are introduced? Please give a reason for your answer.**

We **agree** that regulators should be required to assess the impact of proposed changes to their rules, processes and systems before they are introduced, however, the duty needs to clearly state that regulators should still take necessary regulatory action or introduce new rules, systems or processes, if there is an overriding public safety or regulatory objective to do so, even if they have an impact on the groups listed.

We also recognise the need to develop a proportionate and consistent test amongst regulators. We seek clarity on any roll the PSA will play in assessing this test and the decisions regulators make in relation to it, which must not interfere with the independent decision-making role of the regulators.

Unitary Boards

4. **Do you agree or disagree with the proposal for the constitution on appointment arrangements to the Board of the regulators? Please give a reason for your answer.**

We **disagree** with the proposal for the constitution on appointment arrangements to the Board of the regulators.

There is limited to no evidence presented in the consultation as to the benefit of moving to a Unitary Board model; we do not see the argument made out, for the improvement this change may offer. A blend of executive and non-executive directors can often focus on operational rather than strategic and oversight activities. The objectives of regulators are clearly set out in legislation (and will be strengthened under these proposals), and the current Councils are charged with setting the strategy to achieve them and oversee their delivery by the executive arm of each organisation. We consider that this will continue to be the most appropriate model to deliver effective regulation under the legislative framework under consideration.

Whilst we acknowledge Councils will have power to stipulate, to some degree, the makeup of Councils, we have previously made the point that removal of the legal requirement to appoint registrant members and appoint on merit may favour lay members' due to more governance experience. Unbalanced boards, with absence of registrants, has potential to alienate registrants from regulation and leave strategic boards potentially devoid of the necessary professional expertise to ensure regulation and in particular professional standards remain appropriate and effective. The fact that registrants fund the regulators, and as such have a reasonable expectation to ensure the proper use of funds, cannot be ignored. Taking these points into consideration the Unitary Board model is also not entirely consistent with drive of other aspects of reform, which focuses on regulators doing more to work with and support registrants to maintain and improve standards.

The lack of reserved places for registrants is also incongruous with the fact that proposals specifically require a place be reserved to a representative of devolved regions, unless agreed by relevant Assembly.

The consultation is virtually silent on the independence of Regulators and the importance of independent decision making, within a statutory framework set by Government. We consider this a concerning omission from the consultation, which exasperates the concerns outlined above in relation to the Unitary Board proposals.

We have additional concerns that the Unitary Board model may potentially cause problems for all regulators in relation to the proposed Fitness to Practise (FTP) Registrar review powers, (Question 61). Currently most Chief Executives are also the Registrar of the Regulator and would therefore sit on the Unitary Board by default. If the Registrar FTP review powers are introduced, there is a danger that the Councils will become directly embroiled/associated with any controversial FTP decisions, related to the Registrar review. This is a clear example as to why professional regulation lends itself to the current governance model.

Fees and Charging

5. **Do you agree or disagree that regulators should be able to set their own fees in rules without Privy Council approval? Please give a reason for your answer.**

We **agree** that regulators should be able to set their own fees in rules without approval. We will note that the Privy Council does not apply in Northern Ireland, the approving authority currently being the NI Assembly.

The setting of fees should be subject to public consultation, which explains the rationale for fee use and is accompanied by a requirement to publish detailed accounts.

External approval is difficult to justify and may inhibit regulatory performance if activities are not properly funded.

6. **Do you agree or disagree that regulators should be able to set a longer-term approach to fees? Please give a reason for your answer.**

We **agree** that regulators should be able to set a longer-term approach to fees. A business plan that spans a number of years provides greater certainty for those paying the fees, enhancing understanding of a business plan aligned to meet regulatory/statutory objectives. This is extremely important for maintaining confidence amongst registrants in regulation and how it is financed. It will also increase transparency and understanding as to the purpose of fees and how and why they will be spent.

Committees

7. **Do you agree or disagree that regulators should be able to establish their own committees rather than this being set out in legislation? Please give a reason for your answer.**

We **agree** that regulators should be able to establish their own committees rather than this being set out in legislation.

We consider that committees with significant powers, for example Fitness to Practise committees, should have a legislative basis and their core activities set out in a legislative framework. We would therefore **disagree** with Fitness to practise committees being established by regulators. Such an approach would provide confidence to those affected by Fitness to Practise Committee activities, and decision makers operating within such committees.

Other Committees should be established as required and details about their activities published. The setting up of internal committees, should not be subject to public consultation.

Charging for Services

8. **Do you agree or disagree that regulators should be able to charge for services undertaken on a cost recovery basis, and that this should extend to services undertaken outside of the geographical region in which they normally operate? Please give a reason for your answers.**

We **agree** that regulators should be able to charge for services undertaken on a cost recovery basis, and that this should extend to services undertaken outside of the geographical region in which they normally operate. To fairly spread the cost of regulation this seems a reasonable proposal. For example, a complex registration application, which requires detailed analysis, should be able to attract a higher fee than a straightforward application.

There does, however, need to be clarity about what can be charged for. Activities related to core regulatory functions should be covered by fees. Additional services provided can be covered by charging. Clearly defining services amongst regulators will be very important for both regulators and registrants to ensure a broadly consistent approach. For example, some regulators may be able to have relatively lower fees, if their charging list for services is more extensive than others.

