PART 2
THE STRUCTURE OF REFORM AND ACCOUNTABILITY

Provisional Proposal 2-1: All the existing governing legislation should be repealed and a single Act of Parliament introduced which would provide the legal framework for all the professional regulators.

2.1 A large majority of consultees who expressed a view agreed with this proposal.[1] For example, the General Medical Council argued that:

> A single, overarching Act focused on high level principles will support overall consistency across health care regulation while releasing individual regulators to develop policies and operational approaches appropriate to the circumstances of the professions they regulate.

2.2 Similarly, the Professional Standards Authority argued that:

> based on our experience of reviewing the performance of the health professional regulators, such a move would provide greater consistency of approach and outcome, enable the legislation pertinent to all regulatory bodies to be changed at the same time and provide the prospect of better understanding of regulation by registrants and the public.

2.3 The Chartered Society of Physiotherapy thought that the proposal:

> should streamline arrangements, thereby increasing effectiveness and efficiency, and achieve greater transparency, commonality of approach and public understanding. All this should enhance both patient safety and clarity for registrants.

2.4 The General Pharmaceutical Council felt that a single Act presented "opportunities for regulators to learn and adapt from best practice more quickly". Others argued that the existing legislative structure encourages the regulators to work in silos and inhibits joint working and the sharing of functions and facilities.

2.5 A small number of consultees expressed qualified support for the proposal. For example, the British Medical Association felt that unless there is "sufficient flexibility to ensure each regulator can reflect its profession", the single Act could prevent innovation. The Academy of Royal Medical Colleges noted that "the different circumstances in which the regulators operate may mean that differences are justifiable and sometimes vital to their work".

2.6 The proposal was opposed outright by the Royal College of Midwives which argued that a single statute would entail dismantling essential regulatory frameworks. The Royal College supported a system which recognises

[1] Of the 192 submissions which were received, 35 expressed a view on this proposal: 31 agreed, 1 disagreed, whilst 3 held equivocal positions.

professional differences and where nursing is not combined with midwifery. Moreover, at consultation events, a small number of attendees felt that separate statutes for each profession recognised the status and uniqueness of each profession, and therefore ensured professional buy-in and support.

Provisional Proposal 2-2: The new legal framework should impose consistency across the regulators where it is necessary in order to establish the same core functions, guarantee certain minimum procedural requirements and establish certain core requirements in the public interest. But otherwise the regulators should be given greater autonomy in the exercise of their statutory responsibilities and to adopt their own approach to regulation in the light of their circumstances and resources.

2.7 An overwhelming majority supported this proposal.[2] However, in general terms, consultation responses were divided between those who supported greater autonomy and those who wanted greater consistency imposed across the regulators.

Support for greater autonomy

2.8 Most of the regulators supported the need for enhanced autonomy. For example, the General Optical Council argued that consistency should not be imposed "for its own sake at a high level", but limited to certain "core principles":

> The areas in which consistency is sought across regulators through the overarching legislation will need to be carefully chosen, and appropriate safeguards and opportunities for collaboration put in place to ensure an appropriate balance is maintained in respect of consistency and regulator flexibility.

2.9 The General Medical Council also felt that consistency should be limited to certain "core principles":

> It would be wrong for the statute to impose a "one size fits all approach" and regulators must have the policy and operational autonomy to develop regulation in the way that is most appropriate to the sector.

2.10 The General Osteopathic Council also emphasised that:

> Consistency should not imply uniformity. Each regulated profession operates in different circumstances and at different stages of development that determine the most appropriate way for them to be regulated. It is also important to recognise that innovation in the field of regulation comes from regulators doing things differently, not working to a single set formula.

2.11 The General Dental Council argued that the compulsory elements of the legal framework should be "carefully chosen" and that:

[2] Of the 192 submissions which were received, 54 expressed a view on this proposal: 52 agreed, whilst 2 held equivocal positions.

> Simplicity and consistency should not be at the expense of an individual regulator's ability to deliver its functions in a way that is suited to the profession concerned and which promotes confidence in its regulation.

2.12 The General Social Care Council suggested economic reasons for flexibility:

> The increase in referrals which many professional regulators have experienced over recent years, as well as the expectation from Government (and the professions) that the cost of regulation should not be increased, makes this ability to react to changed circumstances imperative.

2.13 A number of professional bodies also supported increased autonomy. For example, the Royal College of Physicians in Edinburgh felt that "regulators must have autonomy to adapt their own approach in light of their circumstances and resources".

Support for consistency

2.14 Many consultees expressed concern that our proposal failed to impose greater consistency across the regulators. For example, the Allied Health Professions Federation argued that increased autonomy could lead to individual regulators "enacting their roles and functions quite differently" and thus "undermining transparency, consistency, public understanding and fairness".

2.15 The Council of Deans of Health said that our proposal presupposes that all of the regulators are equally well prepared "to take on and apply the principles of right touch regulation" and that the regulators will wield their increased powers "sparingly and successfully". The Council felt that, in reality, only some of the regulators will be capable of operating successfully in the new context. Many pointed to the recent difficulties at the Nursing and Midwifery Council as illustrating precisely why the regulators should not be given greater autonomy.

2.16 The Professional Standards Authority argued for "a consistent approach directed to producing the same outcomes". It said that:

> We do not propose a consistency of approach from the regulators for the sake of it; we encourage it because we have seen first-hand the negative outcomes for people that can arise from core functions being undertaken in different ways. Differences in the content of public registers and the sanctions that regulators have available, for instance, have affected confidence in regulation. In addition, such differences will potentially make it more difficult for employers to navigate the different systems.

2.17 Specifically, the Authority argued that fitness to practise adjudication – being the most high profile and public facing of all the regulatory functions – requires greater consistency in order to maintain public confidence. It considered that:

> There should be an expectation that, if different health professionals each erred in their actions over the same issue, for example in the

> prescribing of drugs, the actions taken against them and the sanctions imposed should be similar in similar circumstances.

2.18 Several consultees, such as UNISON, also felt that a consistent approach would be of particular use in dealing with issues arising from the actions of multi-disciplinary teams, which is likely to become a greater regulatory challenge in the future.

2.19 The Scottish Government recognised that "the regulators work in different areas and contexts and need to have the freedom to adopt different procedures" but nonetheless argued that:

> An appropriate balance needs to be struck between the consistency referred to and the degree of discretion/freedom afforded to the regulators. In the event that the new framework offers too great a level of autonomy, this could lead to inconsistency and serve to complicate rather than simplify the regulatory landscape.

2.20 The Department of Health, Social Services and Public Safety for Northern Ireland supported "the concept of legislative consistency" and cautioned that "the freedom proposed does not become licence".

Provisional Proposal 2-3: The regulators should be given broad powers to make or amend rules concerning the exercise of their functions and governance without any direct oversight, including Privy Council approval and Government scrutiny (subject to certain safeguards).

2.21 A significant majority agreed that the regulators should be given broad rule-making powers without Privy Council or Government oversight.[3]

2.22 Both the General Osteopathic Council and the General Social Care Council argued that the difficulties in securing Department of Health resources or Parliamentary time in order to amend rules had prevented their evolution.

