All PSNC members can attend this meeting and may speak with the permission of the Chairman.

PSNC Health Policy and Regulations Subcommittee Agenda

For the meeting to be held on Tuesday 12th May 2015

At York Marriott, Tadcaster Road, York, YO24 1QQ

Commencing at 11:15am in the Classic Suite

Members: Ian Cubbin (Chair), David Evans, Margaret MacRury, Prakash Patel, Janice Perkins.

Apologies for absence

No apologies for absence have been received at the time of setting the agenda.

Minutes of the previous meeting and matters arising

The minutes of the meeting held on 10th March 2015 were shared with the subcommittee and can be downloaded from PSNC's website.

Agenda and Subcommittee Work

Below we set out progress and actions required on the work plan areas for the year. The subcommittee is asked to consider the reports; to address any actions required; and comment on the proposed next steps.

1	Seek the best possible resolution of prescription direction	Status

Report

The General Pharmaceutical Council has published its Guidance on providing pharmacy services at a distance, details of which are available through PSNC's website. During the consultation on the draft, PSNC submitted comments about direction of prescriptions and patient consent, particularly relating to distance selling pharmacies. PSNC also raised concerns about patients and the public being misled as to the identity or location of pharmacies. These points have been taken on board in the final Guidance. A news item and a briefing paper have been added to the PSNC website and LPCs have been alerted to the Guidance. The May edition of CPN will also contain an article.

At the March meeting the subcommittee agreed that the publication of pharmacy level dispensing data, and information identifying the medical practice where prescriptions originate, allows identification of potential direction of prescriptions. The data can provide compelling evidence, and the subcommittee resolved that contractors be informed of the data which is available, and, where local analysis points to direction of prescriptions, be asked to raise this with NHS England local offices and copied to PSNC to add strength to our campaign for NHS England / Department of Health to take effective action. The May edition of CPN will contain an article highlighting the dispensing data available from NHSBSA and PSNC's latest work in this area including the work to develop a poster with NHS England. The article will be promoted via the PSNC website and social media accounts, and alongside it we will publish a video to answer common questions on this topic.

It was reported to the March meeting that Dr David Geddes had a meeting with Kevin Baron and Oliver Colville to discuss NHS England's activity on prescription direction. Dr Geddes gave an assurance that NHS England would press ahead with the poster campaign. NHS England held a meeting with stakeholders, after which an email was circulated by NHS England proposing wording for a poster. Representatives from the General Practitioners Committee and from PSNC acknowledged receipt and submitted comments (to inform that there was a spelling mistake), but NHS England had been

expecting more of a response. A formal response, together with further comments has been sent by PSNC.

Subcommittee Action: The subcommittee is asked to consider whether any additional action should be pursued at this stage.

Next Steps: Maintain a dossier, in the event the light touch regime is ineffective.

2	Secure changes to the regulatory framework governing provision of pharmaceutical services that support and protect the interests of contractors	Status

For decision

Department of Health Consultation on Rebalancing Medicines Legislation

The consultation document on rebalancing medicines legislation and pharmacy regulation published by the Department of Health was discussed at the March meeting and the subcommittee was informed that the proposal is to remove the threat of criminal sanction for inadvertent preparation and dispensing errors, whilst retaining the criminal sanction for those errors or deliberate acts that are such that the pharmacy professionals responsible for them cannot properly be said to have been acting professionally.

A response is being drafted and has been shared with the National Pharmacy Association and Pharmacy Voice to ensure that the response from the pharmacy bodies is consistent.

A summary of the consultation questions and the principles used for the response is circulated as **Appendix HPR 02/05/15.**

The subcommittee is asked for its confirmation that this is the appropriate line to take.

Community Pharmacy Assurance Framework

The discussions that PSNC had with the NHS England and the NHSBSA seem to have been stalled, but a paper is expected to be provided by NHS England setting out its proposals in detail, in time for the meeting.

The subcommittee had expressed concern about the susceptibility of CPAF reports to Freedom of Information requests. NHS England took legal advice and also sought views from the NHSBSA which has extensive experience of the Act. Their position is that CPAF reports would be released by NHS England, if a FoI request was made. NHS England legal advisers also expressed the view that pharmacy contractors, as public authorities in their own right (for the purpose of their NHS work) would be required to respond to FoI requests if they were made directly to the pharmacy for these reports. The Chief Executive and the Director of Regulation and Support have considered these views and the legislation and agree that pharmacy contractors could receive requests individually, although this is less likely than if the reports from many pharmacies are collated by NHS England. There is thus little difference between requests made to NHS England or to the contractors – both are likely to have to release the details if a CPAF report or a PSNC contract workbook is completed. Because PSNC has formerly supported the use of CPAF and encouraged pharmacy contractors to use these processes for self assessment, and to try to minimise the time spent at pharmacies by NHS monitoring teams, a briefing has been issued to LPCs and on the website (with a follow up in the CPN) to alert contractors that if they complete a contract monitoring form or CPAF, they would need to be able to respond to an FoI request, balancing any commercial sensitivities with the public interest.
The briefing paper from NHS England will be circulated at the meeting.

Inducements

The subject of inducements was discussed in October. The link between inducements and direction of prescriptions was noted. A paper with options is circulated as **Appendix HPR 05/05/15.**

The subcommittee is asked for its recommendations.

