



Department
of Health

Promoting professionalism,
reforming regulation –

the response from the
Institute of Biomedical
Science

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Contact details: Contact details: Professional Regulation 2W09 Quarry House Quarry Hill LEEDS LS2 7UE reformingregulation@dh.gsi.gov.uk

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The Institute of Biomedical Science

The Institute of Biomedical Science (the IBMS) is the professional body for biomedical scientists. It is a large and mature professional body that has been in existence for over 100 years and has extensive experience of regulated professions since its membership has been a regulated profession for almost 60 years.

As an organisation we have over 40 years' experience of accrediting undergraduate and postgraduate degrees linked to statutory regulation and have been approved by the HCPC as an education provider for a number of routes to registration for biomedical and clinical scientists. This includes approval to assess and confer 'equivalence' against the existing qualifications and experience mapped to the outcomes of formalised quality assured training programmes.

In addition, the IBMS quality assures education and work based training in partnership with other stakeholders and promotes and supports professional development through a quality assured professional qualifications and a CPD scheme established over 25 years.

1. Summary of the questions

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Response:

The Institute of Biomedical Science (IBMS) has reservations about the proposals for the role of the PSA and feels this could constitute a conflict of interest if this proposal were to be executed and would be a significant deviation away from the current remit of the PSA. Its current role of regulatory oversight is a key method for ensuring quality and consistency of care within the NHS and the wider healthcare sector but is entirely separate from that of the regulatory bodies who we feel are better placed to assess the strength of a petition for regulation. Our view is that the involvement of the PSA should only be as part of a wider Department of Health led consultation involving professional bodies, patient representatives and the general public. The consultation does not make a convincing argument in support of its proposal and as the current system appears to operate safely and effectively there is insufficient evidence to support a change.

Q2: What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

Response:

It is of paramount importance that the purpose of regulation is not eroded through this review. The criteria suggested by the PSA are, in our opinion, too basic and are insufficient to adequately assess the actual, or potential, implications for patient safety of aspirant or currently regulated professions. Although the proposed criteria set out in the consultation document provide a starting point more detail is required on assessment levels relating to complexity of activities.

It is disappointing that the criteria do not include any requirement for, or reference to, a representative professional body. Without such a body it is difficult to see how the specific body of knowledge that underpins a profession can be identified and developed and against which educational standards can be set. With all regulated bodies, and also those aspirant professions, their body of knowledge and professional standards are defined by their representative professional body.

With respect to the proposed assessment criteria, the scale of risk posed by an aspirant or currently regulated group would be strengthened if the criteria were to consider the nature of adverse incidents that do or could occur, not simply the size of the professional group or the location. If location is of primary significance it would suggest that the multitude of care workers that are currently occupied in a support worker capacity, while working unsupervised in patients' homes, should be candidates for statutory regulation or the converse argument would be the extended use of unregulated staff to perform tasks which, in other locations, would be undertaken by a regulated workforce. The net result would be that those deemed less vulnerable, or with hidden vulnerabilities could be afforded a less safe and effective service.

We feel it is inappropriate for cost and recruitment difficulties to be criteria for setting a regulatory regime as this could introduce perverse incentives to de-regulate and increase risk failure in hazardous procedures and situations

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

Response:

This is a contentious issue as it would require a considerable evidence base and accompanying risk assessment to deregulate a profession that has previously been deemed to require statutory regulation in order to provide adequate patient protection. However, it is recognised that practices change and this can reduce the potential to do harm. Any decision to reassess would first require stringent assessment criteria that should take in to account the comments made against the PSA proposed criteria contained within this consultation, which in their current form are inadequate. Any reassessment of currently regulated professions should be applied equally to all to ensure fairness and transparency.