2.23 The General Osteopathic Council argued that removing Privy Council or Government scrutiny should not automatically imply that regulators "couldn't or shouldn't work with the Government to ensure that new rules are compatible with European or public law requirements".

2.24 The Department of Health agreed that the regulators should be given rule-making powers, but also suggested that, in order to address any risks in relation to the capability of the Councils:

> It may therefore be necessary to include provision so that existing rule-making processes continue, subject to any necessary modifications, until such time as the regulators have the capacity to operate without the Department of Health's scrutiny. We would suggest that there should be an assessment (a "test of readiness") of a regulator's ability to take on its new powers before they would be commenced, and that consideration be given to other safeguards,

[3] Of the 192 submissions which were received, 51 expressed a view on this proposal: 42 agreed, 5 disagreed, whilst 4 held equivocal positions.

such as whether the Professional Standards Authority may be given a greater role in oversight of the regulators' rules.

2.25 The Scottish Government agreed that the regulators should have broad rule-making powers but was concerned about the legal capacity of the regulators to do this and suggested that "cross subsidisation of public monies should also be considered".

2.26 The Department of Health, Social Services and Public Safety for Northern Ireland argued that "some form of scrutiny is required" and "it cannot be a 'free for all'". The Welsh Government stated that it "will want to be assured that processes in the regulatory bodies will take account of devolved differences" and that "working arrangements are in place with the Department of Health for a UK approach to any changes". It also suggested that it may be more cost effective for the smaller regulators "to commission the Professional Standards Authority to provide services on their behalf".

2.27 Further risks identified by the General Optical Council included poorly drafted rules being put in place by regulators, frequent amendment of these rules and additional legal challenges, all of which would create additional expense and uncertainty. Similarly, the Nursing and Midwifery Council argued that "the current system helps to ensure that rules are fit for purpose, thereby reducing [that] risk and maximising public safety" and that the removal of the Government's role would have resource implications for each regulator.

2.28 Some expressed concern that our proposals will only work for the larger and better resourced regulators, whereas the smaller regulators will struggle. Once again, several consultees pointed to the current difficulties at the Nursing and Midwifery Council as illustrating why the regulators should not be given greater autonomy and why enhanced oversight is essential.

2.29 The Institute of Medical Illustrators argued that our proposed approach would undermine the ability of members of the public to challenge the regulators' rules, as the only available option would be judicial review.

2.30 Some felt that the proposal would lead to a disparate approach to the development of rules. For example, Action Against Medical Accidents argued that "simply giving regulators broad powers is a recipe for even more inconsistency" and that "all the regulators should be bound by overarching regulations which guarantee a consistent approach". The Professional Standards Authority argued that our proposal would work against "the drive for greater consistency in outcomes across the regulators".

Question 2-4: Would the perceived status of legal rules be less clear or certain without Parliamentary approval? Should the Professional Standards Authority be given an active role in scrutinising new rules, or should a limited number of the rules be subject to Secretary of State approval and contained in a statutory instrument?

2.31 A slim majority felt that the status of rules would be less clear.[4]

2.32 The Department of Health felt that there was no reason why the status of rules should be less clear without Parliamentary approval, but suggested requiring the regulators to be explicit about the version of the rules they apply and to publish "the latest, consolidated version of their rules in a specific place to ensure ease of access for registrants and the public". It also expressed some concerns about the resource implications of an enhanced role for the Professional Standards Authority.

2.33 Opinion was divided over whether the Professional Standards Authority should be given an active role in scrutinising new rules.[5]

2.34 The Professional Standards Authority accepted that it could perform an oversight or rule-approval role to "ensure that any proposed rule changes take into account the wider context and do not lead to unintended consequences on others". However, this would require "additional legal resources and extended Parliamentary accountability". The Authority also called for clarity on whether it would have the power to stop a regulatory body from proceeding or merely to issue advice – or whether it could refer such matters to the Secretary of State.

2.35 The Council of Deans of Health argued that formal oversight by the Authority was necessary to mitigate against the risk of the regulators implementing new rules which are "over-burdensome, unnecessary or are duplicated elsewhere". The Association of Regulatory and Disciplinary Lawyers suggested the Authority's role should include formal approval of rules in key areas (such as fitness to practise). In the event of any dispute between a regulator and the Authority, the matter could be reported to the Health Select Committee or, as a last resort, dealt with by way of judicial review proceedings.

2.36 Many of the regulators opposed giving the Authority an active role in scrutinising new rules. The General Medical Council argued this would turn the Authority into a "regulator of regulators" and would compromise its ability to comment upon performance because "it would be implicated in the approval of the policies and procedures it was being asked to judge". The General Optical Council shared this concern.

2.37 The General Pharmaceutical Council argued that:

> Accountability and transparency are enhanced by clarity and certainty on the question of who is responsible for what. The more the

[4] Of the 192 submissions which were received, 21 expressed a view on this question: 11 said the status of rules would be less clear, whilst 10 said it would not be less clear.

[5] Of the 192 submissions which were received, 34 expressed a view on this question: 18 said the PSA should be given such a role, 13 disagreed, whilst 3 held equivocal positions.

> regulators (which are the bodies with responsibility for regulation) are explicitly, or in effect, subject to direction by the Professional Standards Authority the less accountable and transparent regulation as a whole will become, with (almost inevitably) more and more control being exercised, less transparently and with less accountability, by a body which is not legally responsible for regulation.

2.38 The Health and Care Professions Council supported a role for the Authority in scrutinising new rules, but argued this did not require any change in role because the Authority can report on this area as part of its annual performance review of the regulators. It argued that oversight should take the form of "ensuring that each regulator undertakes a transparent consultation process and is able to justify the rules it is proposing or has implemented".

2.39 The General Osteopathic Council argued that the Authority has "no greater expertise in this area than the regulators and, in the case of larger regulators, arguably less" but accepted it may have a role in setting standards for new rules "to underpin quality and transparency".

2.40 The Scottish Government also felt that the Professional Standards Authority "does not currently have sufficient legal, policy or human resource capacity/capability/expertise" to perform an enhanced oversight role, and that a system would need to be put in place to monitor its performance. The Department of Health, Social Services and Public Safety for Northern Ireland also pointed to the need to ensure the accountability of the Professional Standards Authority if its role were enhanced.

2.41 A majority agreed that a limited number of rules should be subject to Secretary of State approval and contained in a statutory instrument.[6] For example, the General Dental Council suggested that such approval should be required for constitutional orders and matters relating to public protection. The Nursing and Midwifery Council suggested that approval should be limited to fitness to practise and registration rules. The General Osteopathic Council argued that a limited number of rules could be approved by the Secretary of State but the regime "should be one where the approval process is about granting authority rather than exercising a veto". UNISON suggested that only specific matters, such as "entrance, maintenance and removal from the register" should be subject to Secretary of State approval.

2.42 The General Medical Council argued that the key distinction is between operational concerns which should be left to the regulators to determine and matters which relate to the nature of the regulator (such as the composition of the Council) which need additional Parliamentary oversight.