Power to Delegate

9. **Do you agree or disagree that regulators should have the power to delegate the performance of a function to a third party including another regulator? Please give a reason for your answer.**

We **agree** that regulators should have the power to delegate the performance of a function to a third party including another regulator. This could provide efficiencies, for example, joint accreditation of courses through a single delegated body. It may also assist in formalising inter-regulatory activities, that regulators are currently managing through MOUs and agreements. This will provide greater certainty to Councils and registrants in relation to clear lines of accountability and governance.

Data handling, sharing and collection

10. **Do you agree or disagree that regulators should be able to require data from and share data with those groups listed above? Please give a reason for your answer.**

We **agree** in principle that regulators should be able to require data from and share data with those groups listed. We seek clarity on the specificities of the powers and duties being sought, and assurance that the powers are ICO compliant. In order to continue to carry out the core function of protecting the public, it is very important that regulators do not lose any of their current data requiring and sharing powers in this area. We will welcome the continued engagement from DHSC with us and other regulators on the specificities and consider the continuation of this work to be very important, as DHSC works towards the GMC's initial legislation.

We request clarification on the role of the PSA in overseeing compliance by regulators on data handling, sharing and collection. It is our strong opinion that this should be done exclusively by the ICO, which has the clear legislative competence in this area and compliance with their standards should be deemed sufficient.

Accountability to the UK Government and Devolved Administrations

11. **Do you agree or disagree that regulators should produce an annual report to the Parliament of each UK country in which it operates? Please give a reason for your answer.**

We **agree** that regulators should produce an annual report to the Parliament of each UK country in which it operates**.** This is an opportunity to enhance public protection and accountability at the regional level. It will assist in driving cooperation amongst regulators at the devolved level. Reports should be bespoke and relate to activity in the region.

When considering the importance of devolution and regulation, we have concerns as to the legislative mechanism that will be used to implement these reforms. The regulation of healthcare professionals is a transferred matter, meaning the Northern Ireland Assembly has full legislative authority over the regulation of all healthcare professionals. Under the Scotland Act 1998 regulation of existing health professions

is reserved to the Westminster Parliament but regulation of health professions created since devolution (1998), is devolved to the Scottish Parliament. Section 62 of the Health Act 1999 makes certain provisions in respect of Scotland to have parliamentary oversight of changes to regulation for those professions created post 1998. By contrast there is no provision for any Section 60 Order to be laid and approved by resolution of the Northern Ireland Assembly.

This means that even though the entirety of the regulation of healthcare professions is transferred to the Northern Ireland Assembly, there is no mechanism for the Northern Ireland Assembly to have oversight or scrutiny of legislative amendments made in relation to the regulation of healthcare professionals, using Section 60 Orders, under the Health Act 1999. This includes the entirety of the proposals under consideration.

Given that the Pharmaceutical Society NI only has jurisdiction in Northern Ireland and has an established relationship with the NI Assembly and Department of Health, we consider it most appropriate for the legislative changes under consideration in relation to the Pharmaceutical Society NI to be brought forward by the Department of Health in Belfast, using the framework developed during this consultation. The alternative approach may be considered out of step with the devolutionary settlement and the stated objectives of this consultation in relation to accountability of regulators to the devolved regions.

Powers of the Privy Council

12. **Do you agree or disagree that the Privy Council's default powers should apply to the GDC and GPhC? Please give a reason for your answer.**

We have **no comment** on this question.

13. **Do you agree or disagree that all regulators should have the power to set:**
    - **standards for the outcomes of education and training which leads to registration or annotation of the register for individual learners;**
    - **standards for providers who deliver courses or programmes of training which lead to registration;**
    - **standards for specific courses or programmes of training which lead to registration;**
    - **additional standards for providers who deliver post-registration courses of programmes of training which lead to annotation of the register; and**

- **additional standards for specific courses or programmes of training which lead to annotation of the register? Please give a reason for your answer.**

We agree that all regulators should have the powers to set the standards listed above. Registration and annotation are both important safety critical processes and regulators need these powers to approve, restrict or remove courses/providers.

Approvals Warnings and Conditions

14. **Do you agree or disagree that all regulators should have the power to approve, refuse, re-approve and withdraw approval of education and training providers, qualifications, courses or programmes of training which lead to registration or annotation of the register? Please give a reason for your answer.**

We **agree** that regulators should have the powers as set out above. Entry to the register or receipt of an annotation are critical processes in public safety. These compliment powers around health and character, which together restricts access to the register or annotation, in order to ensure public safety.

15. **Do you agree that all regulators should have the power to issue warnings and impose conditions? Please give a reason for your answer.**

We **agree** in principle that regulators should have the power to issue warnings and impose conditions. This more nuanced approach seems sensible and will be a useful tool to drive improvements. However, the appeals process proposals are based in the language of Fitness to Practise and we are in doubt as to whether this is the most appropriate approach.

DHSC should reflect on the language used and consider moving away from language ensconced in that of Fitness to Practise. For example, instead of imposing a ‘warning’ an ‘Improvement Notice’ may be more appropriate, and instead of imposing Conditions ‘improvement obligations/requirements’, may be more appropriate.