Report

Same or adjacent premises and Pharmacy Closures

In regards to the same or adjacent premises (Regulation 31) and market entry barriers to Pharmacy closures / mergers, the subcommittee agreed that steps should be taken to remove any barriers to pharmacy mergers caused by Regulation 31. The subcommittee also discussed how market entry arrangements (PNA Supplementary Statements and Unforeseen benefits) can act as a disincentive to contractors that might consider rationalising their premises.

The subcommittee recommended that the Department of Health (DH) should be asked to consider amending Regulation 31 to allow mergers and it should also consider amending the guidance to Local Authorities on supplementary statements so that they do not automatically issue a Supplementary Statement when a pharmacy closes as a planned rationalisation. A letter has been sent to the DH and any response will be brought to the attention of the subcommittee.

The subcommittee also recommended that NHS England should update its guidance to Regions on the handling of unforeseen benefits applications, where there has been a pharmacy closure which took place as part of planned rationalisation.

The Director of Regulation and Support was invited by NHS England to speak to Pharmacy Advisors and Contract Managers on Market Entry applications at their meeting in March and took the opportunity to raise the points raised by the subcommittee about barriers to pharmacy closures. The same points were also made at a training event for LPC 'new' members and at a Market Entry Masterclass in April.

Local Authority Commissioning

A small number of LPCs have contacted PSNC about the failure of local authorities to consult them when considering commissioning NHS services which could be provided by pharmacies (e.g. health checks). As there is no requirement in the NHS Regulations 2013 requiring local authorities to consult LPCs (apart from the contents of the PNA), the subcommittee recommended that the DH be asked to consider issuing guidance to the LGA on the value of engaging with LPCs and consider requiring consultation of LRCs when commissioning NHS services.

NHS bodies and Local Authorities Partnership Arrangements (Amendment) Regulations 2015

PSNC responded to the consultation on the above regulations. PSNC suggested that Essential and Advanced services must remain outside any such pooled arrangements. In responding to the consultation PSNC expressed a desire to discuss concerns it has for partnership arrangements to include pharmacy funding (the response to the consultation is circulated as **Appendix HPR 06/05/15**. In response the NHS England has agreed a meeting in June.

Greater Manchester

The subcommittee is aware of the proposal to devolve to Greater Manchester and NHS England a £6bn budget. This area covers 12 CCGs, 10 Local Authorities and 14 NHS providers. It is hoped that a full agreement will be reached around partnership working in Greater Manchester on health and social care, recognising the link between physical, mental and social wellbeing.

The report from NHS England states that there would not be a need for any NHS administrative reorganisation and makes use of existing legislative freedoms. The local NHS will be expected to meet or exceed service improvements set for the NHS in the annual mandate agreed by government and NHS England.

Following the original devolution deal, NHS England invited the GMCA, Greater Manchester Clinical Commissioning Groups (CCGs) and the area's NHS providers to develop a plan for joining up – or integrating – health and social care across Greater Manchester. These plans also fit within a place-based approach to health and care reform in the context of the national Five Year Forward View set out by NHS England.

It was agreed at the March meeting that there is still no clarity on the arrangements for commissioning, and the subcommittee will want to keep a close eye on developments. There are many opportunities in Manchester as a result of the changes, and the LPCs across the area will need to review their governance arrangements as consultation may be required on a pan-Manchester basis. It was reported at the March meeting that Pharmacy Voice are due to discuss, and it expected that PSNC will be invited to attend.

No further information is available at the time of preparing the agenda.

GPhC Consultation on fees

The GPhC has consulted on the draft 2015 fees rules. The fees are proposed to increase from £221 to £241 for pharmacy premises, £240 - £250 for pharmacists, and £108 - £118 for pharmacy technicians. These are the first increases in premises fees since 2012 and the first increase in pharmacist fees since 2013. It was proposed at the March meeting that a response should be prepared making the general point that a 9% increase in fees is unwelcome, even in circumstances where there has been a pause in the increases. The response will also make the point that fees should be transparent and that the GPhC should ensure that its inspection procedures should be efficient and offer value for money.

The subcommittee is aware of the practice of other regulators (e.g. CQC and MHRA) to adopt a risk based inspection model and it will consider at a future meeting whether a risk based approach would produce a fairer allocation of costs.

This issue is to be brought to a future meeting.

Regulations Amendments – Schedule 2 & 3 Controlled Drugs

The subcommittee was informed in January about proposals to amend the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (PhS). Following the consultation the Department of Health decided against taking forward the proposals to permit electronic transmission of all controlled drugs.

The subcommittee was concerned that electronic prescribing of CDs has not been pursued. It was confirmed that the delay did not mark a policy shift, it was just to allow alignment with the Home Office. The Office was asked to seek further information on expected timescales.

The subcommittee will be pleased to hear that regulations have subsequently been laid before Parliament and will come into force on 1 July 2015.

When system suppliers were first informed of the change, they expressed concern about the short lead in time, and commented that HSCIC must approve any changes that they make to the pharmacy systems, and this usually takes around three months. The Director of Regulation and Support contacted the Department of Health to ask that it intervenes to ensure that HSCIC processes do not cause undue delay in implementation.

Unfortunately, whilst prescribers will be authorised to issue electronic prescriptions for schedule 2 and 3 CDs from that date, and pharmacists will be able to dispense them, the electronic prescription service architecture does not include provision for the quantity to be expressed in words as well as figures (a requirement of the Misuse of Drugs Regulations – which PSNC opposed during the consultation). This means HSCIC will need to re-engineer the electronic prescription service before pharmacy and prescribing system suppliers are able to amend their systems, and obtain HSCIC approval. It is inconceivable that this will be achieved before 1 July.