2.43 The Scottish Social Services Council pointed out that it has powers to make its own rules with the consent of Scottish Ministers and felt this allows "flexibility" and ensures the draft rules are considered by "skilled Government lawyers" who can offer "helpful comments to us on applicable drafting conventions".

[6] Of the 192 submissions which were received, 21 expressed a view on this question: 13 agreed with Secretary of State approval, 4 disagreed, whilst 4 held equivocal positions.

Provisional Proposal 2-5: The power of the regulators to issue standing orders should be abolished.

2.44 The vast majority agreed that the express power to issue standing orders should be removed.[7]

2.45 The Professional Standards Authority was confident that:

> The procedural standing orders that currently address matters of delegation could be undertaken through internal governance procedures such as corporate standing orders, delegated authorities or schemes of delegation. Transparency of such decisions could be achieved through the publication of the individual arrangements on the regulatory bodies' websites.

2.46 However, the General Dental Council wanted "an explicit power for the regulators to make rules governing their internal procedures … this then leaves no room for dispute about implicit powers". Similarly, the Nursing and Midwifery Council argued that the maintenance of standing orders "demonstrates a commitment to good governance" since they would help to prevent governance processes and procedures being by-passed.

Provisional Proposal 2-6: The regulators should have the ability to implement their statutory powers by making rules, instead of a mixture of rules and regulations.

2.47 The vast majority of consultees who expressed a view on this proposal agreed that the regulators should use rules to implement their statutory powers.[8]

2.48 The Patients Association and the British Association for Counselling and Psychotherapy were amongst several consultees who thought the proposal would make the system less confusing.

2.49 The UK-wide Nursing and Midwifery Council Lead Midwives for Education Group opposed the proposal, on the basis that it did not offer sufficient protection against potential bias between professional groups.

[7] Of the 192 submissions which were received, 31 expressed a view on this proposal: 28 agreed, 1 disagreed, whilst 2 held equivocal positions.

[8] Of the 192 submissions which were received, 36 expressed a view on this proposal: 34 agreed, 1 disagreed, whilst 1 held an equivocal position.

Provisional Proposal 2-7: The statute should require the regulators to consult whenever issuing or varying anything which is binding, anything which sets a benchmark or standard, and a competency. The regulators should be required to consult such persons it considers appropriate, including:

(1) members of the public, patients and service users;

(2) registrants (including business registrants);

(3) employers of registrants;

(4) the other health and social care professional regulators, the Professional Standards Authority, the health and social care inspectorates, the independent safeguarding authorities and any other regulatory bodies;

(5) the Department of Health, Northern Ireland Executive, Scottish Government and Welsh Government;

(6) professional bodies that represent registrants; and

(7) persons or bodies commissioning or funding the services provided by registrants or at a registered premises/business.

2.50 An overwhelming majority supported the proposed duty to consult.[9]

2.51 However, there was some concern about how this duty had been formulated. Some of the regulators argued that it was overly prescriptive and inflexible in places. For instance, the General Pharmaceutical Council had concerns "about what is meant by 'anything which is binding'." The General Medical Council agreed that the formulation is too rigid, and stated that:

> A statutory requirement to consult on "anything that is binding" … risks forcing regulators to consult in a tokenistic manner when there is no genuine opportunity for respondents to affect the outcome. For example, a change to rules necessary to achieve compliance with aspects of European Union law may require outcomes which are binding on registrants who are subject to those rules. Even if respondents oppose the change, the regulator would be obliged to make it anyway.

2.52 The Council argued that regulators should be expected to use their judgment on "when it is appropriate to consult and when it is not" in the knowledge that if they fail to do so, judicial review proceedings may follow.

2.53 Similarly, the General Optical Council argued that the proposal would "take away the ability of regulators to use their own knowledge of their sectors to gauge whether a consultation is necessary for the issue and audience". The Association of Regulatory and Disciplinary Lawyers also questioned whether consultation on every rule change would be practicable or proportionate, and argued it could

[9] Of the 192 submissions which were received, 60 expressed a view on this proposal: 59 agreed, whilst 1 held an equivocal position.

undermine the regulators' ability to respond quickly where there was a need for urgency. The Nursing and Midwifery Council suggested there should be no requirement to consult if the change relates to providing clarification, correcting a mistake or bringing a document in line with other legislation. The Royal College of Obstetricians and Gynaecologists supported consultation on legally binding measures, and competencies, but also favoured "a consultation process that is not bureaucratic and time consuming".

2.54 However, this view was not accepted by all consultees. For example, the Institute of Biomedical Science felt that there should still be a requirement to consult on all changes to rules, guidance and competence standards "as even minor changes can have profound or unanticipated consequences". The General Chiropractic Council supported a "mandatory requirement to consult". The Department of Health also considered that "it would be realistic to expect the regulatory bodies to consult on every substantial variation of a rule etc".

2.55 Many felt that the proposed duty to consult needed to be strengthened in order to prevent the regulators only paying lip service to this requirement. The Department of Health, Social Services and Public Safety for Northern Ireland queried how the objectivity of the consultation will be preserved in the statute and pointed out that "leading questions would bias the responses".

2.56 Some responses provided specific examples of where a regulator had consulted inadequately or ignored the views expressed at consultation. For example, UNISON was particularly critical of online consultations which only allow for predetermined answers. Some of the proposed solutions included that:

(1) the regulators should be required to publish a summary of the views expressed at consultation and "their justification of how they have acted on them" (Committee of Contact Lenses Educators);

(2) the regulators should be required to give weight to the responses and recommendations of the relevant professional associations (British Association of Dental Nurses);

(3) there should be a new duty which "prevents cynical or cursory consultation exercises and ensures that the voice of legitimate consultees is heard and taken into account" (Institute of Health Visiting);

(4) there should be a requirement to produce documentation in a variety of formats and media and a "minimum response rate" for responses from patients and service users (Patients Association); and

(5) the legal standards for consultation imposed by the *Coughlan* judgment should be stated in the statute (Medical Defence Union).[10]

2.57 The Professional Standards Authority argued that there should be a framework imposed similar to the Government Code of Practice on Consultation, in places. It pointed out that the Authority is required to develop such a framework in relation to the accreditation of voluntary registers.

2.58 Some consultees made drafting suggestions. It was suggested that phrases such as "that which is binding" or "that which sets a benchmark" are unclear and would lead to argument about their meaning. The Health and Care Professions Council felt it was unhelpful to differentiate between standards, such as a code of conduct, and standards such as standards of proficiency. Instead. It felt that consultation should be required "before making and amending rules; setting or amending standards; and setting or amending guidance". The General Pharmaceutical Council pointed out that some binding requirements will not always be set out in rules. For example, it requires international pharmacist applicants to demonstrate they have achieved level 7 of the International English Language Testing System on language competence, which is not set in rules but is binding.

The list of consultees

2.59 Some consultees contended that the statute should not be overly prescriptive about which organisations or individuals are consulted. For example, the General Medical Council argued that "blanket coverage of every issue risks devaluing attempts to engage with key interests on other occasions where their input will add real value". The General Pharmaceutical Council also cautioned against too much specificity and argued that "good consultation should be tailored to the issue and the format for each consultation will often vary".