Whilst the core purpose of accrediting and approving institutions and courses must be public safety and the maintenance of appropriate standards. Taking into consideration proportionality obligations and wider objectives, regulators should be drivers of improvement in this area, and it would be detrimental if accreditation were focused too

heavily on what could be interpreted as punitive analysis and decisions. However, this suggestion in relation to language should not reduce/remove the fundamentals of the powers necessary to ensure public safety.

Appeals

16. **Do you agree or disagree with the proposal that education and training providers have a right to submit observations and that this should be taken into account in the decision-making process? Please provide a reason for your answer.**

We **agree** with the proposal that education and training providers have a right to submit observations and that this should be taken into account in the decision-making process. We think this is appropriate in the interest of fairness and complements the right to appeal and the need for common grounds to appeal as per the proposals relating Question 17.

17. **Do you agree that:**
    - **education and training providers should have the right to appeal approval decisions;**
    - **this appeal right should not apply when conditions are attached to an approval;**
    - **regulators should be required to set out the grounds for appeals and appeals processes in rules? Please provide a reason for your answer**

Education and training providers should have the right to appeal approval decisions –

We **agree** and consider this to be appropriate in the interests of fairness.

That this appeal right should not apply when conditions are attached to an approval –

We **agree** in principle, subject to our comments on the use of FtP language above (Q 15) and that the imposition of conditions would not impact on an organisation's ability to carry out its educational functions, which conditions focused on improvements should not.

That regulators should be required to set out the grounds for appeals and appeals processes in rules –

We **agree,** the process and consultation on Rules offers opportunity for engagement and shaping processes with engagement of key stakeholders. This approach should ensure its fairness.

Variation in regulators rules and standards setting powers

18. **Do you agree or disagree that regulators should retain all existing approval and standard setting powers? Please provide a reason for your answer.**

We **agree** that regulators should retain all existing approval and standard setting powers. Where there is evidence that the retention of these powers is necessary and that the proposed replacement powers would not provide the relevant regulators with the full 'tool kit', the proposal is sensible.

Exam and Assessment Powers

19. **Do you agree or disagree that all regulators should have the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register? Please provide a reason for your answer**.

We **agree** that all regulators should have the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register. We consider that the approach outlined gives good flexibility going forward and provides opportunities around equivalence.

20. **Do you agree or disagree that this power to set and administer exams or other assessments should not apply to approved courses or programmes of training which lead to registration or annotation of the register? Please provide a reason for your answer.**

We **agree** that the power to set and administer exams or other assessments should not apply to approved courses or programmes of training which lead to registration or annotation of the register. Our understanding is that this proposal is to ensure regulators cannot set exams for courses they accredit and approve for either entry onto the register or annotation. We consider this to be a sensible and proportionate approach.

Delegation and Methods of Assessment

21. **Do you agree or disagree that regulators should be able to assess education and training providers, courses or programmes of training conducted in a range of ways? Please provide a reason for your answer.**

We **agree** that regulators should be able to assess education and training providers, courses or programmes of training conducted in a range of ways.

There is some overlap in accreditation between a range of authorities – being able to accept an Edexcel assessment, for example, may be helpful in the future. This proposal provides potential flexibility and ability to adapt to future educational and training practices and needs.

22. **Do you agree or disagree that the GMC's duty to award CCTs should be replaced with a power to make rules setting out the procedure in relation to, and evidence required in support of, CCTs? Please give a reason for your answer.**

We have **no comment** in relation to this question.

CPD and revalidation

23. **Do you agree or disagree that regulators should be able to set out in rules and guidance their CPD and revalidation requirements? Please give a reason for your answer.**

We **agree** that regulators should be able to set out in rules and guidance their CPD and revalidation requirements. Being able to set revalidation requirements is essential to protect the public and is expected of regulators by them. There is ample evidence

that patients expect their healthcare providers to keep up to date and for there to be regulatory checks on this. In open consultation with employers and key stakeholders, we consider regulators to be best placed to determine what registrants need to demonstrate to prove that they remain safe to practise. Our response to Question 4, in relation to registrant members' expertise and places on Unitary Boards, should however, be considered in this regard.

Main proposals – single register

24. **Do you agree or disagree that the regulators should hold a single register which can be divided into parts for each profession they regulate? Please give a reason for your answer.**

We **agree** in principle that the regulators should hold a single register which can be divided into parts for each profession they regulate. However, in the policy development stage, we expressed our preference to DHSC that we maintain a student register. It was presented that this could be managed through annotating trainees on the full register, outlining the limitations on their ability to practice independently.

We would like to see the detail and wording of the proposed legislation prior to giving our full backing to this proposal. In particular, we want to understand whether we will need a specific primary power to automatically remove trainees from the register, should they fail the Registration Assessment or a requirement of the Foundation Training Year, or whether this can adequately be dealt with through the development of appropriate Rules.

In general, however, we support the approach, and it reflects our current position in relation to a single professional register, which is annotated.

25. **Do you agree or disagree that all regulators should be required to publish the following information about their registrants:**
    - **Name**
    - **Profession**
    - **Qualification (this will only be published if the regulator holds this information. For historical reasons not all regulators hold this information about all of their registrants)**
    - **Registration number or personal identification number (PIN)**
    - **Registration status (any measures in relation to fitness to practise on a registrant's registration should be published in accordance with the rules/policy made by a regulator)**

- **Registration history. Please provide a reason for your answer.**

We **agree** in principle, however, we look forward to seeing the proposals laid out in draft legislation. The categories outlined should provide regulators, the public and employers with the necessary information and assurances that the registered individual is an appropriate person and fit to practise. We would ask for greater clarification on the extent and content of 'registration history' category and any consideration that has been given to potential verification issues.

