Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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A response from the Royal Pharmaceutical Society of Great Britain to the consultation on the duty of co-operation regulations.

The Society welcomes the opportunity to respond to this consultation on the duty of co-operation regulations.

The Society is the regulatory and professional body for pharmacists and the regulatory body for pharmacy technicians in England, Scotland and Wales. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

Jeremy Holmes
Chief Executive and Registrar

Duty of Co-operation – Consultation on proposed regulations
Response from the Royal Pharmaceutical Society of Great Britain

The Society is the regulatory and professional body for pharmacists and the regulatory body for pharmacy technicians in England, Scotland and Wales. This response reflects the Society's regulatory viewpoint.

Q1 Do you believe that social workers provide services which are connected to health care, as defined in paragraph 2.7?

Yes. We support the definition of 'health care worker' in paragraph 2.7 and agree that social workers will not generally be health care workers but may sometimes provide services connected to health care. We concur that this may occur when a social worker is part of a multi-disciplinary team, for instance in mental health care settings.

Q2 Do you agree that there is no need to designate the police in these regulations? See paragraph 2.16

No. We would wish to see the police included as a designated body. From our experience it can be difficult obtaining information from the police in relation to evidence of impairment of fitness to practise of pharmacy professionals. This is particularly the case where there has not been a conviction or a caution. In order to avoid potential delays in handling cases, the inclusion of the police in the regulations may address this problem.

Q3 Do you have a view on whether we should designate HEIs so that they are subject to the duties of cooperation in respect of health care workers? See paragraph 2.19

Unsure. There may be cases where HEIs have concerns and then the healthcare worker changes sector. In such a case, it would be appropriate for the NHS Trust to have access to information about these concerns. It is also not correct that conduct or performance of a healthcare worker in an HEI would relate only to their teaching. What if they had a health issue, for example a drink problem?

Q4 Do you agree that Regulation 3 designates all those organisations that are connected to all health care workers involved in providing health care (which are not already designated by the Responsible Officers Regulations)?

No.

Q5 If you answered No to Q4, which other organisations should be designated?

We believe the National Clinical Assessment Service (NCAS) should be included as they deal with self referrals of healthcare professionals. We also suggest the Counter Fraud and Security Management Service (CFSMS) and the Prescription Pricing Division (PPD) are included, as both are currently listed as responsible bodies in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

Q6 Do you have suggestions on what might usefully be included in the protocols or MoU to facilitate sharing of information about health care workers, between sectors? See paragraph 2.20

Yes. A standard format for sharing and receiving information would be useful together with some indication of timelines for sharing information.

Q7 What are the existing mechanisms in your organisation which the "relevant officer" could use for identifying and managing concerns about the conduct or performance of health care workers? See paragraph 2.26

As a regulator we have robust systems in place for identifying and managing concerns about the conduct and performance of healthcare workers. Provisions governing the regulation of pharmacy professionals are contained within the Pharmacists and Pharmacy Technicians Order 2007 and the Rules made there under.

Q8 Do you agree that one individual in an organisation should be given responsibility for complying with the organisation's obligations under these proposed regulations?

Yes. This will ensure appropriate accountability. We would like to know who will hold the list of relevant officers, if information should be shared amongst these individuals. We also request clarification as to what action will be taken in cases where a relevant officer is not appointed. In particular who will deal with the organisation to ensure compliance?

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2006 the Accountable Officer central register is held by the Care Quality Commission (CQC) and is accessible online so that the details of the relevant accountable officer are available to designated organisations, responsible bodies and others. We seek clarification as to whether something similar is envisaged in this instance and if so what it will be.

Q9 Do you think we should specify in guidance the minimum level of seniority a relevant officer should have?

No. This should be the responsibility of the organisation. If this view is not accepted there should be consideration of taking a consistent approach to that of the Accountable Officer in the Controlled Drugs (Supervision of Management and Use) Regulations 2006 to ensure that there is not a two-tiered approach to concerns about individuals and controlled drugs and concerns about conduct and performance of individuals.

Q10 How do you think the 'relevant officer' in your organisation might ensure that all the information in the organisation's possession is examined once the trigger (see flow chart at page 38) suggests a need for investigation or there is a request for information from another designated body?