2.60 However, others disagreed and suggested that the list needed to be expanded to ensure it is sufficiently comprehensive. Suggested additions included:

(1) education and training providers (Council of Deans of Health);

(2) other key workforce stakeholders (Skills for Care);

(3) organisations that contract with professionals, for example in primary care (National Clinical Assessment Service);

(4) providers of healthcare, whether in public or private sectors (Association of Clinical Biochemistry);

(5) trade associations – such as those who represent the collective interests of the owners of pharmacies (Pharmacy Voice);

(6) trade unions (Unite);

(7) European regulatory bodies (Pharmaceutical Society of Northern Ireland);

(8) Parliament and the devolved assemblies (consultation event participant);

(9) charities and support groups (Patients Association); and

(10) carers (Professional Standards Authority);

[10] *R v North and East Devon Health Authority ex p Coughlan* [2001] QB 213. See discussion in Joint CP, para 2.41.

2.61 In addition, the Nursing and Midwifery Council argued that the reference to "members of the public" could be problematic and potentially ineffective. Instead, a more robust approach could be achieved by including reference to "groups or organisations representing the views of members of the public". An individual consultee (Don Brand) argued that, unlike social work, most health services and professional functions are available to the public on a universal basis. Therefore "simply lumping in service users with patients and members of the public as a category of people to be consulted is inadequate". The General Dental Council suggested it should be made clear that the duty only applies to UK bodies.

2.62 The Department of Health suggested that the list of consultees should include representatives of patients, registrants and employers. Furthermore:

> Currently the regulators have different practices regarding consultations before making rules. Our view is that there should be statutory obligations on them to consult before making rules (including any amendments in future) and expectations about the period for consultation. For example, in line with cabinet office guidance on public sector consultation, which we consider reflects good practice, there should be an expectation that consultations should be for 12 weeks unless there are compelling public interest reasons for a shorter consultation period.

2.63 The Scottish Government suggested that consultation should be across the four countries and "include appropriate representation from the devolved administrations". Some concern was expressed that the list of consultees might be seen as definitive which could have the effect of "precluding from the consultation essential groups, persons or bodies whom, in certain circumstances, it would be appropriate to consult". The Welsh Government stated "it should be acknowledged that these wider contacts will be different in each part of the UK".

Provisional Proposal 2-8: The formal role of the Privy Council in relation to health and social care professional regulation should be removed entirely.

2.64 A majority agreed that the formal role of the Privy Council in relation to health and social care professional regulation should be removed entirely.[11] For example, the Royal College of Radiologists agreed "with this proposal in view of the complex and lengthy procedure required for Privy Council approval".

2.65 The General Medical Council agreed, and further argued that the Privy Council role "does not ensure distance between the regulators and the Government, it merely masks the relationship". The Council also pointed out that in several areas it can already make regulations that do not require Privy Council approval, such as setting fees, and this does not affect the perceived status of these regulations.

2.66 The Scottish Government felt that the Privy Council role "is something of a formality" and in practice "matters fall to the Department of Health to perform", which was described as contrary to the need for independence from Government.

[11] Of the 192 submissions which were received, 47 expressed a view on this proposal: 33 agreed, 12 disagreed, whilst 2 held equivocal positions.

2.67 The Association of Regulatory and Disciplinary Lawyers argued that:

> The current system is overly bureaucratic and, critically, very slow. This inhibits the ability of regulators to make changes quickly that are necessary and urgent. The current process of approval is weighted very much in favour of safeguards and oversight of the regulators and does not support the regulators' need to make changes that they are best placed to identify as necessary changes.

2.68 However, several consultees – including those who agreed with the proposal – expressed concerns. A small number disagreed that the Privy Council role was largely symbolic and instead argued that it added real value. For example, Optometry Scotland felt that the Privy Council provides an "appeal process for concerned professions with a grievance regarding any aspect of regulation" and resolves disputes through "a fair and balanced approach based on what would be in the best interest of the public".

2.69 This view was supported by the Optical Confederation which stated that:

> The strength of the Privy Council system was that it generally liked to receive joint proposals both from the regulator and the regulated so that it was not forced to arbitrate on controversial issues. This invariably forced the parties to seek reasonable accommodations which were in the public interest.

2.70 Some consultees claimed that the Privy Council guards against political interference. The Royal College of Midwives felt that the Privy Council provides a "counterbalance to the administration of the day" which prevents undue political influence. The Institute of Biomedical Science argued that the role of the Privy Council ensures the separation and independence of the regulators from Government, builds in wider cross-Government participation and is an important part of "joined-up Government".

2.71 The Department of Health disagreed with the removal of the Privy Council role. It felt that:

> The statutory role of the Privy Council indicates a clear intention for there to be distance between these bodies and the Government. Current policy is that professional regulation should be seen as independent from day-to-day political pressures to ensure professional and public confidence in regulation is maintained. Removing the role of the Privy Council could call into question the independence of the regulatory bodies from Government and the Secretary of State for Health. We also have concerns about the impact on the classification of the regulatory bodies as a result of removing the role of the Privy Council.

2.72 The General Pharmaceutical Council argued that one of the benefits of the Privy Council role is that – as a UK-wide body – it can ensure all rules are consistent with legislation in Scotland, Wales and Northern Ireland, and take account of divergent health service delivery and management arrangements.

2.73 Some consultees accepted that, in practical terms, the role of the Privy Council is insignificant but argued that its real significance lay in expediting valuable input from the Government. For example, the General Optical Council contended that:

> We are not certain that the input and expertise that is currently provided by Department of Health lawyers in the process of drafting new rules can easily be obtained elsewhere. Even if that expertise is available privately, there will be substantial additional costs on regulators, and losing the Department as a central resource may create overall inefficiencies among the regulators relative to the current system.

2.74 Some consultees argued that if the role of the Privy Council is removed, greater joint working amongst the regulators would be required. The General Optical Council argued that it would "explore initiatives to share expertise and resources among regulators to help ensure the robustness of future rules". The Professional Standards Authority suggested that greater co-operation could be facilitated through the introduction of "oversight committees" to work on developing the core requirements and the development of template documents and methodologies.

Provisional Proposal 2-9: The House of Commons Health Committee should consider holding annual accountability hearings with the regulators which should be coordinated with the Professional Standards Authority's performance reviews. The Scottish Parliament, National Assembly for Wales and Northern Ireland Assembly should also consider instituting similar forms of accountability.

2.75 A large majority agreed with this proposal.[12]

2.76 Some consultees argued that our proposal should go further. The Royal College of Midwives argued that all regulators should have to attend annual accountability hearings, not just the larger regulators. The College also said that the Health Committee should be mandated to enquire "how the public safety and care quality of those receiving care from registrants is assured by the regulator".

2.77 However, some consultees queried the expertise of the Health Committee. It was suggested that the first accountability hearings, undertaken earlier in 2012 with the General Medical Council and the Nursing and Midwifery Council, had exposed the Committee's lack of resources and knowledge. Specifically, it was felt that the Committee had not asked probing questions and appeared to misunderstand the role of professional regulation. However, some accepted that the Committee's expertise and effectiveness may improve if accountability hearings become a regular occurrence.