26. Do you agree or disagree that all regulators, in line with their statutory objectives, should be given a power allowing them to collect, hold and process data? Please give a reason for your answer.

We **agree** that all regulators, in line with their statutory objectives, should be given a power allowing them to collect, hold and process data. Regulators' ability to carry out its basic functions and meet their core objectives would not be possible without the power to collect, hold and process data in relation to registration. Registration is the foundation stone of all other regulatory functions.

27. Should they be given a discretionary power allowing them to publish specific data about their registrants? Please give a reason for your answer

Yes, regulators be given a discretionary power allowing them to publish specific data about their registrants. This would be an appropriate power to have in relation to the proposed powers concerning administrative removal. We would, however, like more information on the proposals outlined in paragraph 158. Paragraph 158 also states that 'where a registrant does not provide this information, they could potentially be removed from a regulator's register. However, removal would only take place as a last resort when other steps to obtain the required information have failed'. There is no outline of due process or procedures, and we have concerns about fairness to registrants in this regard - please see response to Question 36.

Annotation of the single register

28. Do you agree or disagree that all regulators should be able to annotate their register and that annotations should only be made where they are necessary for the purpose of public protection? Please give a reason for your answer.

We **agree** that all regulators should be able to annotate their register and that annotations should only be made where they are necessary for the purpose of public protection. Doing so ensures alignment with regulatory objectives and provides certainty and clarity for the public. Any appeals process for annotations will need to be limited and we would seek greater clarification on potential grounds for appeal. We can only perceive one potential grounds for appeal, being an administrative error in relation to a qualification.

Emergency registration

29. Do you agree or disagree that all of the regulators should be given a permanent emergency registration power as set out above? Please give a reason for your answer.

We **agree** that all of the regulators should be given a permanent emergency registration power as set out. We are pleased that the proposals reflect the devolutionary settlement and situation of the Pharmaceutical Society NI.

The emergency powers under the Coronavirus Act 2020 worked appropriately for the Pharmaceutical Society NI and served the wider public interest. We would seek clarification on whether the regulators will have the power to write Rules relating to the using this power and the functioning of the emergency register. Some unintended loopholes in relation to the potential movement from the fee-paying register to the emergency register exist under its current iteration.

Offences in relation to protection of title and registration

30. **Do you agree or disagree that all regulators should have the same offences in relation to protection of title and registration within their governing legislation?**

We **agree** that all regulators should have the same offences in relation to protection of title and registration within their governing legislation. Such an approach protects the public and gives them assurance that those healthcare professionals they are engaging with are qualified and competent. However, the 'pharmacy' title protection in relation to regulated premises, currently provided for in the GPhC's governing legislation, should be extended to Pharmaceutical Society NI, subject to the comments outlined in our response to the Question 31.

31. **Do you agree or disagree that the protection of title offences should be intent offences or do you think some offences should be non-intent offences (these are offences where an intent to commit the offence does not have to be proven or demonstrated)? Please give a reason for your answer.**

We consider that more attention needs to be given to the proposals in this area.

Unlike many of the regulators, the Pharmaceutical Society NI do not have prosecutorial powers in relation to protection of title offences. It is our understanding that these offences, relating to pharmacists would be prosecuted in Northern Ireland by the Department of Health. Changing the prosecutorial powers to the Pharmaceutical Society NI would be a significant change and we would seek assurances that the Department of Health NI is fully in agreement with this proposed change**.** This speaks to some of the issues we raised in response to Question 11 and the appropriate mechanism for delivering reform.

On the issue of intent, we think further consideration needs to be given to the proposals, particularly in relation to the threshold for proving intent and whether any other thresholds are potentially available, such as 'recklessness'.

Registrar, deputy Registrar and assistant Registrars

32. Do you agree or disagree with our proposal that regulators should be able to appoint a deputy registrar and/or assistant registrar, where this power does not already exist? Please give a reason for your answer.

We **agree** with the proposal that regulators should be able to appoint a deputy registrar and/or assistant registrar, where this power does not already exist.

Such an approach would provide us with greater flexibility, agility and at adequate continuum of accountability.

The consultation document does not, however, reflect the fact that the Registrar of the Pharmaceutical Society NI is a DoH appointment, under the Pharmacy (Northern Ireland) Order 1976. We note that this is a different approach to the other regulators and would seek greater clarity on what the intent is in relation to this policy area and the Pharmaceutical Society NI. If the current situation, in relation to a DoH appointed registrar is maintained, what does this mean for the appointment of a deputy and assistant registrars and what impact might this have on flexibility, agility and accountability. Again, our reflections in response to Question 11 are relevant.

Registration processes

33. Do you agree or disagree with our proposal that regulators should be able to set out their registration processes in rules and guidance? Please give a reason for your answer.

We **agree** with the proposal that regulators should be able to set out their registration processes in rules and guidance. Such an approach will give regulators added flexibility and an ability to adapt. This is particularly important as the UK has left the EU and registration procedures may require greater flexibility and change**.**

GMC's registration processes

34. Should all registrars be given a discretion to turn down an applicant for registration or should applicants be only turned down because they have

failed to meet the new criteria for registration? Please give a reason for your answer.