The amendment regulations also remove the exemption from the prescription writing requirements for temazepam. This amendment comes into force on 1 June.

Consultation on market entry applications
This will be brought back to the subcommittee in July.

Timescales for applications
This will be brought back to the subcommittee in July.

Clinical Governance (distance selling)
A paper will be brought back to the subcommittee in July.

Fraudulent NHS prescription exemption claims checking
The announcement of electronic systems to allow additional checks by pharmacists of a patient's entitlement to exemption had been made without consultation with PSNC.

Regulations allowing sharing of information: The Social Security (Information-sharing) (NHS Payments and Remission of Charges etc.) (England) Regulations 2015 came into force on 1 April.

The Regulations, made under the Welfare Reform Act 2012, prescribe the extent of information-sharing which is permitted for purposes relating to entitlement, based on receipt of a relevant social security benefit, to health service benefits such as exemptions from National Health Service charges, free sight tests, and payments or vouchers towards expenses or appliances – and to related enforcement action.

The Act allows the Secretary of State for Work and Pensions (or a person providing services to the Secretary of State for Work and Pensions) to supply relevant information relating to certain social security benefits or welfare services to a "qualifying person".
Those who are required to make and recover charges (which would include pharmacy contractors) are included in the list of "qualifying persons" and so are persons to whom the Secretary of State for Work and Pensions may supply information for prescribed purposes.
The prescribed purposes includes 'providing the persons [who are due to pay the prescription charge, but who are attempting to claim exemption] with advice, assistance and support in relation to entitlement to remission of a charge payable on the grounds of a social security benefit.

This means that the legislative framework to allow sharing of eligibility for exemption from charges on the grounds of receipt of social security benefits is now in place.

NHS Standard Contract
It was noted that the Manchester arrangements are just a 12 page MoU. It was agreed that the office will make representations to NHS England Standard Contract team, and a letter has been sent. Any feedback will be brought to the subcommittee.

Boxing Day

As part of the meeting mentioned in item 4 above, the Director of Regulation and Support was invited to attend and present to NHS England staff, the work PSNC had done in highlighting Boxing Day as an issue, and the encouragement of LPCs to work with NHS England local offices and contractors to ensure adequate coverage of pharmacies. However, NHS England was due to have a further internal discussion on the day after that meeting, and it was decided that it would reduce the potential for confusion if no mention was made. There has been no further feedback from NHS England about its processes for ensuring adequate cover over the Christmas 2015 period.

Pregabalin

Following the last meeting of the subcommittee, Pfizer responded to the Director of Regulation and Support's email questioning the decision to not supply Lyrica when prescribed for the patent indication (neuropathic pain) when quotas had been exceeded. They appear to have reviewed their policy as set out in their letter which is circulated as **Appendix HPR 07/05/15 (pages 29 - 31).**

Pfizer's Legal affairs department has been in further contact with PSNC to say that an appeal against the first judgment not to grant an injunction, was due to be heard at the end of April/beginning of May and the substantive case is due in June. It is likely that the substantive case will result in a deferred judgment.

Pulse magazine has published a series of articles following expressions of concern by GPs about the additional unfunded work of reviewing all the patients for whom they prescribe pregabalin, to switch to Lyrica if the indication is neuropathic pain. In one case reported in the articles, a CCG has carried out an assessment of patients on behalf of its GPs and has sent an invoice to NHS England for the costs of the exercise.

Pulse also contacted PSNC questioning why pharmacists are advised by PSNC to refer prescriptions back to GPs if pregabalin is ordered, where the pharmacist has grounds to believe it is being prescribed for neuropathic pain. The Head of Communications and Public Affairs and the Director of Regulation and Support provided a substantial amount of feedback and responses to further questions. Unfortunately the article that appeared on the Pulse on-line publication erroneously reported that PSNC's position was that pharmacies would not otherwise get paid for the brand, if the generic was ordered. This had not been stated by PSNC, and in fact it is incorrect because the price for the generic is the same as the brand. The reporter was contacted by the Head of Communications and Public Affairs, and the reporter said that she had been told that by someone – PSNC's records confirmed it had not been PSNC. The reporter returned the call a short time later, saying the offending paragraph would be removed (it was removed a very short time after the call).

Information Governance Toolkit & Business Continuity Plan

The subcommittee is aware that following intervention by the Chief Executive and the Director of Regulation and Support, NHS England again granted exemption from requirement 319 – Business Continuity plan for 2014 - 15. NHS England said that it would not grant a further exemption for 2015-16.

A follow up meeting with NHS England and HSCIC to discuss BCPs has taken place. The template available on the PSNC website is thought by NHS England and HSCIC to provide a good starting position for pharmacies that have not yet developed a BCP, although the contents of the template are not binding and pharmacies that have developed their own BCP will be able to self declare (through the IG Toolkit) that they have a suitable BCP.

The template would benefit from reformatting into a template and separate guidance, and this is being undertaken in the office. HSCIC will prepare a section on the electronic prescription service, and

this will be incorporated. It is likely that NHS England will then approve this for those contractors that wish to use it (in other words, other suitable BCPs will be permitted).

