November 2015

# Pharmacists' Defence Association Response to Independent Patient Safety Investigations Service (IPSIS) Consultation

| representing **your** interests |

pda
the pharmacists' defence association

# Contents

# About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 25,000 individual pharmacist members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

**The primary aims of the PDA are to:**

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

# Executive Summary

It is proposed that the Independent Patient Safety Investigations Service (IPSIS) will operate from April 2016. It will offer support to NHS organisations on investigations into serious patient safety incidents, and carry out certain investigations itself. An Expert Advisory Group (EAG) has been set up to make recommendations on how the new investigation service should work, and is seeking views from a wide range of stakeholder. It wants views on 5 related themes:

- independence, governance and accountability
- engagement and transparency
- what IPSIS should investigate
- supporting improvement and learning
- people, skills, operation

The PDA welcomes the introduction of the IPSIS function, but makes the following stipulations in its response to the consultation.

- The most frequently used medical intervention in the NHS is medicine and the most frequently used point of access to NHS services is pharmacy. It is imperative that IPSIS includes pharmacy within its scope.
- IPSIS must encompass pharmacy and the Expert Advisory Group must include pharmacy representation (it currently does not). Without encompassing pharmacy, the IPSIS function will be severely impaired and non-holistic, resulting in a fundamental gap in its ability to fulfil its purpose of improving patient safety. It would be failing to consider a key area of healthcare provision which may require its focus in isolation or as a result of overlap with other multidisciplinary investigations to improve the safety of patients.
- Whilst retaining healthcare expertise, there must be significant representation on the IPSIS board from non-healthcare professions in order to enhance its risk management expertise, reduce the risk of situational over-familiarity and ensure an appropriate level of independence from the healthcare professions is maintained. Healthcare expertise on the board would need to be impartial or appropriately representative of the healthcare professions and independent from external influence.
- Within reason, IPSIS must be in a position to offer legal privilege. There must, however, be limits to this; where an individual may present, by virtue of his/her deliberate actions or incompetence, a risk to the public, IPSIS must be able to refer that individual to the appropriate authorities.
- IPSIS must be able to identify instances in which individuals or organisations are seeking to use IPSIS involvement for their own ends – for example to obscure a problem through misdirection or falsely embracing the IPSIS function, head off a complaint or supplement their own resources.
- Monitoring of recommendations made must be a function of IPSIS. The PDA strongly believes IPSIS should have the necessary powers to follow up any recommendations it makes.
- Eventually IPSIS should become a function that trains others to carry out more effective safety investigations, reviews and carries out quality control on investigations, shares learning and conducts its own investigations only when something extraordinary happens or an organisation providing NHS services fails in its duty to carry out its own investigation.
- IPSIS must work independently, without boundaries and remain free from corporate influence. There must be no patient safety issue which IPSIS is unable or afraid to address. It should support and encourage learning first and foremost, but must also be able to hold organisations to account to the same extent, proportionately and appropriately, for taking action as a result of its recommendations.
- IPSIS' right of entry in to premises and associated offices of organisations providing NHS services under contract (such as community pharmacies and privately operated hospital pharmacies) should be set out in law to enable IPSIS to function effectively. It is fundamental that IPSIS be able to conduct investigations itself and retain control of those investigations in any setting providing NHS services.

# Introduction

We believe that the Independent Patient Safety Investigation Service (IPSIS) will provide a much needed independent and objective agency to help to improve the quality and timeliness of investigations in to patient safety issues within the NHS and organisations providing NHS services. In particular, we believe that the ability of the service to look at higher-level systemic issues, with a focus on improvement rather than seeking to apportion blame and punish individuals, will be a great step forward. In this respect the inclusion on the advisory board of representatives from the Air Accidents Investigations Branch will provide valuable input from what is widely regarded as the exemplar for safety improvement.

***Recommendation***

*The most frequently used medical intervention in the NHS is medicine and the most frequently used point of access to NHS services is pharmacy. It is imperative that IPSIS includes pharmacy within its scope.*

- Over 1 billion prescriptions are dispensed in the community each year at a cost to the NHS of £9 billion [1] [3]
- 1.6 million people visit a pharmacy each day [10]
- 84% of the adult population visit a pharmacy each year [10]
- the average adult visits a pharmacy 16 times a year [10]

These vital aspects of NHS services are often overlooked and we are concerned that the Expert Advisory Group (EAG) includes no-one with an expertise in medicines in general or pharmacy in particular. Despite medication being a factor in many of the incidents at Stafford Hospital the Francis Report contained only one reference to medicines and none whatsoever of the role of pharmacy or of the pharmacist. This was a major oversight in the report and one which IPSIS is in a position to avoid repeating.