2.78 However, the Optical Confederation remained unconvinced that accountability hearings could ever be effective, describing them as "post hoc, largely self-congratulatory PR exercises and seldom hard-hitting or genuinely effective in holding regulators to account". The Royal College of Radiologists suggested that the Health Committee does not have the appropriate level of independence since

[12] Of the 192 submissions which were received, 49 expressed a view on this proposal: 43 agreed, 4 disagreed, whilst 2 held equivocal positions.

it can too easily become "a party political tool". The General Dental Council argued that the Health Committee "has too wide a brief to be able to satisfactorily take on the systematic holding to account of the health and social care regulators". Optometry Scotland also drew attention to the cost implications of such hearings which it felt would be passed on to registrants.

2.79 Several consultees expressed support for the establishment of a specialist Joint Committee to oversee the regulators. For example, the Institute of Medical Illustrators argued this would reassure practitioners "that a political agenda would not be followed if there were a strong representation from experts from the upper House rather than only from professional politicians". The Professional Standards Authority argued that a Joint Committee would "facilitate a more overarching coordinated approach", but also recognised that the effectiveness of Parliamentary scrutiny through any committee will depend in part on the quality of the evidence submitted.

2.80 Some consultees also commented on the devolution aspects of this proposal. The General Medical Council argued that if accountability hearings were put in place for all four legislatures it would be important that "there was an agreement for managing this to avoid potentially competing and conflicting demands on regulators and to minimise the duplication of regulatory effort". The Nursing and Midwifery Council stated that:

> Under our current legislation, we are only legally accountable to the UK Parliament. Our concern is that, if we were legally accountable to the legislative bodies of Northern Ireland, Scotland and Wales, there would be a strong risk of being pulled in different directions by divergent policy concerns, undermining the four nations approach to nursing and midwifery regulation. We would be pleased to consider ways of addressing the interest of the devolved administrations, while avoiding the risk of fragmentation.

Provisional Proposal 2-10: The Secretary of State should be given formal powers to make decisions on matters that require a political policy decision to be made, including matters where there is a sufficient public interest and matters that give rise to questions about the allocation of public resources.

2.81 A majority agreed that the Secretary of State should be given formal powers on matters that require a political policy decision to be made.[13] The Department of Health agreed generally with our approach to conferring powers of this nature (including default powers) but argued they should be vested in the Privy Council.

2.82 The Scottish Government agreed that the Secretary of State should retain responsibility for public policy decisions but emphasised that any change in this regard "must take into account devolved interests and allow for Scottish Government input into any decisions which are within devolved competence".

[13] Of the 192 submissions which were received, 42 expressed a view on this proposal: 27 agreed, 4 disagreed, whilst 11 held equivocal positions.

2.83 The Department of Health, Social Services and Public Safety for Northern Ireland agreed with our proposals for Government regulation-making powers but noted that "there is still a need for Government to administratively support".

2.84 Several consultees qualified their support by pointing to the dangers of unnecessary Government interference in professional regulation. The National Clinical Assessment Service argued that while the policy of the present Government is a more hands-off approach, future Government interventions based on "knee jerk reactions to emerging issues which have high public interest eg child protection issues or rogue doctor issues" are possible. The Royal College of General Practitioners argued that the Secretary of State's intervention powers need to be "very carefully delineated" in order to prevent unnecessary intervention on the basis of short-term political expediency.

2.85 Some, including the Association of Clinical Biochemistry and the Patients Association, were concerned about the impact of the proposal on the independence of the regulators. The General Osteopathic Council stated that:

> Part of the raison d'être of independent regulation is to separate it from the dominant supplier of health care (ie the Government) and this proposal could undermine that principle if regulation simply becomes part of the health service funding/policy mix.

2.86 The Royal Pharmaceutical Society of Great Britain suggested that the Government's role should be "more overarching" and the Professional Standards Authority should be given formal powers over political policy decisions.

2.87 The General Dental Council argued that, in some areas, we had not drawn the line in the correct place between political policy decisions and matters that should be left to the regulators. For example, it considered that the constitution of the Councils should fall within the former since it is properly a matter for the Government, while financial penalties and costs awards should fall within the latter and left to the regulators to decide. Coventry and Warwickshire Partnership Trust also thought that the proposal required further clarification.

2.88 The Nursing and Midwifery Council was cautious about our overall approach and sought clarification over whether the Secretary of State would be required to consult on all decisions and whether the exercise of Government powers would be subject to Parliamentary approval, as is the case with section 60 orders. Some consultees wanted clarification on how the Government would decide to exercise its powers and argued that there needed to be statutory criteria.

Provisional Proposal 2-11: The statute should place a duty on each regulator to provide information to the public and registrants about its work.

2.89 The vast majority agreed that the regulators should be required to provide information to the public and registrants about its work.[14] For example, the Chartered Society of Physiotherapy thought the requirements "essential to

[14] Of the 192 submissions which were received, 53 expressed a view on this proposal: 51 agreed, whilst 2 held equivocal positions.

ensure transparency", whilst West Sussex County Council supported an "expectation of transparency and honesty in the work the regulators do".

2.90 Some felt that this duty needed to be strengthened. The Patients Association for example supported "a duty to publish such information in a public place, in a variety of formats and media". The Medical Defence Union argued there should be a requirement for consistency in terms of the information that is made available by each regulator. It claimed that at least one regulator always requires registrants or their representatives to make a request under the Freedom of Information Act 2000 in order to gain access to information that other regulators provide freely.

2.91 The General Dental Council was concerned that the duty does not replicate or overlap with other statutory duties and does not extend the application of the Freedom of Information Act 2000 by introducing an additional class of information which individuals can request. The Council further argued that the Professional Standards Authority should identify and promulgate best practice.

2.92 An individual consultee (Anonymous) felt an express duty was unnecessary and could force the regulators to take their eye off "the central objective of protecting the public" and lead to higher fees because "the regulator feels they need to produce lots of information". The Association of Regulatory and Disciplinary Lawyers argued that while a duty to provide information would do no harm, it does not need to be provided for by statute since each regulator currently maintains a website with such information. Furthermore, any requirement to publish information should "recognise the role and experience of individual regulators on how much information it chooses to publish". The Royal College of Radiologists agreed that any requirements must respect the regulators' independence.

Provisional Proposal 2-12: Each regulator and the Professional Standards Authority should be required to lay copies of their annual reports, statistical reports, strategic plans and accounts before Parliament and also in all cases the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly.

2.93 An overwhelming majority agreed that the statute should require the regulators to lay copies of their annual reports, statistical reports, strategic plans and accounts before Parliament, the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly.[15]

2.94 The Pharmaceutical Society for Northern Ireland said, in addition, that:

> It would be helpful if there were formal arrangements for the relevant administration to review, comment upon or seek further detail from the regulators or Professional Standards Authority.

2.95 While the Nursing and Midwifery Council had no objection to laying its reports formally in all four legislatures, it suggested that this would involve "considerable administrative work" and did not want this to affect the timing of its reporting.