Applicants should only be turned down because they have failed to meet the new criteria for registration. To introduce an element of Registrar discretion, removes ability of regulators to maintain complete consistency, transparency and fairness for applicants and the public. Using any discretionary power will only be justifiable by qualitative means, rather than quantitative measures. This would leave unfavourable decisions to either party open to scrutiny and potential challenge. There is a viable risk that the use of such discretionary powers could be subject to judicial review.

35. **Do you agree or disagree that the GMC's provisions relating to the licence to practise should be removed from primary legislation and that any requirements to hold a licence to practise and the procedure for granting or refusing a licence to practise should instead be set out in rules and guidance? Please give a reason for your answer.**

We have **no comment** to make in relation to this question.

Removal Suspension and readmission to the register

36. **Do you agree or disagree that in specific circumstances regulators should be able to suspend registrants from their registers rather than remove them? Please give a reason for your answer.**

We consider that a suspension may be appropriate when outstanding administrative issues means that the Regulator cannot automatically verify that that a registrant is fit to practise, such as failure to meet revalidation and renewal requirements. Under our current powers, however, we go through a process of writing to registrants with outstanding CPD and if they do not respond with a certain period, we will move to remove them from the register.

We would not necessarily support suspensions being used in some instances, to automatically suspend a registrant for an outstanding fee or an address not being up to date, as the process of requesting the outstanding information is completed, seems disproportionate if there is no other evidence to suggest that the registrant poses a risk to the public. This is unlikely to be proportionate and in the wider public interest.

Fairness to registrants needs to be built into considerations around the potential introduction of this power.

This power if granted would have to be used proportionately and consistently by regulators and it would have to be utilised within an appropriate assessment of risk.

37. **Do you agree or disagree that the regulators should be able to set out their removal and readmittance processes to the register for administrative reasons in rules, rather than having these set out in primary legislation? Please give a reason for your answer.**

We have concerns as to the powers proposed for administrative removal in this section. Administrative removal is not appropriate for issues relating to a registrant's health. Health should only be considered as a part of a Fitness to Practise process, to ensure rigour of investigation and fairness to the registrant. The proposals relating to health are devoid of appropriate due process and would be unfair to registrants. We have similar, if less acute, concerns in relation to the Knowledge of English Language, and would seek further clarification from DHSC on how they envisage the consistent application of an administrative removal power in this area will work.

Bar our comments on Health and English Language, we agree that the regulators should be able to set out their removal and readmittance processes to the register for administrative reasons in rules, rather than having these set out in primary legislation. However, we consider a broadly consistent approach across the regulators to be appropriate.

Registration Appeals

38. **Do you think any additional appealable decisions should be included within legislation? Please give a reason for your answer.**

Yes, additional appealable decisions should be included within legislation. However, the list provided does not include a pharmacy owner's right to appeal a refusal to register a pharmacy premise. This is mentioned in paragraph 215 in relation to GPhC, but the consultation does not reflect the position of the Pharmaceutical Society NI and is not formalised as part of the list outlined in paragraph 214.

39. Do you agree or disagree that regulators should set out their registration appeals procedures in rules or should these be set out in their governing legislation? Please give a reason for your answer

We **agree** that regulators should set out their registration appeals procedures in rules. This is in line with approach to Fitness to Practise and the overall thrust of the consultation. It will allow regulators flexibility to amend any appeals process more easily, facilitating a proportionate and learning approach in consultation with key stakeholders.

Student Registers

40. Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish student registers? Please give a reason for your answer

We **agree** in principle with the proposal that the regulators should not have discretionary powers to establish student registers defining students as undergraduates. This is subject to our comments outlined in response to Question 25. In the policy development stage, we expressed our preference to DHSC that we maintain a student register. It was presented that this could be managed through annotating trainees on the full register, outlining the limitations on their ability to practice independently.

We would like to see the detail and wording of the proposed legislation prior to giving our full backing to this proposal. In particular, we want to understand whether we will need a specific primary power to automatically remove trainees from the register, should they fail the Registration Assessment or a requirement of the Foundation Training Year, or whether this can adequately be dealt with through the development of appropriate Rules.

Registration and non-practising professionals

41. Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish non-practising registers? Please give a reason for your answer.

We **agree** with the proposal that the regulators should not have discretionary powers to establish non-practising registers**.** This approach will provide greater clarity to public

that those on the register are fit to practise. This does, however, raise further issues in relation to annotating pre-registration trainees as we currently consider them not fit to practise unsupervised, and again we will work with DHSC to ensure the legislative proposals are adequate to meet our regulatory objectives of protecting the public in this regard.

Registration of internationally qualified professionals

42. **Do you agree or disagree that the prescriptive detail on international registration requirements should be removed from legislation? Please give a reason for your answer.**

We **agree** that the prescriptive detail on international registration requirements should be removed from legislation. This will provide regulators with greater flexibility and adaptability. We do, however, seek further clarification on what the Pharmaceutical Society NI's role will be in relation to international applicants in the legislation. At present the GPhC effectively carries out this function for us – we would seek assurances that this power would fall within the delegation functions should we wish to maintain current arrangements.