We already have procedures in place for notifying organisations about concerns about the management and use of controlled drugs and procedures in place for undertaking investigations. We would use similar procedures to those already in operation. .

Q11 Do you think guidance should set out any other responsibilities for the 'relevant officer' role? See paragraph 2.28

No. However, we suggest that the relevant officer's responsibility for sharing information with professional regulators outlined in paragraphs 2.29 and 2.30 is made more explicit.

Q12 Do you believe the safeguarding measures will ensure that information about health care workers will be dealt with in an open and fair way? See paragraph 2.33 – 2.34

Unsure. This will depend on the consistent and appropriate application of Regulation 6, in particular Regulation 6(5). Also, we cannot see anywhere where you have to tell the individual that you are passing their information to one or more designated bodies. This information should be included.

Q13 Are there any other safeguarding measures we should include in the regulations?

No response.

Q14 Do you agree that draft Regulation 6 provides a robust process for a designated body to substantiate an allegation against a health care worker before information based on it is shared with another designated body?

Unsure. While we would support, in principle, the need to carry out an investigation to substantiate allegations, this could lead to undue delay where allegations are serious and another designated body (for instance, the regulator, police, CFSMS) is in a better position to investigate. As such, Regulation 6(5) should include a statement that, where it is in order to protect the safety of patients and the public, the designated body may consider that step Regulation 6 (4)(a) should not be carried out prior to information sharing. The main concern is delay in serious cases, where local investigations could be protracted.

Also see our response to question 12.

Q15 Do you agree that there is already robust guidance on how to handle confidential patient information? See paragraph 2.36 – 2.38

Yes. Think all the NHS requirements around information governance cover this. We also provide guidance to our registrants on handling confidential patient information.

Q16 When, in a recruitment process, does your organisation seek information / references about the conduct or performance of a health care workers? Does your organisation seek information from current or ex-employers prior to a request for a formal reference being made?

No response.

Q17 Do you think regulation 7 as it stands strike the right balance between the aims set out in paragraphs 2.46? Do you think we should provide in regulation 7 that designated bodies should only provide to a recruiting designated body information about a health care worker's conduct or performance prior to the stage where references are sought, where there is an immediate threat to patient safety (with regulation 7 being compiled with in full when the provision of references stage is reached)?

Unsure. This will depend on the consistent and appropriate application of Regulation 7, in particular Regulation 7(5).

Q18 If a request for information about a health care worker is made by a designated body during an appointment process, should all the relevant clinical governance information held on file by the designated body receiving the request be transferred to the requesting designated body once the appointment process has been completed?

Yes. We support the transfer of all relevant information.

Q19 Do you foresee any difficulties with agreeing joint action where more than one designated body employs or contracts with a health care worker after one such designated body shares information under regulation 6(1) with the other designated bodies?

Yes. We can foresee enormous difficulties. Different organisations have different thresholds for taking action, different approaches to concerns and there may be particular difficulties if employers are in competition with each other. Paragraph 2.21 identified tensions and cultural barriers to sharing information between independent healthcare providers and the NHS. These concerns are equally applicable to possible joint actions between designated bodies. We suggest that these issues are addressed as part of the Department of Health's discussions referred to in paragraph 2.21.

Q20 What is current practice within your organisation about retaining information relating to verified allegations? See paragraph 2.61 – 2.62

No response.

Q21 Do you have a view on retaining information for 5 years (or until completion of the next revalidation cycle if later) on allegations that are not possible to investigate fully or where the allegation is unfounded?

We cannot see the point of retaining information where the allegation was completely unfounded. For instance, an allegation was made against an individual, but it was proven that that individual was not the person concerned or the complaint was malicious. Also, in cases of anonymous allegations, where there is no opportunity to test the allegation. We seek clarification as to whether it is anticipated that these allegations will be retained and shared.

Q22 Are you aware of any body, other than those listed above, whose guidance is of relevance to the proposed new regulations?

No. We are not aware of any other bodies.

Q23 Are there issues on which guidance or clarification would help your organisation meet its obligations under these proposed regulations? See Paragraph 2.63

Yes. We request clarification on the retention of records. If records of concerns are to be kept indefinitely, who needs to keep them? What if a designated body dissolves? What if an employee goes to work elsewhere, should all concerns be passed on to the new employer who should be under an onus to retain the documents indefinitely

or does each designated body have to retain the same records indefinitely on the same person?