[15] Of the 192 submissions which were received, 50 expressed a view on this proposal: 48 agreed, whilst 2 held an equivocal position.

2.96 An individual consultee (Anonymous) described the requirement of laying copies of reports in Parliament as "old fashioned" and "a relatively expensive exercise", and was not convinced that "anything more than a duty to produce and make these reports available is necessary". The Professional Standards Authority also described the laying requirements as being largely symbolic, and questioned whether there should be a general requirement for all the regulators to "make available to the public all publications that report on its performance".

Provisional Proposal 2-13: The statute should not require the regulators to send a copy of their accounts to the Comptroller and Auditor General or to the Auditor General for Scotland.

2.97 A significant majority agreed that the duty to send accounts to the Comptroller and Auditor General or to the Auditor General for Scotland should be removed.[16]

2.98 The Nursing and Midwifery Council argued that this proposal would remove "an unnecessary layer of bureaucracy and additional expense". The Pharmaceutical Society of Northern Ireland pointed out that it is not required to send a copy of accounts to the Comptroller and Auditor General. The General Dental Council suggested that the National Audit Office should instead be responsible for the guidance as to the content of the report and accounts.

2.99 However, the National Audit Office argued that it should continue to be responsible for auditing the accounts of the regulators because although the regulators do not receive public funds, they have powers that derive from legislation and therefore remain accountable to Parliament for how they use those powers and how they spend their funds. The analogy was made with Ofcom which does not directly receive public funds but the Comptroller and Auditor General audits through Parliamentary authority. In its view, the regulators would in any event meet the criteria under the Government Resources and Accounts Act 2000, which would enable the Treasury to provide by order for their accounts to be audited by the Comptroller and Auditor General. This would be a decision for the Treasury.

Provisional Proposal 2-14: The order making power in section 60 of the Health Act 1999 should be repealed and instead the Government should be given regulation-making powers on certain issues.

2.100 A significant majority agreed with this proposal.[17]

2.101 Many noted that under our proposal the Government would be given regulation-making powers on most matters currently dealt with by section 60 orders (such as powers to establish, merge or abolish regulators). Some support was conditional on Government powers being delineated clearly in the new statute. The Scottish Government supported this proposal "on the assumption that

[16] Of the 192 submissions which were received, 39 expressed a view on this proposal: 33 agreed, 4 disagreed, whilst 2 held an equivocal position.

[17] Of the 192 submissions which were received, 49 expressed a view on this proposal: 43 agreed, 5 disagreed, whilst 1 held equivocal positions.

Governments are given similar regulation-making powers which reflect the devolution settlement".

2.102 The Local Supervising Authority Midwifery Officers Forum UK thought that section 60 orders should be retained on the basis that they allow "amendment of legislation without the need to pass primary legislation and are subject to parliamentary approval". UNISON also supported the retention of the power as it "allows all parties including the Secretary of State to consider proposals in a clear and transparent way."

2.103 The Nursing and Midwifery Council opposed the abolition of section 60 orders. It argued that "however carefully the new statute is drafted, it will not be possible to include provision for every possible change that may be required in the future". The Council felt that the regulators will need some provision to request a change if, for example, some aspect of the new statute proves to be unworkable. Similarly, the General Optical Council suggested that a section 60 mechanism should be retained as a safeguard against "unforeseen difficulties".

Provisional Proposal 2-15: The Government should be given a regulation-making power to abolish or merge any existing regulator, or to establish a new regulatory body. This power would also enable the Government to add new professional groups to, or remove professional groups from, statutory regulation.

2.104 A significant majority agreed with the proposal.[18] The Department of Health agreed, but argued that the power should be vested in the Privy Council.

2.105 Several consultees argued that safeguards were needed to protect the position of registrants. The Osteopathic Alliance felt that any proposal to alter the number of regulators should be subject to consultation and the full agreement of the members of the professions concerned. The Royal College of Midwives argued, in respect of the power to remove a professional group from statutory regulation, that there must be "a clear process to show that public protection was not compromised" and that the employment prospects of current registrants would not be adversely affected.

2.106 Some suggested a role for the regulators before these powers are exercised. The Institute of Biomedical Science argued that "the addition or removal of a profession to or from statutory regulation should only take place with the full support of the regulator in question". The British Pharmaceutical Students' Association was concerned that our proposal may enable the Government to force proposals through and argued that the regulators should be "able to make recommendations on which professional groups should be registered and whether their regulatory function needs to be merged or abolished".

2.107 Many consultees suggested additional procedural safeguards before the proposed powers could be exercised. For example, the General Dental Council argued that before any proposal to abolish or merge regulators, the statute should "specify prior steps to be gone through such as the giving of directions and the taking over by the Government of particular functions". The British

Association and College of Occupational Therapists argued that any decision should be subject to a full day's debate on the floor of the House of Commons and subject to a vote of the whole House. The Association for Regulatory and Disciplinary Lawyers argued that the Secretary of State should be required to demonstrate that the use of this power does not undermine "the health, safety and well-being of the public" or "public confidence in the independent regulation of the health care or social care professions and the lowering of professional standards".

2.108 A small number categorically opposed the proposal. The Association of Clinical Biochemistry argued that the ability to abolish a regulator "would only be relevant where a whole sphere of health care activity was deemed obsolete – a situation we cannot easily envisage occurring". The General Chiropractic Council argued there is no need for such powers because the Government already can regulate, abolish or merge regulators and establish a new regulatory body.

Question 2-16: Should the Professional Standards Authority be given a power to recommend a profession for statutory regulation, or the removal of a profession from statutory regulation? If the Government decided not to comply, it would be required to issue a report setting out its reasons.

2.109 A large majority of consultees agreed that the Professional Standards Authority should be given a power to recommend a profession for statutory regulation, or the removal of a profession from statutory regulation.[19] Rescare and the British Dental Association were amongst those who answered the question in the affirmative.

2.110 The Professional Standards Authority itself argued that this power could be linked to its existing statutory power to provide advice to the Secretary of State and Ministers in the devolved administrations. In effect, the Government could request that the Authority undertakes an investigation – for example on whether a specific profession should be brought under statutory regulation – and the Authority could provide advice on the basis of a risk assessment.

2.111 The Health and Care Professions Council agreed that this role could rest with the Authority. Currently, the Council itself has a power to make recommendations on statutory regulation but it accepted that the Authority's:

> oversight role independent of the regulators and of Government means that it is in a better position than the individual regulators to make such a recommendation. Further, its forthcoming role in quality assuring voluntary registers means that it may be able to draw on this experience to identify where voluntary registration may be insufficient and statutory regulation may be merited.

[18] Of the 192 submissions which were received, 53 expressed a view on this proposal: 42 agreed, 6 disagreed, whilst 5 held equivocal positions.

[19] Of the 192 submissions which were received, 55 expressed a view on this question: 42 said the Professional Standards Authority should be given such a power, 9 disagreed, whilst 4 held equivocal positions.