***Recommendation***

*IPSIS must encompass pharmacy and the Expert Advisory Group must include pharmacy representation. Without encompassing pharmacy, the IPSIS function will be severely impaired and non-holistic, resulting in a fundamental gap in its ability to fulfil its purpose of improving patient safety. It would be failing to consider a key area of healthcare provision which may require its focus in isolation or as a result of overlap with other multidisciplinary investigations to improve the safety of patients.*

## Context

According to NHS England, every year: [1]

**In hospitals:**

- Over 2.5 million doses of medicines are administered in the average acute hospital
  - Of these over 215,000 include errors
- Over half a million prescriptions are written in the average acute hospital; of these
  - There are 45,000 prescribing errors
  - Of which 550 are potentially fatal
  - There are 40 – 100 dispensing errors
- 97,000 patients admitted to all acute hospitals suffer harm due to medicines
- 2,500 preventable deaths across all acute hospitals are due to medication

**In the community:**

- Over one billion prescriptions are dispensed. Included in this total:
  - There are 50 million prescribing errors
  - Estimates of the number of dispensing errors range between 400,000 and 33 million. This corresponds to a dispensing error rate of 0.04% to 3.32 [4]
- 600,000 non-elective hospital admissions are due to medicines
  - Of which 70% are preventable

According to an MHRA Patient Safety Alert, 5%-7% of prescription items include a prescribing error. [2]. A study by the GMC shows that prescribing or monitoring errors were detected for one in eight patients. [5]

Whilst we accept that the incidence of harm is low, the sheer scale of medication supply in both hospital and community settings means that the overall numbers of patients harmed is high and the cost to the NHS is very significant.

Our own research shows that medication errors in the community lead to over 600 civil claims for compensation each year; this excludes claims settled by arrangement between the patient and a pharmacy company. More worryingly, we know that issues with prescription and over-the-counter-medicines were cited on the death certificates of 3,346 people in England and Wales in 2014. [9] The issues were multifactorial but pharmacy is in a prime position to intervene and to make a significant difference.

## The Role of Pharmacy in the NHS

Pharmacy and pharmacists perform a vital role in both primary and secondary care and in the link between the two. However, the potential of the role is barely being exploited – particularly in respect of improving patient safety in primary care and in the transfer of care between primary and secondary care. A recent development in the role of community pharmacy is that pharmacists will be given access to summary care records. In the proof of concept phase it was found that pharmacist involvement resulted in an 18% reduction in prescribing errors. [6]

## Overlap Between IPSIS and GPhC Responsibilities

The role of healthcare professional regulators is concentrated on the fitness to practice of individuals. The operational environment in which they function and certain other wider issues with direct or indirect impact on public safety are beyond their remit and are often neglected. This is particularly true for pharmacy. The General Pharmaceutical Council (GPhC) has little scope to influence the practice of pharmacy (which is largely controlled by multinational corporate organisations whose ownership is based outside the UK) or the role that pharmacy and pharmacists play in the prescribing, supply and administration of medicines to patients. The General Pharmaceutical Council do not maintain a register of pharmacy owners and at present the proposed revisions set out in the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2015 draft SI make no provision nor proposal for them to do so. As such, the GPhC's influence is restricted to the application of sanctions to registrants (pharmacists and pharmacy technicians).

## IPSIS' Sphere of Influence

IPSIS needs to be able to extend its influence more widely, for example through its ability to hold non-regulated persons and organisations to account for improving patient safety, or to highlight where an organisational issue has been identified or the input of a non-registered professional would be helpful or necessary in influencing a safety-related issue.

IPSIS has the potential to address these issues and we believe that it can and should. The EAG must include some expertise on medicines and pharmacy and the scope of IPSIS work must include those organisations contracted to provide patient services on behalf of the NHS – including pharmacy. IPSIS would certainly have a role to play in supporting safety improvement in pharmacy itself and its investigations will frequently involve working across multiple sectors of healthcare practice, necessarily including pharmacy.

# Questions

### 1. What is your name?

The Pharmacists' Defence Association.