NHS England was informed at the meeting that there would need to be negotiations around funding, once the template has been agreed.

Discretionary payments

NHS England has had an informal meeting with the Director of Regulation and Support and the Head of Pricing. It has considered the question of discretionary payments and believes that there are very limited circumstances where it would have authority to authorise payments – the authority in other cases being required from the Secretary of State (effectively the Department of Health). The areas which NHS England believes are within its powers are those where it is the sole determining authority for payment. This would cover remuneration of contractors, but not reimbursement, which is reserved to the Secretary of State. Therefore any request for a discretionary payment involving prescriptions would require the Department of Health's authorisation, even though the budget is held entirely by NHS England.

NHS England is consulting the Department of Health and will give its response to PSNC's request for standardisation of discretionary payments once it has a reply.

Distance Selling Pharmacies

A paper is to be brought back to the subcommittee in due course, to also include exemption checking.

Supply of controlled drugs to persons in police custody

The Director of Regulation and Support was invited to attend a meeting with NHS England, the General Pharmaceutical Council, Pharmacy Voice and medical stakeholders to discuss guidance for police custody officers, Healthcare professionals and GPs called by custody officers to attend and provide clinical services to persons in custody, and for pharmacies supplying controlled drugs, particularly those which the pharmacy has been commissioned to provide by way of supervised administration.

Recent examples of problems had been combined to create a test scenario against which various models could be assessed. NHS England was keen to explore solutions as it took over the responsibility for medical treatment of persons in police custody in April.

It was agreed that there is no statutory obstacle to pharmacies handing CDs to police officers or other personnel carrying authority from the patient and the police custody staff, so that the CDs could be administered in the police station. The Police and Criminal Evidence Act has been amended to create obligations on the police for how persons in custody should be treated where they have a clinical need. All schedule 2 & 3 controlled drugs must be administered only by the GP authorising the administration or by a healthcare professional (usually a nurse). Pharmacists can therefore be confident that the prescriber's intention to require supervision of administration to prevent leakage onto the illicit market can be achieved.

The guidance will be developed further to ensure pharmacies are clear about their obligations.

Homecare

The Chief Executive has held discussions with a community pharmacist with a background in independent and multiple pharmacy, who is currently undertaking an MBA at Durham Business School, and who will be undertaking a project for PSNC on Homecare over the summer as part of his MBA.

Discussions have also taken place with representatives of BAPW and the Chair of the Homecare trade association as well as with a hospital pharmacist who chairs the Department of Health Homecare Committee. These discussions were also attended by representatives from two homecare providers (Alcura- WBA, and Evolution – Celesio).

In the discussions it became clear that there are opportunities for wholesale and pharmacy to support the homecare supply for many of the patients. The economics of the sector are fragile, which is a major cause for concern, particularly following the exit of Medco last year. It was stated that hospital outpatient departments would not have the capacity to cope with the c250,000 homecare patients should homecare services collapse.

The Chair of the Department of Health Homecare Committee was keen for the homecare providers to produce an options paper on a confidential basis to share with Keith Ridge. Following the meeting BAPW are considering approaching PwC to undertake a market study, and the Chief Executive has said that PSNC might be interested in partnering in this.

At this stage, further information is awaited, and this will be presented if received before the meeting.

The Francis Review

The Francis Review, and the Report submitted to government incudes proposals to amend the legislation (Public Interest Disclosure Act). A summary of the report has been prepared and is circulated for information as **Appendix HPR 08/05/15 (pages 32 - 37).**

The 20 changes recommended in the report includes at point 19 changes to Primary Care.

Subcommittee Action: To consider the above items and confirm if any action is required.

Next Steps: None

3	Develop alliances and collaborate with other trade organisations to lobby for desirable changes in legislation governing supply of pharmaceutical services	Status

Report

GPhC Inspection Model

The subcommittee was informed in March about the report published by the General Pharmaceutical Council which sets out a provisional timetable (dependent on parliamentary approval) for full implementation of the inspection model, with publication of inspection reports. Pharmacy Voice is working on this and common members will keep PSNC informed.

No further information has been provided to PSNC at the time of writing the agenda.

Subcommittee Action: No further action by the subcommittee is required at this time

Next Steps: None

4	Work with DH, other pharmacy organisations and MHRA to prepare for FMD implementation and ensure financial implications for pharmacy are captured and resolved	Status

Report

The subcommittee was informed that the National Pharmacy Association (NPA) had hosted a meeting, but that PSNC was not invited to the meeting.

Contact has been made and a meeting is scheduled for May.

Subcommittee Action: None

Next Steps: A report will be brought back to the next meeting.

5	Develop stakeholder understanding of community pharmacy's knowledge, skills and behaviours (professionalism) and their core values, including finances, the pharmaceuticals market, pharmacy procurement and distribution	Status

Report:

Essential Small Pharmacies

The office has been informed of the outcome of several local negotiations concerning LPS. In one case a five year LPS contract has been offered by NHS England on terms similar to the ESPLPS. In others, the contracts are limited to two or three years, and most are characterised by having a reducing level of funding after year one, aiming to reduce to zero by the end of year two. In the worst of those types of case, the proposed contract provides top up payment of £3500 per month in month one, but thereafter reduces by 7.5% per month. It is inconceivable that a pharmacy contractor can improve efficiency or increase profit by 7.5% each month, every month and this has been raised with NHS England. In a small number of cases, the contractors have been returned to the pharmaceutical list with no further top up funding.