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

Response:

Unregulated groups and individuals generate the biggest risk of harm to the public. Prohibition orders can operate as part of a structured approach to fitness to practice (ftp), but should not be seen as an alternative to statutory regulation. The standards of proficiency to which all HCPC registrants must adhere require a set of threshold competencies to have been achieved and for competence relevant to an individual's scope of practice to be maintained. Prohibition orders do not provide evidence of competence, but evidence of failure after harm or risk of harm has occurred, which is very different.

While the use of prohibition orders may be justified as a means of giving protection from individuals not subject to professional regulation there is the risk of making additional complex administrative processes that run counter to a central theme of this review which is to achieve a more 'nimble' approach to patient protection. In crudest term prohibition orders could be viewed as simply a 'cheap' way of enforcing a form of statutory regulation.

Q5: Do you agree that there should be fewer regulatory bodies?

Response:

Yes. The HCPC regulatory model demonstrates that effective regulation for multiple professional groups can be achieved through a single regulator, which in itself could justify a reduction in the number of regulators.

Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

Response:

The key benefits would be more consistent regulatory standards across professions, more consistent educational and continuing professional development standards. From a patient perspective it could be easier to lodge a complaint if there were to be a smaller number of regulators covering multiple professions. From a financial and administrative perspective there would be the benefit of economies of scale, greater centralisation of processes and the added benefit of the potential for closer working between professional groups.

We do not feel that there would be any significant disadvantages to a reduction in the number of regulators.

Q7: Do you have views on how the regulators could be configured if they are reduced in number?

Response:

The following configuration under three regulators would provide a logical regulatory structure although with the volume of professions in the third category it may be preferable and logical to move ambulance paramedics and operating department practitioners in with the nurses and midwives.

- medical and dental
- nursing and midwifery
- Social workers*
- all others (an expanded HCPC)

*We note that a new regulatory body, Social Work England, is already planned despite social workers in England currently coming under the jurisdiction of the HCPC. In the context of this consultation this seems a somewhat contradictory move when consolidation appears a strong objective and do not see the justification for creating a new regulator when regulation is already achieved under a multi-profession regulator.

Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Response:

Yes. A major flaw in the current regulatory system is the lack of consistency between regulators in respect of the actions or sanctions they are able to impose in fitness to practise cases. This leads to inequality of fairness across the regulated profession and is counter to a culture of transparency. All of the regulators should be given the same full powers for resolving cases and should have a common appeals process.

Q9: What are your views on the role of mediation in the fitness to practise process?

Response:

It is our view that this is a matter that now requires serious consideration, not least because a significant proportion of registration fees are used for fitness to practise investigations and hearings. It is of concern that there is an apparent misunderstanding between employers, complainants and regulators in the context of fitness to practise whereby service users often feel that errant professionals go unpunished, while employers frequently feel unsure when to refer and consequently regard the regulator as a complaints resolution service often for 'low level' issues that could be better resolved nearer to source.

Mediation is, in our view, an underused option in the context of regulation and should be an option early in the investigative process, where appropriate, to attempt to rectify "problems" and avoid automatic progression to a formal legal process. An additional benefit of a mediation option would be to help remove the blame culture approach that inhibits improvement in practice.

Q10: Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance?

Response:

The PSA should consider all factors relating to regulator performance, including ensuring consistency across all professions with regard to fitness to practice, with common regulations applied across

professions. It is important that an independent body such as the PSA provides oversight to the regulators at an organisational level.

Q11: Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

Response:

Yes.

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

Response:

The IBMS is an HCPC approved education provider for a number of routes to HCPC registration and accredit more than 100 undergraduate and post graduate courses. As such we have extensive experience of regulatory process and the interactions between regulators, professional bodies and other quality assurance organisation. Intrinsically we are concerned by the views expressed and opinions staked in sections 3.27 to 3.37:

The consultation states that regulatory bodies set standards of education and training and assess how education providers meet these standards. We agree with this statement but would point out that they are not prescriptive; it is for the education provider to justify their approach and rationale for how they meet the standards.

The PSA has recommended that health profession regulators should focus on setting and assessing the learning outcomes, leaving other regulators to deal with broader issues of management. The phrasing suggests the regulator would set and assess, rather than focus on the setting and assessing (i.e. by the education provider).