2.112 Some consultees felt it was inappropriate for this power to be given to individual regulators – such as the Health and Care Professions Council – which has a vested interested in extending its remit.

2.113 However, the General Dental Council and General Osteopathic Council queried whether an express power for the Authority was necessary, since it is an independent authority in its own right and would be at liberty to make such recommendations in any event (as would any of the regulators).

2.114 The Nursing and Midwifery Council opposed giving the Authority any formal powers of recommendation, arguing that:

> Since it is soon to be funded by the regulators, there is a clear question of whether the Authority can be perceived by the Government, regulators and the public to act as a disinterested party in making such recommendation.

2.115 The Association for Regulatory and Disciplinary Lawyers argued there was no reason to extend the role of the Authority from overseeing the regulators to an area that is more to do with political policy. The Department of Health also disagreed with the proposal since the decision has "political elements".

2.116 The Scottish Government felt there were a number of important considerations that needed to be addressed before it could decide whether the Professional Standards Authority should be given powers in this area. It sought further information about the criteria that would be used to make such a determination, the sequence of events if one or more of the four countries did not support a recommendation and the extent to which these deliberations would be made public.

2.117 The Welsh Government commented on the role of the Professional Standards Authority and stated "there would need to be clarity how each part of the UK could influence the Authority to recommend a profession for statutory regulation". It continued that "issues of transferability will need to be considered if the requirement is for a new profession in only one part of the UK".

2.118 Several consultees, including the Registration Council for Clinical Physiologists and UNISON, commented on the importance of the Government being required to provide reasons for any decision not to implement a recommendation made by the Professional Standards Authority.

Provisional Proposal 2-17: The Government should be given powers to issue a direction in circumstances where a regulator has failed to perform any of its functions, and if the regulator fails to comply with the direction, the Government may itself give effect to the direction (see also provisional proposal 13-2).

2.119 A large majority agreed with the proposals.[20] For example, the Dental Schools Council and Optometry Scotland welcomed the proposal on the grounds of safety.

2.120 The Health and Care Professions Council and Coventry and Warwickshire Partnership Trust were among several consultees who stressed that their support for the proposals was on the basis that they should only be used as a "last resort".

2.121 While agreeing in principle with our proposal, the General Medical Council expressed concern that default powers might extend to failures to implement the Qualifications Directive. The Council argued that while it was legitimate that the Government would wish to "avoid costly infraction proceedings and a fine if a regulator's actions are in conflict with European Union law", it has "powers under the Localism Act 2011 to pass such fines onto the regulator concerned". Furthermore, the Council said that:

> It may be far from clear whether a regulator is failing to perform its functions or, more specifically, failing to implement [European Union law] appropriately. Some issues may be interpreted differently by the regulator and the Government and may need to be tested in the courts. It is important that regulators pursuing their prime purpose of protecting the public are not subject to undue political pressure for Government.

2.122 Many consultees expressed concern about the potential abuse of Government default powers, and the impact on the independence of the regulators. The General Optical Council argued that:

> While these powers are currently held by the Privy Council, they are somewhat limited in scope and have never been used. We believe that if such broad powers are to be held by the Secretary of State there would again be the potential for the political independence of regulators to be compromised without appropriate safeguards.

2.123 The Nursing and Midwifery Council argued that the introduction of Government default powers has the "potential to erode the independence of the regulators". It felt that:

> Formalising such a transferral of powers to the Government does raise the question of when regulators cease to be independent and become non-departmental public bodies … we would like clarification on when and how such powers would be used and, in particular, what the role of the Professional Standards Authority would be in these

[20] Of the 192 submissions which were received, 47 expressed a view on this proposal: 38 agreed, 5 disagreed, whilst 4 held equivocal positions.

> situations. As the scrutiny and oversight body for regulators, it would seem necessary for it to have a role in identifying when a regulator is failing to perform its functions and whether it has subsequently failed to comply with directions.

2.124 The College of Social Work reported:

> serious reservations about the broad nature of this power. The independence of the regulator may be compromised unless the circumstances in which the Government may act are defined and limited. The circumstances in which Government is entitled to declare that a regulator has "failed to perform" must be clearly set out in regulations.

2.125 The General Pharmaceutical Council felt that Government default powers – unless they are tightly prescribed – have the potential to undermine the independence of the regulators. Moreover, the Council argued that:

> It is not in the best interests of patients and the public, nor likely to support consistent and proportionate regulation if regulators look "up" to Government for "direction" about what is expected, rather than looking "out" to patients and the public.

2.126 The Association of Regulatory and Disciplinary Lawyers argued that the Government should be required to consult the Professional Standards Authority and appoint a nominee who should be accountable to and report to the Health Select Committee.

2.127 Others suggested that the Government should be required to submit a report to the Health Committee if such powers are used and that Parliament should be required to authorise the use of default powers and nominate a body to implement these powers on its behalf.

2.128 Several consultees pointed to the existing problems being experienced by the Nursing and Midwifery Council and argued that intervention had been achieved without the use of default powers through the Government requesting the Professional Standards Authority to step in and investigate. It was therefore suggested that default powers are unnecessary.

Provisional Proposal 2-18: The Government should be given powers to take over a regulator which is failing to carry out its functions.

2.129 A significant majority also agreed that the Government should be given powers to take over a regulator which is failing to carry out its functions.[21] The majority of the reasons given in support reflected those provided in response to the previous proposal.

2.130 The General Dental Council supported the proposal, but believed that it should be "explicitly circumscribed". It felt that:

[21] Of the 192 submissions which were received, 44 expressed a view on this proposal: 33 agreed, 5 disagreed, whilst 6 held equivocal positions.

The Secretary of State should be obliged to set out in regulations the process to be followed in such an eventuality (directions, timescale, consultation and time for submissions, time for compliance, alternative proposals, justification.)

2.131 The Department of Health agreed there should be a power to take over a failing body, but this power should be vested in the Privy Council. It thought the power should be extended to provide for "the Privy Council to make arrangements with another regulatory body to provide assistance to, or to exercise the functions of, the failing body" (and regulators could be merged if necessary).

2.132 The Royal College of General Practitioners did not consider that the Government would have the "expertise required to directly take over the regulator", and suggested instead that Parliament should be given power in this area, for example, to transfer the authority of the regulator to an alternative body.

2.133 The General Pharmaceutical Council did not support the proposal. The Council rejected our analogy of Government powers to take over a local authority, since local authorities are funded by taxpayers whereas the regulators are independent bodies funded by fees charged to registrant groups.

Provisional Proposal 2-19: The Government should not have express powers in the statute to initiate a public inquiry. This would continue to be provided for under other existing Government powers.

2.134 The vast majority agreed that Government should not have express powers in the statute to initiate a public inquiry.[22]

2.135 However, the South Staffordshire and Shropshire Healthcare NHS Foundation Trust (Social Care) considered that the powers should be retained to ensure consistency.

2.136 The Scottish Government sought reassurance that it had suitable powers to initiate a public inquiry and that "such legislation is clearly stated/referred to within the statute".

