

IPSIS Secretariat Team
Department of Health
Richmond House
London SW1A 2NS

IPSIS.SEC@dh.gsi.gov.uk

4 November 2015

Dear Sir/Madam,

Independent Patient Safety Investigation Service Expert Advisory Group – Call for Evidence

Introduction

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It is our role to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmacy services in England, Scotland and Wales. Our core statutory functions include:

- setting the standards of education and training which pharmacists and pharmacy technicians must meet in order to join our register and to remain registered throughout their professional life
- registering pharmacists and pharmacy technicians and setting the standards of conduct and performance which they must meet to stay on our register
- setting standards which must be met by the owners of registered pharmacies and the pharmacists who act as superintendents in company-owned pharmacies
- registering pharmacies which meet those standards and inspecting them to check that they continue to do so, as the services they provide and the environment within which they operate constantly change
- taking action when our standards are not met – typically through Fitness to Practise (FtP) proceedings and enforcement action

We welcome the opportunity to contribute to this call for evidence and are happy to further engage with the Expert Advisory Group in relation to the design and operation of IPSIS.

In the present response we have included some general observations and overall concerns regarding the proposals. We have also addressed each section of the call for evidence, in the order in which it appears in the online form.

IPSIS vision and principles of operation

We are entirely supportive of the vision for IPSIS to create “a system which instils confidence and drives improvement in safety”, driven by principles such as objectivity, transparency, independence, expertise and learning for improvement.

This vision is in line with our own statutory objective to protect, promote and maintain the health, safety and wellbeing of patients and the public, as well as with our vision for pharmacy regulation to play its part in improving quality in pharmacy practice and ultimately health and wellbeing in England, Scotland and Wales.

In principle the creation of a standing fact-finding resource sitting outwith any specific judicial, quasi-judicial or regulatory process should meet a real need and we warmly welcome the initiative.

General feedback about the proposals

We feel that the proposals regarding IPSIS are currently at too early a stage for us to be able to provide any detailed comments to the specific consultation questions. There may be an opportunity to provide greater clarity regarding the scope, role and remit of IPSIS. Having considered the IPSIS Terms of Reference and the IPSIS Expert Advisory Group webpage, we would welcome further information regarding:

- the geographical scope of IPSIS
- the resources that IPSIS will have
- the scope of IPSIS investigations (For example, will it only be dealing with NHS-related investigations?)

- the relationship between IPSIS and the future NHS Improvement (Will IPSIS only deal with investigations regarding those regulated by NHS Improvement, or will they also cover primary care/community pharmacy?)
- the ultimate accountability and legal powers of IPSIS
- the timing and interdependencies between IPSIS investigations and those carried out by professional and systems regulators

The proposals for a “no blame” learning culture

A particular area we would welcome further clarity on is the proposals around a “no blame” culture and how this fits with the work of professional regulators. We would need to understand how the principle of a “no blame” investigation, together with any possible “immunity of those giving evidence” would fit with an FtP case against one of our registrants. At present, it is not clear whether you are suggesting that the concept of immunity should apply to whistleblowers and witnesses only, or to those against whom a case of negligence or wrongdoing is raised as well.

Another aspect we are concerned about is the mobility of individuals – from setting to setting, and possibly from profession to profession – and how this is going to be reflected in any outcomes from IPSIS investigations.

Independence, governance and accountability

As mentioned above, we do not feel that we have all the necessary information to comment on the specific consultation questions in this section. However, we want to highlight the importance of having Memoranda of Understanding (MoUs) or other channels to ensure greater coordination of approach between IPSIS and existing organisations with potentially overlapping functions. This could include professional regulators (including the GPhC), but also the CQC, the PHSO, the HSE, and the National Guardian, among others. Having an understanding of each other’s functions and boundaries of responsibility is important, both in view of the government’s Red tape challenge and in terms of the quality and timeliness of investigations and their impact on people giving evidence.