It is important that the regulator takes a holistic overview of the programme. Broader issues of management can include the employment environment in which HEIs are operating and how employers can be engaged in teaching, assessment and providing work based learning opportunities. The partnership between the HEI, employers and professional bodies guides the setting and assessment of learning outcomes against the application of regulatory/professional standards in professional practice. Regulatory standards are usually set at a threshold level for entry into the profession but remain in force during the period of registration that can develop in depth and breadth beyond the level of registration. The regulators should be independent of the setting of learning outcomes and assessment in order to retain flexibility and innovation in how standards can be met and applied in a range of environments.

In future the PSA expects professional regulators to work in partnerships with employers and HEIs. This is a model that already operates successfully with HCPC approval and IBMS accreditation, which have complementary processes.

“All of the regulatory bodies assessing continuing fitness to practice of registrants” (3.32). Regulators have standards for continuing fitness to practice and assess a registrant’s ability to meet them rather than actually assess their fitness to practice. Fitness to practice is self-regulated professionally through compliance with these standards which require evidence of continuing professional development. Fitness to practice is usually assessed by the employer in accordance with regulatory standards that require active monitoring of competency assessment (e.g. UKAS accreditation standards against ISO 15189).

In specific response to Question 12 our view is that regulators are the gatekeepers of minimum standards that are required for professional practice. Having minimum standards common across professions is arguably more manageable for regulators who can then rely on professional bodies to interpret the standards in the context of the unique aspects of professional practice.

Regulators provide the framework for professionalism; professional bodies support individuals to achieve them and employers to measure individuals against them. Regulators can best support registrants by working with professional bodies and employers to provide clarity to the requirements of the registration process.

Q13: Do you agree that the regulators should work more closely together? Why?

Response:

In the interests of fairness, transparency and consistency there should be greater collaboration and cross-regulator working to permit alignment of generic standards across all professions with the option for profession specific standards if required. If this could be achieved it would enable standardisation of procedures/documentation/re-validation requirements, providing greater clarity of regulatory processes and ethics for registrants, employers and the public. A reduction in the number of regulators would encourage a move towards greater consistency and harmonisation between regulators and the opportunity for sharing good practice. There is also the potential to reduce costs by allowing some sharing of practice and reducing duplication of work.

Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

Response:

To reiterate the point made in response to Question 13, a single set of standards, agreed between all regulators, would provide consistency, better transparency and also be better placed to support the increasing number of extended and advanced roles and also new professional groups such as the Physicians Associates. Again, reducing the number of bodies would make this easier. As already noted in the consultation, the HCPC works successfully this way anyway across all the professions they cover. An additional area where joint working could be beneficial would be a single public complaints process.

Q15: Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

Response:

Yes, we would support this and feel it would help identify systemic issues and certain behavioral patterns at an earlier stage and hence prevent potential harm. In respect of individuals, the process should enable easy identification at the point of application for registration if the applicant has previously been barred by another regulatory body, or been subject to fitness to practice hearings.

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

Response:

It has long been recognised that due to the legal framework within which they operate regulators can be neither flexible nor agile when desiring to make changes to their operating procedures. It could even be argued that regulators could be impeded in carrying out their duty of protecting the public through their inability to respond quickly when circumstances require change. Therefore the IBMS would support a change that permitted regulators to set their own operating procedures. However, as stressed in the consultation, this would need to be balanced by clear rules, full transparency and accountability to the legislator. In addition, if there is to be a greater degree of standardisation between regulators (irrespective of their number) then ideally operating procedures and any subsequent changes should be standard, wherever possible, across all regulators.

Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?

Response:

The regulatory bodies should maintain accountability to the UK government only – accountability to devolved governments may lead to different regulatory standards across the different nations of the UK. However, all regulators should be bound to report to any parliament or assembly, should this be required, but not be held accountable by them. It is recognised that in the case of Northern Ireland, where the NI Assembly has not been in place for the last year, then this approach would not work and would require further thought.