Three stage FtP process

43. **Do you agree or disagree with our proposal that regulators should be given powers to operate a three-step fitness to practise process, covering:**
    - **1: initial assessment**
    - **2: case examiner stage**
    - **3: fitness to practise panel stage? Please give a reason for your answer.**

We **agree** in principle with the proposal that regulators should be given powers to operate a three-step fitness to practise process, as outlined. There is an argument for having more detail at the initial assessment stage on the face of the legislation. It is silent on a jurisdictional test, who has the legal authority to investigate the complaints (the Registrar?) and what the threshold is for referring a case to the case examiners or closing a case before it reaches them. This suggests there could be a significant degree of variation on how regulators approach cases, with some regulators referring

cases to Case Examiners, when others would not. This lack of detail reduces the consistency argument somewhat. We are of the view that the jurisdictional test, who has the legal authority to carry out investigations and any threshold criteria should be cited in the primary legislation, with a view to providing a stronger framework for regulators and greater certainty for registrants and the public.

Grounds for action

44. Do you agree or disagree that:

- **All regulators should be provided with two grounds for action – lack of competence, and misconduct?**
- **Lack of competence and misconduct are the most appropriate terminology for these grounds for action?**
- **Any separate grounds for action relating to health and English language should be removed from the legislation, and concerns of this kind investigated under the ground of lack of competence?**
- **This proposal provides sufficient scope for regulators to investigate concerns about registrants and ensure public protection? Please give a reason for your answers**

We **disagree** that all regulators should be provided with two grounds for action – lack of competence and misconduct.

We are concerned at the lack of evidence that has been presented in the consultation to suggest why the proposed change is necessary. The current grounds for action within the Pharmacy (Northern Ireland) Order 1976, which largely reflects a number of other regulators' grounds for action, work well. There is an element of trying to fix a problem that does not exist.

Having health as a separate ground for action also allows both our investigations and Fitness to Practise Committees to engage with such cases with appropriate sensitivity. We are concerned that this approach may be diminished by moving health into the competence grounds for action and registrants' perception of their regulator's sensitivities to their personal circumstances may be damaged.

Linked to this, our current legislation does not allow a registrant to be removed from the register in purely health fitness to practise cases. What is the intention with regards to sanction of the current proposals and health cases, and how would this be accommodated within a single ground for action, namely competence?

We also concerned by the language used to describe lack of competence and misconduct in the consultation. As described, we are unsure how we would differentiate between lack of competence and misconduct in several scenarios.

In general, we consider this section to not have adequately reflected on how the current regime is working, the legal context and precedents that currently exist and the potential implications of the approach. We recommend that this section is given considerably more thought and development time.

Measures available

45. Do you agree or disagree that:

a. all measures (warnings, conditions, suspension orders and removal orders) should be made available to both Case Examiners and Fitness to Practise panels; and

b. automatic removal orders should be made available to a regulator following conviction for a listed offence? Please give a reason for your answers.

We are concerned that Warnings will no longer be available when impairment is found. There are examples of misconduct being of such a nature which warrants a panel to find that a registrant's FtP is impaired to ensure public confidence in the profession, regardless of insight and remediation. However, when the case moves to sanction stage the insight and remediation shown by the registrant demonstrates that a warning is the appropriate sanction, because conditions are not workable, and suspension is disproportionate. It should be noted that current case law dictates that a sanction is not punitive and that a sanction should be the lowest required to meet the regulatory objective. There is a danger that removing warning with impairment will shift the threshold for impairment and/or increase the number of short suspensions. This could change registrants' perception that Fitness to Practise is not intended to be punitive. Again, the consultation has not outlined adequate evidence to suggest that this change is necessary.

Review Powers

46. Do you agree or disagree with the proposed powers for reviewing measures? Please give a reason for your answer.

We **agree** in principle with the proposed powers for reviewing measures. However, we are uncertain as to the rationale for removing interim measures to cover an appeal

period. This power currently works well and ensures fairness for registrants. It is also uncertain as to what happens when an appeal is successful, but a measure has come into effect immediately. Is the decision overturned at that point? Interim Measures are a different category of decision than a sanction and require an FtP Committee to make a separate Interim Measures decision, after considering representations by both parties to any proceedings. Decision on sanction is not impacted upon by Interim Measure decision. Again, the analysis of current powers and legal context relating to interim measures is limited and the rationale and evidence for the proposed change is not clearly set out.

Rules relating to FtP procedures

47. **Do you agree or disagree with our proposal on notification provisions, including the duty to keep the person(s) who raised the concern informed at key points during the fitness to practise process? Please give a reason for your answer**

We **agree** with the proposal on notification provisions, including the duty to keep the person(s) who raised the concern informed at key points during the fitness to practise process ensuring that participants are full informed is vitally important for the fairness of the proceedings and the wellbeing of those involved.

The duties outlined appear reasonable and comprehensive. We welcome the right of the registrant to request updates as this will empower them in the process. However, we would want the legislation to reflect that the duty to keep persons up to date must be proportionate.

Initial assessment stage

48. **Do you agree or disagree with our proposal that regulators should have discretion to decide whether to investigate, and if so, how best to investigate a fitness to practise concern? Please give a reason for your answer.**

We **agree** with the proposal that regulators should have discretion to decide whether to investigate, and if so, how best to investigate a fitness to practise concern. As outlined above we have some concerns that there is not enough detail on the face of

the proposals in this section. For example, will all regulators develop the same jurisdictional test to initiate an initial assessment – divergence could lead to different outcomes on similar cases.