The Director of Regulation and Support has attended a meeting with two staff from an NHS England local office and two LPCs in the area, to try to find an acceptable way to make progress with development of LPS proposals. The local office is to write to contractors setting out a timetable for action, including a user engagement exercise to start in June (to avoid purdah). In the meantime the local office has granted all essential small pharmacy contractors a six month LPS to continue support until the user engagement exercise has been completed and amended LPS proposals have been considered and, where appropriate, accepted for development.

Following an unsatisfactory informal meeting with the member of staff leading on essential small pharmacies a formal letter has been sent, escalating this to Deborah Jaines. This may be the last opportunity to intervene before remaining LPS contracts are agreed.

It was agreed in March that the office will write to all essential small pharmacy contractors to establish eventual outcomes. A letter has been sent to all Essential Small Pharmacies to provide further guidance and to ask them to report to PSNC the outcome of their local negotiations.

Subcommittee Action: The subcommittee is asked if there is any further action that should be taken.

Next Steps: The office will continue to support former essential small pharmacy contractors who seek assistance, and will bring back to a future meeting a report of the outcomes of the local negotiations.

Post-election lobbying priorities

We have now had confirmation of our fringe event at the Labour Party conference which will be held on Tuesday 29th September, at 1pm. We have not yet heard from the Liberal Democrats or Conservatives but expect to soon and will begin planning for those after the election.

We are continuing with the review of our support for the All-Party Pharmacy Group, working closely with Pharmacy Voice. We have had very constructive discussions with them in recent weeks and are considering a number of options. We have also agreed to work with Pharmacy Voice on a plan to engage with politicians after the election. This will include resources for LPCs and briefings for MPs and a short note on the messages we are aiming to include is circulated as **Appendix HPR 09/05/15** This joint working will also cover the party conferences where we will work together to promote our events and exhibition stands and to consider whether any additional meetings with MPs would be beneficial.

Subcommittee Action: The subcommittee is asked if there is any further action that should be taken.

Next Steps: As above, we will continue to work with PV on a post-election campaign and the APPG; and to plan our own fringe events.

Other stakeholder activities

The subcommittee will be aware of the HSJ supplement on community pharmacy services that we have agreed to sponsor – the brief for the publication is included in the SDS Agenda. The intention is that this will both help us to reach commissioners directly (via the HSJ circulation) and give us a communication which we and LPCs can then use in our own contacts with commissioners.

In addition to exhibiting at the RCGP Annual Conference to try to improve GPs' understanding of pharmacy and all it has to offer, we have discussed with Pharmacy Voice the possibility of jointly exhibiting at NHS Expo. This will minimise costs but allow us to access a wide range of NHS professionals and policy makers. Gary Warner and Liz Colling will attend the HSJ integration summit in June (at which attendees will receive a copy of the supplement) to help ensure that pharmacy's role is recognised and discussed at the event, and we are working with the organisers of the Primary Care Summit (organised by GP Magazine Pulse and others) to ensure pharmacy is on the agenda. We will also consider whether to exhibit at the National Children and Adult Services Conference which will bring together directors of public health from across the country.

Subcommittee Action: The subcommittee is asked if there is any further action that should be taken.

Next Steps: The HSJ supplement will help us to raise the profile of pharmacy services and contribute to the effort to improve stakeholder understanding of the sector. We plan to use the supplement in our work with external stakeholders in the future including at the RCGP Annual Conference, party conferences, and other events. As outlined in the LIS agenda the supplement will also tie in with a range of other work focused on commissioners, including the targeted emails and prospectuses, and we will measure success looking at the popularity of our website pages for commissioners and via an LPC survey. We will continue to work to prepare for the other events outlined above.

6	Pursue action against the current practice of 'switching' as advised by Counsel	Status

PSNC is to hold another meeting with the Department of Health in June 2015.

7	Examine opportunities for a national provider company, implementing if agreed	Status

Report

Following the March PSNC meeting, a meeting took place with representatives of the National Pharmacy Association, Association of Independent Multiple Pharmacies, Company Chemists Association and Pharmacy Voice.

It was agreed that a working group should be established to include the national pharmacy bodies as well as LPC members who have established local provider companies, or who are suitably engaged with the principles.

See LPC Implementation and Support subcommittee agenda.

Subcommittee Action: None

Next Steps: A working group to be established.

Any other business

Appendix HPR 02/05/15

Department of Health Consultation on Rebalancing Medicines Legislation

The consultation document on rebalancing medicines legislation and pharmacy regulation published by the Department of Health was discussed at the March meeting and the subcommittee was informed that the proposal is to remove the threat of criminal sanction for inadvertent preparation and dispensing errors, while retaining the criminal sanction for those errors or deliberate acts that are such that the pharmacy professionals responsible for them cannot properly be said to have been acting professionally.

A draft response has been prepared and shared with Pharmacy Voice and the National Pharmacy Association, to seek to ensure the bodies are aligned (if the bodies are not aligned there is a risk that this may stall the government's progress on 'decriminalisation' of dispensing errors). It is anticipated the PV and NPA responses will be shared with PSNC so that there is an opportunity for minor amendment.