Provisional Proposal 2-20: If the Scotland Bill 2010 does not become law, any use of the proposed regulation-making power set out in provisional proposal 2-13 in respect of a profession for which the Scottish Parliament has legislative competence, must be consulted on by Scottish Ministers and laid before the Scottish Parliament as well as the UK Parliament.

2.137 A large majority agreed with this proposal.[23]

2.138 The Scottish Government supported the proposal and stated that:

[22] Of the 192 submissions which were received, 35 expressed a view on this proposal: 34 agreed, whilst 1 disagreed.

[23] Of the 192 submissions which were received, 27 expressed a view on this proposal: 24 agreed, whilst 3 held equivocal positions.

> We would want the use of any new regulation-making powers to be consulted on by Scottish Ministers and laid in the Scottish Parliament. We would also want the current arrangements for making section 60 powers to remain whereby any consultation by UK Government and Scottish Ministers has been run as a joint exercise, with the Department of Health leading.

2.139 Some consultees made general comments about the importance of UK-wide regulation of health and care professionals. For example, the Professional Standards Authority pointed out that the public has "shared expectations" about health and social care professionals across the UK and that "UK-wide regulation also supports the free movement of labour and we anticipate that regulation will need to support greater flexibility in the workforce in the future". Coventry and Warwickshire Partnership Trust also argued that:

> There are high levels of movement from different parts of the UK within professional groups and changes to regulation in different parts of the country could hinder people transferring employment.

Question 2-21: Should the Pharmacy (Northern Ireland) Order 1976 be reconstituted and retained as a separate part of the new statute?

2.140 A large majority felt that the Pharmacy (Northern Ireland) Order 1976 should be reconstituted and retained as a separate part of the new statute.[24] Most consultees covered this question and the next in the same response.

Question 2-22: Should the proposed regulation-making power set out in provisional proposal 2-15 include a general provision to incorporate the Pharmaceutical Society of Northern Ireland into the main legal framework of the new statute (following approval by the Northern Ireland Assembly)?

2.141 A majority agreed that the Government regulation-making powers should include a general provision to incorporate the Pharmaceutical Society of Northern Ireland into the main legal framework of the new statute.[25]

2.142 Many argued that professional regulation should be consistent across the UK. For example, the Professional Standards Authority stated that our review:

> presents a unique opportunity to establish consistency across the four countries in the regulation of all health and care professions, wherever possible. While respecting the devolved powers in Northern Ireland, the position of the Pharmaceutical Society of Northern Ireland should wherever possible be brought into greater consistency with the other UK professional regulators.

2.143 The Northern Ireland Practice and Education Council for Nursing and Midwifery also argued that the powers of all the regulators should be harmonised. UNISON

[24] Of the 192 submissions which were received, 13 expressed a view on this question: 10 said the Order should be retained, 2 disagreed, whilst 1 held an equivocal position.

[25] Of the 192 submissions which were received, 10 expressed a view on this question: 7 said a general provision should be included, 1 disagreed, whilst 2 held equivocal positions.

went a step further and argued that the Society should be merged with the General Pharmaceutical Council to form a single UK-wide body.

2.144 The Pharmaceutical Society of Northern Ireland supported inclusion in the single statute only on the basis that:

(1) the use of Government default powers in relation to the Society must be approved by the Northern Ireland Assembly or exercised by the Northern Ireland Executive; and

(2) the Society's dual role of regulation and professional leadership is retained.

2.145 The Professional Forum of the Pharmaceutical Society of Northern Ireland supported the incorporation of the Society into the statute only on the basis of certain safeguards being introduced such as:

> the provision of similar protections as afforded to Scotland in section 62 of the Health Act 1999 … and a recognition that the Northern Ireland Assembly remains the primary legislature for health care regulation in Northern Ireland.

2.146 The Forum also stated that the Westminster Government should not be empowered to abolish or merge the Society or to merge it without the explicit support of the Northern Ireland Assembly and any such proposal should be subject to full consultation.

Question 2-23: Which, if any, of the specific proposals which follow in this consultation paper should be applied to the Pharmaceutical Society of Northern Ireland?

2.147 All those who expressed a view argued that the proposals should be applied to the Society, generally on the basis that it would promote consistency.[26]

2.148 UNISON also thought the proposals would "allow for equality across differing professional groups". It said that registration fees were a key issue, and noted that "pharmacy technicians are having to pay a registration fee which is disproportionate to their earnings and those imposed by comparative regulators".

Question 2-24: How should the new legal framework deal with cases left over from the previous legal regimes? What practical difficulties are likely to arise from the repeal of existing legislation and rules?

2.149 Of the consultees who responded to this question, a small majority thought that transitional provisions would be required to deal with cases left over from the previous legal regimes.[27]

[26] Of the 192 submissions which were received, 8 expressed a view on this question: all said that all of the proposals should apply to the Pharmaceutical Society of Northern Ireland.

2.150 The Scottish Government supported giving Government transitional provision-making powers. It anticipated an increased number of appeals, and considered that measures would be required to deal with that situation.

2.151 The Medical Defence Union stated that when the General Medical Council and the General Dental Council changed their fitness to practise procedures substantially they produced transitional rules that ensured cases were dealt with appropriately. Therefore, the Union felt that as long as "the legislation specifies that regulators will need to make and agree with stakeholders clear transitional arrangements for legal cases arising under a previous legal regime", there should not be any significant difficulties.

2.152 However, the British Psychological Society reported a different experience when the Health and Care Professions Council took over the statutory regulation for psychologists from the Society in 2009, resulting in some members having been subject to the disciplinary procedures of both bodies. The Society suggested "a transition period to be agreed during which all active cases could be completed under the old system". The Professional Standards Authority agreed that existing cases "should be dealt with under the old rules".

2.153 The Nursing and Midwifery Council stated, based on its experience of managing the changeover from the United Kingdom Central Council for Nursing, Midwifery and Health Visiting, the "challenges of maintaining the current framework, while preparing for the implementation of a new one, should not be underestimated". The Council stated that considerable resources are required, both in terms of costs and staff time and that there was a particular need to ensure that the regulatory framework to support the supervision of midwives across the UK should not suddenly cease to exist.

2.154 The British Association for Counselling and Psychotherapy suggested that the timetable for change should be consistent for all the regulators. The General Osteopathic Council argued that there will need to be a "considerable period of transition between Royal Assent and the switching on of new powers". In particular it highlighted that regulators will need time to:

(1) draft new rules and associated consultation documents,

(2) seek approval from their Council;

(3) consult;

(4) analyse consultations, redraft rules and undertake legal scrutiny;

(5) seek final approval from their Council and make rules;

(6) adapt information technology and other administrative systems; and

[27] Of the 192 submissions received, 37 expressed a view; 8 said that the cases should be dealt with under the old regime, 8 said that the method used by the General Pharmaceutical Council should be adopted, whilst 21 said that some form of transitional provisions should be provided.

(7) train staff and panellists (where appropriate).

2.155 The Professional Forum of the Pharmaceutical Society of Northern Ireland, together with several other respondents, suggested that the approach used previously by the General Pharmaceutical Council should be adopted; namely a general provision should be made in legislation to allow the new structures to deal with legacy cases in a manner they consider just.