We also seek clarification on who will have the legal authority to carry out investigations. Under current legislation this sits with the Registrar. However, if this is the proposal in consultation this has significant implications for the Registrar review power. Please reference our response to Question 61.

49. Do you agree or disagree that the current restrictions on regulators being able to consider concerns more than five years after they came to light should be removed? Please give a reason for your answer

We **disagree** that the current restrictions on regulators being able to consider concerns more than five years after they came to light should be removed. Our current legislation states that we should only investigate cases that are less than 5 years old, unless the Registrar deems it is in the public interest to do so. We consider that this provides a proportionate approach, which is fair to registrants, but allows regulators discretion to investigate older cases should it be in the public interest. Again, the rationale for change from current position is limited and we consider that current system works well.

Non-compliance

50. Do you think that regulators should be provided with a separate power to address noncompliance, or should non-compliance be managed using existing powers such as "adverse inferences"? Please give a reason for your answer.

We would prefer a more detailed analysis of the use of the GMC's current power against adverse inferences. It is very difficult to adequately assess the merits of the proposal based on the limited amount of information provided. We can, however, see potential merit in the proposal in relation to registrants that refuse to comply with a Fitness to Practise investigation, the nature of which poses significant public safety questions.

Onward referral following initial assessment

51. Do you agree or disagree with our proposed approach for onward referral of a case at the end of the initial assessment stage? Please give a reason for your answer.

We **agree** with the proposed approach for onward referral of a case at the end of the initial assessment stage. We seek more clarity on what the onward referral test will be, who has legal authority to carry out the test and set its thresholds. Consultation describes onward referral by the 'regulator', our current legislation is written as the Registrar will refer (or Scrutiny Committee). Will this be the case under the current proposals? This has implications for Registrar review power and unitary board issues, dealt with at Questions 4, and 61.

Automatic removal following specified criminal offences

52. Do you agree or disagree with our proposal that regulators should be given a new power to automatically remove a registrant from the Register, if they have been convicted of a listed offence, in line with the powers set out in the Social Workers Regulations? Please give a reason for your answer.

We **agree** with the proposal that regulators should be given a new power to automatically remove a registrant from the Register, if they have been convicted of a listed offence, in line with the powers set out in the Social Workers. The proposals acknowledge the serious public protection/public confidence issues raised by offences listed, helps protect the public and gives public confidence in respective professions. It also reduces financial burden on regulators/registrants by removing the cost of proceeding to FtP. We do, however, ask why the list of offences is limited to the ones listed, e.g. violent crime is not on the list?

In relation to fairness, facts have been proven in another jurisdiction and position is clear that these convictions are incompatible with registration as a healthcare professional.

Case Examiner Stage

53. Do you agree or disagree with our proposals that case examiners should:

- **have the full suite of measures available to them, including removal from the register?**
- **make final decisions on impairment if they have sufficient written evidence and the registrant has had the opportunity to make representations?**
- **be able to conclude such a case through an accepted outcome, where the registrant must accept both the finding of impairment and the proposed measure?**
- **be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days? Please give a reason for your answers.**

We **agree** with the proposals in relation to the first 3 bullet points outlined in the question. However, more information needs to be provided on the nature of a case examiner stage decisions. For example, will it clearly outline the agreed facts of the case? This has clear implications for the Registrar review power and any appeals at this stage.

We **disagree** with the last bullet point that a CE should be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days. Such a decision is of a different category to consensual disposal. It is a finding of impairment without consent, and to be 'fair' requires that adequate fairness and appropriate tests have been applied. Based on the evidence presented in the consultation, we would prefer such cases to be referred to full FtP panel, under the 'cannot make a decisions category', in the interest of fairness and transparency.

Interim Measures

54. Do you agree or disagree with our proposed powers for Interim Measures, set out above? Please give a reason for your answer.

We **agree** in principle with the proposed powers for Interim Measures, as set out. There is however, a need to make sure that those making decisions on interim measures are different decision makers to those considering substantive case and that CEs considering substantive case are not influenced by Interim Measure decisions. If the suggestion is the same Case Examiners can do both, then this would

be problematic. Greater clarity is needed in relation to the intent of the proposals in this regard.

FtP Panel stage

55. **Do you agree or disagree that regulators should be able to determine in rules the details of how the Fitness to Practise panel stage operates? Please give a reason for your answer.**

We **agree** that regulators should be able to determine in rules the details of how the Fitness to Practise panel stage operates. This approach provides regulators with flexibility to amend procedures in the future to meet needs of all participants and drive efficiency where possible.

Registrant Appeals

56. **Do you agree or disagree that a registrant should have a right of appeal against a decision by a case examiner, Fitness to Practise panel or Interim Measures panel? Please give a reason for your answer.**

We **agree** that a registrant should have a right of appeal against a decision by a case examiner, Fitness to Practise panel or Interim Measures panel. However, the logic of allowing registrants to appeal a consensually disposed case, without procedural issues, is unclear and not established. We seek further clarification on the grounds available for appeal in this instance.

57. **Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland? Please give a reason for your answer.**

Yes, this is the appropriate course of action, which reflects the current legal system in the UK.