The main points of the draft response include:

The response states that it would have been better to remove dispensing errors from the scope of the section 64 offence rather than to provide a defence to such an offence – however, if the Department of Health and the devolved nations agree the proposals and are able to make progress quickly, then the response says that PSNC will support the proposals. If, however, there is any significant delay involving re-examination of the proposals, PSNC's response suggests that consideration be given to the removal of dispensing errors from the scope of the section 64 offence.

The defence is only available if the person making the error 'notifies' the error if he or she is aware of it. The response sought clarification – as not all errors need to be (or should be) reported to the patient – e.g. a minor out of date, discovered some time after the medicine will have been administered. The response suggests that if the notification is limited to those patient safety incidents that did or could have caused harm being reported through the National Reporting and Learning Service (NRLS), then PSNC would be supportive.

The consultation also asked about the situation that should apply if a pharmacist, exercising professional judgement, deviates from a pharmacy SOP. The response suggests that registrants must be free to exercise professional judgement, and in that case the defence should continue to be available if the registrant has made a professional decision to deviate from the SOP and is able to justify that decision.

PGDs for NHS supplies are out of scope of the offence but private PGDs which involve a sale may be caught. The response states that the defence should be available for this and also for those sales made by a pharmacist of an extemporaneously prepared product made to the specification furnished by the purchaser and also 'counter prescribed' extemporaneously prepared products.

The consultation also covers the powers of the General Pharmaceutical Council and seeks opinion on whether the setting of standards should be taken out of the 'Rules' This is proposed because the Rules are subject to the oversight of the Privy Council and means they cannot be amended quickly. Whilst it would be sensible to remove barriers to timely amendment, to reflect developments in pharmacy practice, the suggestion is made in the response that there should be a statutory duty for the GPhC to consult stakeholders before amending standards.

It is also proposed that the failure to meet premises standards should be a fitness to practise matter rather than a registration matter, meaning that the case could be considered through the

disciplinary procedures instead of the registration committee. The PSNC response opposes this if the finding of a superintendent or owner as unfit to practise because of failings in the standards of one pharmacy should affect the person's fitness to practise with respect to other pharmacies within the business. The Medicines Act 1968 allows the removal of single premises from the register rather than all the premises – and it would be irrational to replace these provisions with a system that could result in the owner / superintendent pharmacist being found unfit to practise for breach in one pharmacy, resulting in the removal of all pharmacies.

The final substantive part of the consultation deals with publication of the inspection reports. Subject to the GPhC finding an acceptable grading system, the response is supportive, but only if the owner of the business has the ability to challenge the inspection findings and also is able to have the inspection report updated promptly if the remedial action is taken (rather than waiting for three or more years until the next inspection).

Appendix HPR 05/05/15

Inducements

The subcommittee considered Inducements at its first meeting in October, and resolved that a paper be brought back to the subcommittee with options.

Background

The terms of service prohibit a pharmacy contractor from giving a gift or reward (including dividends) in return for the presentation of a prescription, for the provision of an Advanced service, or for nominating the pharmacy under the electronic prescription service. (Schedule 4, paragraph 30 – reproduced below).

The prohibition has been extended in 30(4) to prohibit the giving of a gift or reward to a medical practice or their staff, in return for recommending to patients that they use the pharmacy for prescriptions or Advanced services.

NHS London local offices do not have routine access to nomination data so they cannot pro-actively investigate unusual patterns of behaviour. This might be alleviated now that data is freely available on the prescription number dispensed in each pharmacy, and the source of those prescriptions. Where a medical practice is EPS r2 live, this can be factored into analysis of changes in prescription volume.

The lack of any meaningful equivalents to our Inducements prohibition in the GP contract means that in many cases of direction of prescription, the only means of addressing it are to take action against the receiving pharmacy (but that is activity that NHS England has too few resources to consider dealing with pro-actively).

Regulations

30. Inducements etc.

(1) An NHS pharmacist (P) (including P's staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of P's business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

(a) presenting an order for drugs or appliances on a prescription form or repeatable prescription, non-electronic prescription form or non-electronic repeatable prescription;

(b) nominating P as X's dispensing contractor (or one of them) in X's PDS patient details; or

(c) receiving from P any directed services.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) Nothing in sub-paragraph (1) prohibits P from providing to a patient to whom P is providing any directed services any gift which—

(a) is supplied as part of the provision of any directed service to that patient;

(b) is directly related to that directed service;

(c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and

(d) in the case of a gift which—

(i) is not a medicine, has a monetary value not exceeding £10, or

(ii) is a medicine, is supplied as part of the provision of a minor ailments service.

(4) P (including P's staff) must not give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of P's business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—

(a) present to P an order for drugs or appliances on a prescription form or repeatable prescription;

(b) nominate P as their dispensing contractor (or one of them) in their entry in their PDS patient details; or

(c) ask P to provide them with any directed service.

(5) For the purpose of sub-paragraph (4), "relevant person" means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

(a) any NHS body or provider of primary medical services; and

(b) any person employed or engaged by any of the persons mentioned in paragraph (a).

(6) In the case of the provision of appliances, P (including P's staff) must not accept or receive any gift or reward in respect of only—

(a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 12(4) or 20(2)(b); or

(b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 10(2) (a) or 20(2) (a) and providing no additional service in connection with the item on that prescription.

<u>Problems with existing regulations</u>

These provisions should prevent most cases of direction of prescriptions, but (a) breach is hard to detect, and (b) NHS England does not have the resource to proactively monitor and enforce these provisions.

There is no similar provision in the GP contract (other than a prohibition relating to nomination).