Engagement and transparency

We believe that transparency and engagement with patients is vitally important for an organisation of the kind that IPSIS aspires to be. We appreciate that the intention is for IPSIS to “act as an exemplary model of openness and transparency including genuine engagement with patients and their families throughout the investigation process, from start to completion”. Obviously, keeping people affected by the actions of investigated individuals/organisations in touch with the progress of investigations is crucial.

We think that transparency should be a key feature of the new body and that information should be readily available on the internet, including reports, outcomes of investigations, etc. However, we would encourage a commitment to fairness and respect for individuals’ confidentiality whilst investigations are ongoing.

We recognise the value of a learning culture, duty of candour and freedom to speak up, which seem to be the very foundation stones of IPSIS. In a joint statement published a year ago by eight of the UK’s health and care regulators, the GPhC reaffirmed the requirement that pharmacists and pharmacy technicians need to be open and transparent at all times, and provided a reminder that candour is an essential duty for all professionals. We also recognise the importance of a learning culture, where people are encouraged to reflect back on and learn from their mistakes.

However, while appreciating the learning from the Air Accident Investigation Branch, we feel that the aspect of a “no blame” culture needs to be further explored. The idea of a “no blame” culture might not be compatible with professional regulation. Certainly in the pharmacy sector, there has been significant work to develop the concept of a ‘just culture’ which recognises the importance of learning and avoiding a culture of blame. However, the ‘just culture’ concept recognises that there may be occasions where accountability is equally important in ensuring public confidence. Thinking about our investigations into poor professional practice and misconduct, we doubt that this will always satisfy the expectations of patients and the families of those affected by negligence, misconduct or a systemic failure.

What should IPSIS investigate?

We are unable to comment on this aspect, as we are still unclear about the resources that IPSIS will have at its disposal, to whom it will report, and what the scope of its operation will be.

Whatever the case, we believe that the remit of IPSIS investigations should be very clear, as should its boundaries of responsibility be in respect to other organisations with similar functions.

Supporting improvement and learning

As we understand the potential role of IPSIS, we believe that “longer-term, sustained improvement in the quality of investigations” and reduction/prevention of incidents from happening again should be a key role of IPSIS. Again, we would like to understand how this function will be compatible with a potentially high number of individual investigations and with a potentially limited resource.

People, skills, operations

We believe that the skills and capabilities required for those undertaking investigations should not differ from those expected of others carrying out investigations – including professional and systems regulators. In particular, they should be asking the right questions, rather than necessarily representing the profession/setting under investigation. In our own experience as a regulator, our Investigating Committee and Fitness to Practise Committee have both professional and lay member representation, to maximise the opportunity to reach an impartial solution, considering all aspects of the case.

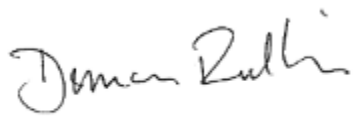
In terms of potential duplication with the processes for handling complaints and whistleblowing, we believe that this might indeed be the case with bodies such as the PHSO, the new National Guardian function, professional regulators and others. As recommended earlier, we believe that one solution to this problem could be the signing of agreements, such as MoUs, clarifying each organisation’s functions and boundaries of responsibility.

Other comments and suggested next steps

Earlier this month the GPhC met with other health and care regulators to consider the possible implications of the creation of IPSIS. Although acknowledging the importance of the potential functions of IPSIS, we thought that there remains an opportunity for greater clarity from IPSIS in relation to its scope and remit, before we can form an opinion and understand the potential impact for us as a professional and systems regulator.

One particular option would be for a meeting between the Expert Advisory Group and representatives from some or all of the nine UK health and care regulators, to discuss emerging issues and clarify the possible implications of the creation of IPSIS. We hope you would find this response helpful.

Yours faithfully,



Duncan Rudkin
Chief Executive
Tel: 0203 713 7811
Email: duncan.rudkin@pharmacyregulation.org