### 2. What is your email address?

john.murphy@the-pda.org

### 3. Would you categorise your response as from

- Individual
- Public sector organisation
- Charitable/voluntary sector
- Private sector - Healthcare
- Private sector - other

### 4. What should independence in relation to this investigation function mean?

Independence must mean that IPSIS is free of any intervention or undue influence which may have an adverse effect on its ability to exercise its functions. This must include financial independence, political independence and organisational independence. To be truly independent it must sit (and be seen as sitting) outside any party with a vested interest; in particular, it must be free (and seen as free) from influence by any organisation involved with patient care and any organisation with a direct or indirect commercial interest.

We are concerned that the plan to fund IPSIS through NHS Trusts puts its financial and organisational independence at risk. Separate funding should be identified.

### 5. What are the conditions necessary for this service to secure and maintain its independence and impartiality? How can these conditions be achieved?

It is vital that IPSIS is seen to be independent and impartial both by the public and healthcare professions. Furthermore, it must drive improvements to patient safety rather than seeking to apportion blame or punish organisations and individuals and be seen to be achieving the same.

To achieve these objectives, the driving force and executive management structure must be drawn from industries and disciplines with safety at heart, such as risk management disciplines.

> **Recommendation**
>
> *Whilst retaining healthcare expertise, there must be significant representation on the IPSIS board from non-healthcare professions in order to enhance its risk management expertise, reduce the risk of situational over-familiarity and ensure an appropriate level of independence from the healthcare professions is maintained. Healthcare expertise on the board would need to be impartial or appropriately representative of the healthcare professions and independent from external influence.*

Effective representation of healthcare professions outside the board should be made through a panel of experts who provide particular expertise and aid IPSIS executives to understand the healthcare issues, as well as individuals who are required to further understand or expedite investigations.

Appointments to the IPSIS board must be made independently of its function. The appointment process must be open and transparent and subject to oversight by a publicly accountable body. Appointments and the rationale for that appointment must be published and available for scrutiny at all times. Any conflict of interest must be declared and openly disclosed.

### 6. What are the necessary accountability arrangements to ensure this investigation service maintains its independence and impartiality?

IPSIS must be seen to be accountable to the public and subject to public scrutiny. We do not believe that this can be achieved within the structure of the Department of Health. It may be necessary to make IPSIS accountable to the Secretary of State for Health, however safeguards need to be put in place to protect it from political influence.

We do not believe that Monitor is the appropriate body to which IPSIS should be accountable. Monitor's function is concerned with quality and efficiency; these are not always fully aligned to a focus on patient safety. There is a danger that IPSIS' vital function will be subsumed under Monitor's broader remit and its impact will be adversely affected as a result.

### 7. What are the necessary internal and external governance arrangements to ensure this investigation service maintains its independence and impartiality?

Carefully and correctly setting the remit and terms of reference of IPSIS are vital. These need to be clearly framed and widely published. It is against these that its processes and performance will be judged.

Performance against its remit and terms of reference must be reviewed and published annually. Where there is variance, the causes must be analysed and the implications made clear and discussed with stakeholders and government. This might result in confirmation of scope and terms or reference; alternatively, it might result in changes to the board of IPSIS or to the terms of reference.

This process must be replicated within the organisation so that each investigation team has its own terms of reference and is subject to the same level of scrutiny, both from within and outside the organisation. This should include a self-assessment toolkit to ensure that:

- A risk assessment is carried out and published each year and for each investigation
- Potential conflicts of interest are declared and disclosed
- The independence of the board, management and investigation team members can be established and disclosed
- External influence, whether at board, management or investigation level, can be recognised, identified and mitigated as appropriate
- No individual is in a position to have his/ her ideology, opinion or interests affect the work of the organisation, functions or actions

### 8. What are legal and other implications for aligning with and supporting existing and developing statutory bodies such as coroners, regulators or medical examiners?

IPSIS can learn from existing statutory bodies and can use some of their structures and processes as a model for its own. However, IPSIS must maintain its separation and independence. It must not be subservient to or influenced by pressure from any of those statutory bodies. Nor should it, by virtue of its composition, be seen as being allied or aligned with any statutory body.

It is vital that IPSIS can obtain information from Coroners, Medical Examiners and regulatory bodies and its lines of communication must be open and dynamic. Speed of investigation will be key to IPSIS' credibility; the flow of information must not be slowed by judicial delay or obfuscation.

