17 December 2015

Dear Mr Denning

National Data Guardian Consultation

The General Pharmaceutical Council (GphC) is the regulator of pharmacists, pharmacy technicians and registered pharmacies in Great Britain. Our principal functions include:

- approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises;
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns.

We aim to promote and support patient-centred professionalism in members of the pharmacy team as we believe this has the greatest influence on the quality and safety of services to the public and on patient care. A key element of this is respect for the confidentiality of patients' personal information.

The GPhC supports the proposed National Data Guardian initiative as an additional safeguarding mechanism for health and care data. However, we suggest that the National Data Guardian’s roles and responsibilities are clearly defined and publicised to avoid confusion with other organisations with similar roles. The response below covers the consultation questions that affect the GPhC in its regulatory role.
1. The Government proposes that: the remit of the National Data Guardian for Health and Social Care role should follow the health and care data.

We agree with this proposal. Health and care data needs to be used and managed securely regardless of setting.

We note that the remit of the National Data Guardian covers England only. The Information Commissioner’s Office (ICO) and healthcare regulators cover different geographic areas. We suggest that clear guidance would be helpful in highlighting the options available in other UK countries.

In relation to the proposed powers to challenge and refer organisations that fail to meet standards to a regulator, the GPhC suggests that clear guidelines are drawn up so that the process and the roles and responsibilities of the different types of regulatory authority are clearly understood. Without clarity, the burden of regulation is likely to increase and there is also the possibility that significant issues or trends may not be picked up by the relevant organisations.

2. The Government is seeking your views on: what are the key factors and issues that need to be considered when determining whether children’s social care should be part of the National Data Guardian remit and where the National Data Guardian could make a positive contribution to care services for children and young people?

As above, we would like to see greater clarity in the roles and responsibilities of the National Data Guardian and the Children’s Commissioner for England. There would be benefits in having a consistent approach to all health and care data and a single data champion for all sectors.

3. The Government proposes that: the National Data Guardian should be able to provide advice to all organisations that hold health and care data which could be used to identify individuals.

While it is important that the National Data Guardian can provide advice where appropriate, it is in the interest of better regulation that this does not duplicate work already undertaken by the ICO. There would be benefit in publications from the National Guardian being joint with the ICO rather than standalone. This would avoid confusion and ensure that there was a single authority on these types of issue.

4. The Government proposes that: any regulators with a responsibility for overseeing organisations which routinely hold, use and share health and care data, should consult the National Data Guardian on the criteria they use to assess an organisation’s use of data.

It will be important for healthcare regulators and the National Data Guardian to work closely together in this area. This could be achieved by establishing memoranda of understanding between the National Data Guardian and the regulators. As a regulator, we would be concerned that consultation with the National Data Guardian does not adversely impact our planned consultation timetables. Ideally consultation with the National Data Guardian would be accommodated within existing consultation procedures.

5. The Government proposes that: organisations holding health and care data which could be used to identify individuals should be required to publish all materials
demonstrating how they have responded to advice from the National Data Guardian.

We agree that transparency is in the public interest. We further agree with the statement that, where possible, reporting requirements are integrated into existing reporting processes, such as an annual report. We note that in some instances the timing and format of reporting may be determined by the National Data Guardian and it would be helpful to provide guidance on threshold criteria for this type of reporting.

7. The Government proposes that: the referral role of the National Data Guardian with the CQC and ICO should be set out in a Memorandum of Understanding.

We agree with this proposal and suggest that there are similar memoranda of understanding with other regulators in the health and care sector not mentioned in this section. It is important that referrals are made in a timely manner to the right organisation, so the roles and responsibilities of the different organisations must be made clear. Please also see our earlier responses in relation to the publication of guidance.

8. The Government proposes that: the National Data Guardian should have power to refer actions by an individual to the appropriate regulator for the profession concerned.

This is sensible and will help to avoid a duplication of regulation. As with 7 above, it would be important to refer cases quickly and to be clear about when a referral is appropriate.

10. Please also provide any other comments on how the National Data Guardian and regulators can maximise the appropriate use of existing sanctions and fines.

The National Data Guardian and regulators will need to co-operate and support each other's investigations to be effective. Generally, evidence of action taken by other regulators would support fitness to practise proceedings taken by a professional regulator.

11. The Government is seeking views on the most suitable long-term location for the National Data Guardian.

It is important that the chosen location supports the National Data Guardian's independence and can demonstrate cost effectiveness.

Yours sincerely

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