Q18: Do you agree that the councils of the regulatory bodies should be changed so that they comprise of both non-executive and executive members?

Response:

The IBMS recognises the arguments put forward in the consultation in favour of a change to a unitary board but is not clear as to the justification or evidence for such a change. There may be some benefits to having unitary boards such as quicker decision making and co-production between executive and non-executive members, but unitary boards are not a guarantee of good or improved governance.

We feel that the consultation is promoting a negative view of current regulatory oversight without evidence or examples of where this has not been effective or appropriate, with the risk that this is change for change sake. We appreciate that our view is probably coloured by what we see as the successful operation of the HCPC council and suspect that the justification may be found in those regulators that regulate a single profession. It is therefore possible that this issue could be solved by the reduction in the number of regulators and an increase in the number and diversity of those professions falling within the responsibility of the respective regulators.

We suspect that the change to a unitary board will be the way forward and the IBMS would want to be assured that appointments are fully independent from government.

Q19: Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

Response:

We would want to see the benefits of employer representation on regulatory councils clearly articulated, which at this point they are not. We have a concern that employers could have a significant conflict of interest if members of a regulatory board or council. Now, and in the foreseeable future, employers are operating within a challenging business environment and regulation could be seen as an impediment to flexibility and cost saving rather than a benchmark for professional standards.

The views of employers can be communicated to regulators through consultation processes but to have voting rights on a council or board would shift power and authority to individuals with a potentially different objective. In addition, with the move to outsource pathology services to the private sector, there is the even greater potential for a conflict of interest should representatives of commercial providers employing regulated biomedical and clinical scientists be members of a regulatory board.

Q20: Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

Response:

We believe this should be normal good practice but with the caveat that while it is important that each regulatory body should set out its own proposals, there should be consistency across the different bodies.

Q21: Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

Response:

We strongly support the expansion of statutory regulation, not a contraction, which is in accordance with the view expressed by Robert Francis QC in his report on Mid Staffordshire NHS Foundation Trust. Recognising that there is a cost attached to statutory regulation the IBMS recommends that savings generated through the consolidation of regulators would be well directed towards the inclusion of the currently aspirant professional groups in to statutory regulation.

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?

Please explain your answer and provide an estimate of impact if possible.

Response:

We do not have the detail or information to make any realistic assessment of costs.

Please explain your answer and provide an estimate of impact if possible.

We would anticipate that further information would be provided subsequent to the closure of the consultation to enable a more informed assessment of impact.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

Response:

The IBMS has recently responded to the consultation "Regulation of Medical Associate Professions in the UK" and sees the benefit and need for statutory regulation to be extended to other professional groups. We feel that a reduction in the number of regulators and the inevitable economies of scale that will be realised through the consolidation process will enable the savings to be reinvested in an expansion of statutory regulation. Where statutory regulation is not appropriate or necessary a strengthened form of voluntary regulation with use of prohibition orders would offer an improvement in patient safety beyond that which is currently available.

Greater standardisation of regulation and fitness to practice processes should lead to increased standards and improved patient care. However, it should be recognised that with a more 'open' public register and clearer procedures for complaints, there may initially be more complaints/fitness to practice hearings but ultimately there should be a reduction in litigation from complainants and potentially a reduction in medical negligence awards

Q24: Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?

We are not sure how this would be achieved. Change is more likely to be brought about through employers rather than regulators. It is important that regulatory bodies continue to highlight good practice and promote equality, but there is nothing in the proposals that will further enhance what already exists. It is worth noting that in Northern Ireland all public bodies are required under Section 75 to equality check all policies such as employment, recruitment etc therefore eliminating discrimination.

Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?

Standardisation of regulation and amalgamation of professional regulatory bodies may help to reduce the perceived separation of standards between medical and non-medical staff.

- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

We are not clear how this would be achieved