As an example, a pharmacy paying a medical practice a premium in order to locate a prescription collection point prominently within the waiting area of the medical practice, with the pharmacy owner providing no services other than to accept prescriptions and send them electronically to its distant pharmacy. Examples may arise where the amount of the premium is based on the likely prescription volume. The payment is said to be for the space taken, with a further payment for IT connectivity which exceeds what a connection would cost. The sole purpose is for the collection of prescriptions, and the payments to the medical practice are made because patients will be handing prescriptions into the collection point. The payment to the medical practice is probably not caught by paragraph 30(4) unless there was to be explicit reference to the pharmacy paying the medical practice for the recommendation to use the pharmacy. Additionally it would be impossible to gather evidence because that would also require a patient to give evidence against their GP that they have been recommended to take their prescription to the collection point. In fact the GP may not say anything at all to the patient – it may be that the GP's acquiescence to the situation, with the collection point given a prominent position has the same effect as the regulations seek to prohibit.

To try to formulate law to deal with exceptional cases rarely achieves the objective, but the subcommittee is keen to reduce direction of prescriptions – and key to that is to reduce the opportunities for inducements to be paid.

Options

The following are potential options, but all would require support from NHS England and the Department of Health. For those affecting medical practitioners, any suggestions would be for negotiation between NHS England / DH / BMA's General Practitioners Committee. The options are therefore for discussion not only as to whether they are worth pursuing, but also as to whether there is any likelihood that they will be pursued.

The NHS (General Medical Services Contracts) Regulations 2004 ("GMS Regs") do not contain any prohibition on receiving inducements (gifts or rewards paid by a provider of pharmaceutical services in return for the medical practitioner recommending that a patient takes a prescription to a particular pharmacy).

- The first option could be to include a parallel provision prohibiting a GP or medical practice from seeking or accepting payment (including payments in kind) in return for recommending that a patient uses a particular pharmacy.

NHS England's lack of resources means that there is no capacity to pro-actively monitor financial dealings between medical practices and pharmacies. Even where there is an allegation to be investigated, NHS England may find it difficult to obtain information.

- The second option could be to amend both the GMS Regulations and the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("PhS regulations") , to require both medical practices and pharmacies to make periodic disclosures to NHS England setting out all payments (including payments in kind) together with an explanation of what the payment is for. The presumption could be that the payment is an inducement unless the relevant party satisfies NHS England that the payment is appropriate for services / goods being provided.

The example above demonstrates the difficulty in preventing arrangements that seek to exploit location as a way of generating prescription volume. We must take care to ensure that nothing is done to prevent the establishment of a pharmacy in or adjacent to a medical practice – but payment of a premium for a collection point, a notice in a practice leaflet offered as an exclusivity deal and other promotional assistance given by a medical practice might be presumed to be linked to direction of prescriptions.

Should the PhS regulations be amended in paragraph 30 to prohibit the payment of a premium for location of a collection point, display stand or an entry in a practice leaflet? The payments for lease costs for a registered pharmacy co-located in a medical practice is likely to be covered by the National Health Service (General Medical Services – Premises Costs) Directions 2013 which requires the payments made to medical practices by NHS England to be adjusted to reflect income received in respect of those premises under paragraphs 48 or 49 of the NHS General Medical Services Premises Costs Directions 2013:

Abatements in respect of contributions towards recurring premises costs from third parties

48. Where a contractor's practice premises, or any part thereof, are or form part of premises that are owned or rented by any person other than the contractor, and that person—

(a) is required by any agreement (which includes a licence or a lease) to make or makes any contribution towards any recurring premises costs in respect of which the Board is providing financial assistance to the contractor in accordance with this Part; or

(b) is required by any agreement (which includes a licence or a lease) to pay or pays to the contractor any amount—

(i) by way of rent in respect of the practice premises or any part thereof, or

(ii) in respect of the running costs of the practice premises,

the Board must set off that contribution or that amount, equitably, against the payments made to the contractor pursuant to this Part.

Payments in kind

49.—(1) Where a payment that is to be made pursuant to this Part would be abated, or abated by a greater amount, if instead of receiving money or obtaining a pecuniary advantage a contractor, or a member or employee of a contractor, receives a payment in kind, the Board must take into account the value of the payment in kind in determining the amount of the payment to be made pursuant to this Part.

(2) The Board is to take all reasonable steps to agree with the contractor the value of the payment in kind and must justify the value it does determine.

- The third option is that making of a payment by a pharmacy or the receipt of a payment by a medical practise in cash or in kind, which is not required to be disclosed under the GMS Premises Costs Directions 2013, (for example for a collection point or for inclusion in a practice leaflet) should be notified to NHS England on a periodic basis.

Some pharmacies seek to exploit the doctor – patient relationship through an implied recommendation from a GP or medical practice to use a particular pharmacy. One method of achieving this is to pay a medical practice to promote the pharmacy. This may not be done through the actual payment, but by paying for joint publicity, for example including pharmacy promotional materials in GP mailings calling patients for their influenza vaccination. The payment may be payment in kind where the pharmacy funds the GP letters, on the understanding that the pharmacy promotional materials will be included.

- The fourth option is that the PhS regulations could be amended to prohibit the payment, including payment in kind, for medical practices circulating pharmacy promotional materials with their own communications with patients.