The role of IPSIS is to promote patient safety; this will be effected by looking at higher-level systemic issues rather than individual fitness to practice – that is the work of a healthcare professional regulator. In order to achieve this, IPSIS will need to get to the heart of what the system and the individuals did, thought and felt in any incident. All those involved must feel that they are not incriminating themselves in the eyes of the law, their profession or their employers.

***Recommendation***

*Within reason, IPSIS must be in a position to offer legal privilege. There must, however, be limits to this; where an individual may present, by virtue of his/her deliberate actions or incompetence, a risk to the public, IPSIS must be able to refer that individual to the appropriate authorities.*

### 9. How can the function make sure patients, their families, carers and healthcare staff feel supported when things go wrong, and have the confidence to act appropriately? Are there any other elements that could be introduced to ensure the function is valued and credible?

IPSIS must be approachable, clear in its remit and terms of reference and have a very robust and transparent investigation process. Clear, timely and concise communication will be fundamental to ensuring that patients, carers and healthcare staff feel supported.

From the initial contact that any individual or organisation has with IPSIS it must be clear that their concerns will be taken seriously and that their input will be confidential. The process by which their concerns will be assessed must be made clear and timescales put to it. A named contact, method of communication and timetable must be given to the person or persons making contact with IPSIS.

Where IPSIS determines that it is better for the concern to be raised with another body, this must be made clear to the person or organisation raising the concern as soon as possible and IPSIS should offer support in referring the concern to that body.

Where IPSIS determines that an investigation is necessary or desirable it must make it clear what the process will be. This must include a communication plan with the person or persons raising the concern.

When IPSIS begins to call for evidence or interview stakeholders, the confidentiality of their input must be protected. Where appropriate the communication plan should be amended to include updates to individuals or organisations as appropriate.

Investigation teams and IPSIS as a whole must have their performance measured against adherence to its timetables and communication plans.

### 10. What information should IPSIS be sharing and putting into the public domain?

For each investigation, IPSIS must report its determination and its recommendations. It should not report full details of individuals obtained in its investigations; exceptionally it may wish to include particular items where they are useful in illustrating an issue and/or its resolution. However, the principle that IPSIS is there to improve patient safety by addressing systemic issues should be paramount. IPSIS will be less successful if it publishes information that allows individuals to be identified and subject to pressure from their colleagues, peers or organisations.

IPSIS should be publishing high-level aggregated anonymised data relating to performance and investigations conducted. This should include a breakdown of the number of investigations by criteria and parameters that are useful to stakeholders.

Equally it should be publishing data about approaches to it that have not resulted in investigations and the reasons why these have been referred or rejected.

IPSIS should be reporting on common threads and learning points that it has identified in the course of its investigations. It may choose to make learning points sector-specific and publish specific reports for different stakeholders where it considers this to be helpful in improving patient safety.

### 11. The service may respond to requests from providers or others to conduct investigations, and proactively identify incidents or concerns to investigate, What are the advantages and disadvantages of doing both or one or the other?

IPSIS must be capable of responding to concerns raised by individuals or organisations AND it must be capable of initiating its own investigations.

IPSIS is not being established to be the arbiter of complaints against health service providers; rather, it is being established to seek improvements to patient safety through system change. As such it may choose not to respond to any request except where that request reveals or is symptomatic of a systemic issue.

Any individual, whether patient, carer or healthcare employee, must feel that they can raise an issue with IPSIS. IPSIS must ensure that existing and appropriate complaints procedures have been followed and must be able to judge whether the outcomes of those complaints procedures are fair and just. It is only when ISPSIS identifies a systemic issue that it should initiate an investigation. Its processes must be robust in the elimination of the malicious, misinformed or simply frustrated individual.

IPSIS must be in a position to judge whether any request – by any individual or organisation – is an appropriate trigger for an investigation. It will have limited resources and these need to be spent in a way which maximizes improvement.

> ***Recommendation***
>
> *IPSIS must be able to identify instances in which individuals or organisations are seeking to use IPSIS involvement for their own ends – for example to obscure a problem through misdirection or falsely embracing the IPSIS function, head off a complaint or supplement their own resources.*

### 12. Given the scale of patient safety incidents in the NHS, the function could not hope to investigate all reported incidents. How should the new service prioritise the incidents or concerns required for investigation? What type of criteria could it apply?