Restoration to the register

58. **Do you agree or disagree that regulators should be able to set out in Rules their own restoration to the register processes in relation to fitness to practise cases? Please give a reason for your answer.**

We **agree** that regulators should be able to set out in Rules their own restoration to the register processes in relation to fitness to practise cases. This approach will provide flexibility, for example, some removal cases can vary in seriousness, so additional flexibility on time frames for when an application for restoration may be made would assist in meeting regulatory objectives.

59. **Do you agree or disagree that a registrant should have a further onward right of appeal against a decision not to permit restoration to the register? Please give a reason for your answer.**

We **agree** that a registrant should have a further onward right of appeal against a decision not to permit restoration to the register, the reason for this is fairness to the registrant.

60. **Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland? Please give a reason for your answer.**

Yes, this is the appropriate course of action, which reflects the current legal system in the UK.

Registrar Review Powers

61. **Do you agree or disagree that the proposed Registrar Review power provides sufficient oversight of decisions made by case examiners (including accepted outcome decisions) to protect the public? Please provide any reasons for your answer.**

We **disagree** that the proposed Registrar Review power provides sufficient oversight of decisions made by case examiners (including accepted outcome decisions) to protect the public.

We are very uncertain about this power, as outlined above, the role of the Registrar in investigations and case presentation is unclear within the proposals. If the Registrar has overall legal responsibility for investigations, referral and case presentation this could be argued to be a 'second bite' at the case on behalf of regulator. This may be controversial as it would undercut consensual decisions. Such a review power may also influence CE decision makers to reflect Registrar's recommendations/case as they will know their decision can be reviewed.

It also appears incongruous to remove GMC's right to appeal against MTPS decisions and then introduce this review power to all Registrars, which is arguably more internal and potentially less transparent than the GMC's previous review power, which went to the Hight Court.

There is also the very important issue that if Registrars sit on a Regulator's unitary boards, as part of the proposed governance reforms, boards could be immediately associated with controversial Fitness to Practise decisions. We contend that such an outcome could significantly undermine public confidence in individual regulators and regulation at large.

This position would become less problematic if the legal authority to carry out investigations and present cases is not to sit with the Registrar, and the current Board model is maintained. However, not having the Registrar as the legal authority for investigations and referral of FTP cases, may pose its own issues. We understand the rationale for wanting an ability to review to provide sufficient oversight, and we support this principle, however, we consider that the proposals under consideration require further thought.

The Registrar review power combined with proposals for Unitary Boards require careful consideration.

62. Under our proposals, the PSA will not have a right to refer decisions made by case examiners (including accepted outcome decisions) to court, but they will have the right to request a registrar review as detailed above. Do you agree or disagree with this proposed mechanism? Please provide any reasons for your answer.

Notwithstanding our reservations about the Registrar review power, we **agree** that the PSA should not have a right to refer decisions made by case examiners, (including

accepted outcome decisions) to court. There is limited logic in developing an accepted outcome model, for it to be undermined by a third party having the ability to effectively appeal that accepted outcome to the Court system. This would undermine registrant and regulator confidence in using the accepted outcome approach and would undermine the policy objective being pursued. We do, however, consider that the PSA should have some role assessing how the regulators utilise their powers in this area. The PSA should have the right to review accepted outcome decisions as part of its performance review audit. The PSA should have the power to comment on how it is being used in general by each regulator and to share best practice when appropriate. Where the PSA has major concerns about how it is being used, they could have power to require changes and/or suspend an individual regulator's accepted outcome powers, as a last resort.

63. Do you have any further comments on our proposed model for fitness to practise?

We have no further comments at this stage but welcome the continued engagement on all aspects of the consultation by DHSC.

Physician Associates and Anaesthesia Associates

64. Do you agree or disagree with the proposed approach to the regulation of PAs and AAs? Please give a reason for your answer.

No Comment

65. In relation to PAs and AAs, do you agree or disagree that the GMC should be given a power to approve high level curricula and set and administer exams? Please give a reason for your answer.

No Comment

66. Do you agree or disagree with the transitional arrangements for PAs and AAs set out above? Please give a reason for your answer

No Comment

67. Do you agree or disagree that PAs and AAs should be required to demonstrate that they remain fit to practise to maintain their registration? Please give a reason for your answer.

No Comment

Impact assessment and Equality Impact assessments

68. Do you agree or disagree with the benefits identified in the table above? Please set out why you've selected your answer and any alternative benefits you consider to be relevant and any evidence to support your views.

Subject to specific concerns outlined in our response to previous questions, we agree.

69. Do you agree or disagree with the costs identified in the table above? Please set out why you've chosen your answer and any alternative impacts you consider to be relevant and any evidence to support your views.

We **agree** in general, however, the proportionality of costs to regulators of different sizes must be taken into consideration in relation to transitional costs and the need for regulators to work together on transition.

Another important consideration is the role of the PSA in assessing performance during and after transition to the new legislative framework. How will the PSA assess against two different regimes existing simultaneously? What role will the PSA be given in relation to the reforms, on such things as assessing Rules?

69. Do you think any of the proposals in this consultation could impact (positively or negatively) on any persons with protected characteristics covered by the general equality duty that is set out in the Equality Act 2010, or by Section 75 of the Northern Ireland Act 1998?

We welcome the inclusion of Section 75 of the NI Act 1998 in the consultation and consider that there is no bias in the proposals as outlined, and therefore this consultation could **impact positively** on persons covered by Section 75.