Q24 Do you agree with our estimate of the likely costs and benefits? See Impact Assessment

No response.

Q25 According to the evidence presented in the IA, the likely cost of the preferred policy option on different organisations does not seem to be significantly related to their size. Do you agree with this proposition?

No response.

Q26 What might be the barriers (negative impact) to the proposed regulations "Duty of co-operation" and good quality outcomes for everyone from the perspective of ethnicity, gender, disability, age, sexual orientation, religion/belief, socio-economic or rural/geographical considerations? What proportionate measures could address those issues? See Screening EQIA

We have not identified any barriers that have not been included in the screening EQIA.

Q27 What are the positive impact that might result from implementing this policy from the perspective of ethnicity, gender, disability, age, sexual orientation and religion/belief, socio-economic or rural/geographical considerations? What proportionate measures might we implement that could enhance this positive affect?

We agree with the findings of the screening EQIA in relation to the possible positive impact of the Regulations. In relation to discrimination, we would recommend that guidance is provided to support the consistent and appropriate application of Regulations 6 and 7, in particular Regulations 6(5) and 7(5).

Q28 Please identify how the implementation of this policy might affect the Human Rights of patients, carers, service providers or the workforce? In your opinion does this mean that this policy should not be implemented or could proportionate measures be taken to address these issues?

As stated in our response to question 27, the inconsistent or inappropriate application of Regulations 6 and 7, in particular Regulations 6(5) and 7(5), may affect the Human Rights of health care workers. We would recommend that guidance and support is provided to relevant officers and others in organisations that will need to apply these regulations. We support the implementation of these Regulations as we believe that they promote public protection.

Also see our response to previous questions regarding issues of document retention, particularly in relation to unfounded allegations.

Q29 Do you have a view on the suggestion that local health care organisations should maintain a coherent and integrated set of information for all health care workers for whom the organisation which has clinical governance responsibility?

Yes, we support this suggestion.

Q30 Do you agree that these categories of information are good indicators of performance or conduct?

Unsure. We are not entirely sure that 'soft' information is a good indicator of performance or conduct as it is unsubstantiated.

Q31 What concerns do you have about sharing "soft" information?

We share the concerns outlined in paragraph 2.11, in particular, sharing soft information from anonymous sources.

Q32 Does your organisation already share "soft" information about health care workers?

We would disclose where we felt it was in the public interest to do so.

Q33 Do you agree that contractors should notify PCTs of all negligence claims?

Yes, we agree that contractors should notify PCTs of all negligence claims.

Q34 Do you agree with the definition of "claims"?

Yes, we agree with the definition.

Q35 Do you support the above approach on sharing information with patients, carers, or the public about investigations?

Unsure. We are supportive of open and transparent systems but there must be a balance between undermining the public's faith in a healthcare professional before an investigation is concluded. Information should be given in context, for example the public should be told that if there is an investigation ongoing, this does not mean that the healthcare professional is guilty. Complainants should be kept up to date throughout the process of investigation and advised when their complaint is going to be referred to other designated bodies.

Q36 Do you support the view that the national regulator should be alerted to a pattern of conduct or performance that falls below the threshold for referrals about fitness to practise?

Yes. In principle we support this approach subject to the fact that the matters should be investigated prior to referral.

Q37 Are these examples of concerns about a health care worker's conduct or performance helpful to you when making decisions about how you would comply with the proposed regulations on duties of co-operation?

No response.

Q38 Do you have any additional comments on any aspect of this consultation?

There is a great risk of confusion between the roles, remit and possible duplication between responsible officers (legislation to come into force), relevant officers

(proposed in this consultation) and accountable officers (legal position in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

Concerning the indefinite retention of records (paragraph 2.61). There is a need to ensure that there is a consistent approach between this proposal and other proposals being worked upon by the TCL implementation group, where proposals are that warnings for those on performers' lists are retained for only five years.

In paragraph 2.16 there is a statement which says 'Employers are of course obliged to undertake Criminal Records Bureau Check when appointing new staff'. We are not sure where of the origin of the statement. It is probably true in the NHS, but not in private sector.

We request clarification as to whether locum agencies are covered under these Regulations.