IPSIS will require a grading process. This should encompass the severity of any incident and the frequency with which it has occurred or may occur.

It would be very easy for IPSIS to concentrate on those issues that grab media headlines. However, an appropriate balance must be struck; these may be isolated incidents with little likelihood of repetition. While they might be catastrophic for the individual(s) involved they may be once-in-a-decade events.

Other events may be happening with much greater frequency but with lower individual impact. Overall these may have a greater effect on the population and the NHS as a whole. We suggest that medicines-related issues are in this category and are worthy of greater focus.

### 13. Should there be legal powers or legislation for the immunity of those giving evidence?

Disclosures made to IPSIS under the Public Interest Disclosure Act must be protected through IPSIS' inclusion on the Prescribed Persons list.

It is important that people feel able to speak up and provide evidence. Those required to give evidence may incriminate themselves. It may be necessary for them to acknowledge their own shortcomings, and only by them doing so may it be possible to share the learning more widely. Legislative immunity would allow people to do that, which would in turn support the wider sharing of learning from IPSIS investigations.

Similarly, it may be that the evidence of individuals puts them at risk of incurring the displeasure of their colleagues or employers. Protected disclosure would in some cases support better root cause analysis, as it would help to give people the freedom to speak up.

### 14. Should the function develop and/or recommend solutions or be limited to undertaking and reporting the findings from investigations?

IPSIS must be able to make recommendations which must be action-orientated. If it could not make recommendations it would simply be cataloguing incidents and the factors contributing to an event or series of events and would not achieve its primary purpose – improving patient safety.

### 15. What can be done to ensure this support results in longer-term, sustained improvement in the quality of investigations and reduces or prevents incidents happening again? Should this be monitored and, if so, how?

This question is ambiguous; it may refer to the quality of investigations conducted by IPSIS or it may refer to investigations carried out by the organisations being supported by IPSIS.

We will address each in turn.

IPSIS must analyse its own performance in investigations as has been previously addressed. Part of that analysis should include whether its recommendations have been implemented and whether similar incidents have been repeated within the organisation being investigated, or more widely.

With regard to investigations carried out by organisations other than IPSIS, IPSIS should have broad oversight of total incident rates and number of incidents with particular characteristics in order to inform its focus.

The accountability to prevent incidents with similar characteristics must remain with individual organisations, as must the monitoring of incident rates. Safety is the accountability of all healthcare organisations – it is not the province of IPSIS. The provision of guidance or support should be within the scope of IPSIS.

### 16. Should the implementation of recommendations made by the national function, either as a result of individual investigation findings or wider insights be monitored and, if yes, how could this be achieved?

**Recommendation**

*Monitoring of recommendations made must be a function of IPSIS. The PDA strongly believes IPSIS should have the necessary powers to follow up any recommendations it makes.*

Within its report on an investigation, IPSIS should give a timetable for actions and identify who is responsible for implementing those actions. In order to ensure that actions are realistic and achievable, ISPIS should involve stakeholders in development of the action list and timetable.

It is inevitable that there will be conflict between the cost of implementation of recommendations and other issues that an organisation will be attempting to manage. However, we believe that it is essential that IPSIS be in a position to refer poor performance against an improvement plan to the next organisational level or to a regulator.

In that context we are concerned that, with respect to pharmacy, any recommended system improvement may be stalled by non-pharmacist pharmacy owners and pharmacy owners resident outside the UK who are not subject to effective sanctions by the regulator.

### 17. What are the skills and capabilities required for those undertaking investigations and working in the function more widely?

An investigation might involve any NHS service. This encompasses a huge range of disciplines, technologies and cultures.

The core skills for IPSIS and any IPSIS investigation team are based on project management, safety investigation and communication.

A project manager would be required to set a structure for an investigation, identify stakeholders, establish a communication plan and identify resources to carry out the investigation.

The project manager would then call on whatever expertise they needed. We believe that this would include some forensic skills and experience from whatever healthcare profession(s) were involved and from those able to offer key insights through the experience of similar issues or processes.

### 18. How can the function and its staff complement and support the wider patient safety learning and leadership functions?

We believe that IPSIS will develop over time.

Initially it will develop and hone its processes by carrying out a significant proportion of investigations itself.

Over time, it will establish its credibility, expertise and processes and will become a body that helps client organisations carry out their own investigations.

**Recommendation**

*Eventually IPSIS should become a function that trains others to carry out more effective safety investigations, reviews and carries out quality control on investigations, shares learning and conducts its own investigations only when something extraordinary happens or an organisation providing NHS services fails in its duty to carry out its own investigation.*

### 19. Is there any risk of duplication with the processes for handling complaints and whistle-blowing both nationally and at the local level? If so, how might these be overcome?

Simultaneous investigation by a regulator and/or internally within an organisation and IPSIS does not automatically mean duplication of effort. It will be necessary for IPSIS to understand the work already in progress and to agree with interested parties what lines of inquiry each should lead.

However, we believe that some duplication is inevitable but that it is better that there be some duplication rather than issues be missed and improvements precluded.

### 20. What other systems, processes or organisations exist that may play a similar role to IPSIS? Are there any risks of duplication and if so how may these be overcome?

IPSIS should have oversight of any investigations being carried out by other public bodies pertinent to its own investigations. To ensure efficiency and minimise duplication, IPSIS should agree with the other investigating party what their involvement needs to be. This should be initiated as soon as possible, i.e. as soon as it becomes apparent that IPSIS involvement will be required. The approach should be agreed and the investigation carried out jointly or individually as appropriate.

Furthermore, IPSIS should have sight of all information considered by another party. For example, if the GPhC determines that a registrant has no case to answer in a fitness to practice case, all evidence is withheld. IPSIS must have sight of information withheld in the determination in order to identify any systemic issues.

### 21. If you have any other comments on the scope, organisation or function of IPSIS that you would like to submit as part of this Call for Evidence for the Expert Advisory Group to consider, please do so here (stating what aspects it relates to).

The European Court of Justice said in its determination – C-531/06 and in joined cases C171/07 and C172/07, May 2009 - that "a pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence. Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists" and member states may therefore take the view that "the operation of a pharmacy by a non-pharmacist may represent a risk to public health". Furthermore, it was said that "there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator [, which] could make it difficult for them to oppose instructions given by him". (7)

The International Pharmacy Federation Executive Committee and Community Pharmacy Section officially concluded in its summary of its symposium on Professional Autonomy in 2009 that 'Because of prevailing social, economic, and political forces, there will continue to be immense tension between corporate and professional imperatives in pharmacy.' (8)

The professionalism of the healthcare professional is undermined when:

- The system in which they operate is inadequate, pressurised or subject to untenable workload
- Processes are inadequate, inappropriate or undermine the ability of the healthcare professional to act independently
- Support staff levels are inadequate and / or their training is poor
- Funding is inadequate
- Targets are applied inappropriately

Our experience leads us to believe that all of the above affect community pharmacy practice and that IPSIS should consider these issues within its remit.

Since 2009, corporatisation of pharmacy in the UK has increased markedly. Over 50% of community pharmacies in the UK are part of major chains, and at least 40% are owned by groups with their headquarters outside the UK and whose executive directors at their highest level are almost exclusively non-pharmacists. Hospital pharmacy services are being contracted to the same chains. This accentuates the tensions between corporate and professional imperatives and is a high-level issue of which IPSIS should mindful as it considers how to improve patient safety. As such, from a pharmacy and patient safety perspective, IPSIS could not be more valuable.

***Recommendation***

*IPSIS must work independently, without boundaries and remain free from corporate influence. There must be no patient safety issue which IPSIS is unable or afraid to address. It should support and encourage learning first and foremost, but must also be able to hold organisations to account to the same extent, proportionately and appropriately, for taking action as a result of its recommendations.*

In order to be able to exercise its role, a key issue needs to be addressed. It is perhaps a challenging issue and is one which would be easy to overlook, but to overlook it would be to the detriment of patients. The issue to which we refer is that many NHS services, such as is the case in community pharmacy, are provided through third-party organisations where rights of access to premises would need to be established. In order for the EAG to have fulfilled its role in creating an effective IPSIS function, it is essential that this issue be considered and addressed.

***Recommendation***

*IPSIS' right of entry in to premises and associated offices of organisations providing NHS services under contract (such as community pharmacies and privately operated hospital pharmacies) should be set out in law to enable IPSIS to function effectively. It is fundamental that IPSIS be able to conduct investigations itself and retain control of those investigations in any setting providing NHS services.*

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