- The fifth option could be on similar lines - a prohibition of the payment, including payment in kind, for a mailing list obtained from a medical practice – whether the list is handed to the pharmacy or whether the mailing list is provided through a third party on behalf of the medical practice.

The subcommittee is asked to consider whether any of these options could be pursued. If not, are there other amendments that might be made to the Inducements section of the terms of service.

Appendix HPR 06/05/15

Response to consultation on: NHS Bodies and Local Authorities Partnership Arrangements (Amendment) Regulations 2015.

Thank you for consulting PSNC about the Department's proposals to amend the NHS Bodies and Local Authorities Partnership Arrangements Regulations.

PSNC notes that the proposal is limited at this time to enable pooling only of elements of the primary medical services funding, but wishes to respond to the supplementary question of possible extension in the future to pooling of other primary care services, including pharmaceutical services.

For this reason, we make no comment in response to your first consultation question on whether the current proposals provide additional flexibility.

In response to your second consultation question on the appropriateness of limiting the proposed amendments to primary medical services, we make no comment on the proposals for primary medical services to be included in pooled funding, but we do say for reasons set out later, that it is appropriate not to include pharmaceutical services in the pooled funding arrangements at this time.

We would also like to comment on the safeguards and the potential conflicts of interest. If partnerships are formed in which CCGs are a party, the Department already recognises that there are potential conflicts of interest, due to the GP membership of the CCG. We receive information from time to time that calls into question the robustness of the governance arrangements adopted by CCGs and we have no confidence that the existing arrangements and safeguarding measures are adequate.

We also make the point that the partnership will, due to the GP membership of the CCG, have GP representation within the body making the commissioning decisions. In some cases there is competition between GPs and pharmacies to provide services; in such cases these commissioning arrangements would place pharmacy at a disadvantage.

Looking forward to a point where the Department may consider amending the regulations further to include other primary care services, we wish to reserve our position and request that this is the subject of a further consultation, so that we can respond to a detailed proposal rather than a speculative inquiry.

To assist the Department with identifying the issues that will need to be addressed in a consultation, we must also highlight that the core services provided by community pharmacies (their Essential services and Advanced services) do not have any flexibilities of the type that GPs may have in their contracts, and so we would propose that these services should remain outside partnership arrangements. The Enhanced services (i.e. those commissioned from pharmacy by NHS England in accordance with Part 4 of the NHS Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 and other locally commissioned services may be an area where there are opportunities for partnership arrangements, but only when the domination of CCGs by GP interests have been effectively managed.

Appendix HPR 07/05/15

Summary of Pfizer's UK Supply Policy

Let me begin by saying that Pfizer is committed to ensuring continuity of supply of its medicines to patients and strives to ensure the supply of sufficient quantities of its medicines to pharmacies and dispensaries to meet the requirements of patients in the UK. Allocations of stock are made to pharmacy customers, in our absolute discretion, in sufficient quantities so that demand from patients and healthcare professionals in the UK can be satisfied.

Pfizer controls the supply of medicines through Direct to Pharmacy (DTP) distribution via a combination of **National Order Limits** (NOLs) and **Quotas**. The process for setting the NOL for all pharmacy customers and specific quotas for individual accounts **provides for appropriate supply in the vast majority of cases**. However, from time to time pharmacy customers may contact Pfizer requesting additional supplies of medicines over and above the demand understood by Pfizer.

In all cases Pfizer will make one additional supply (of up to 2 packs) of a medicine per pharmacy store per month regardless of the frequency of the NOL or the quota being exceeded, as applicable to the pharmacy customer's query, unless the process exception for products in Manufacturing Shortfall (MSF) applies.

Pfizer also maintains a list of "critical medicines". This list is made up of those Pfizer medicines where there would be significant impact/harm to a patient if they were to go without supply of the medicine AND sufficient alternatives/generics are not available. Specifically for critical medicines, in order to ensure continuity of supply to patients, any further requests for supply of these products (beyond NOL, Quota and additional supply entitlements) would be escalated to the appropriate Pfizer Business Unit Medical Director.

Pfizer supplies 351 stock keeping units (SKUs), to 17,488 retail pharmacy and hospital customers, through its DTP Distribution model, and via its third party Logistics Service Provider (LSP), Alliance Healthcare. During the period 1 January to 31 December 2014 Pfizer maintained a **97% in-stock performance** across its pharmaceutical portfolio and supplied 37.56 million packs, with an average twice-a-day, on-time and in-full, **delivery performance of 99%.** This DTP delivery performance was supported by Pfizer's Customer Contact Centre (CCC) handling 55,000 call enquires, including dealing with additional and emergency order requests. This serves to demonstrate the scale and robustness of the Pfizer DTP supply chain and its general high service level performance.

How does the supply process work for Lyrica?

There should always be sufficient "buffer" in the system for sufficient Lyrica to be available to pharmacies to meet patient demand, and NOLs are regularly checked to ensure that this is the case.

Pfizer reviews its critical medicines list periodically (we did so in Jan/Feb 2014, and have done so again in Jan/Feb 2015). As a consequence, all of Lyrica's indications are on the critical medicine list. In the rare circumstances where a pharmacy phones the CCC requesting exceptional additional supply, the Pfizer CCC will escalate the request to the Medical Director.

As all of Lyrica's indications are on the critical medicines list, we will not be asking about the indication, and the request will be promptly approved by the Medical Director provided that the request is for immediate patient use and not simply to manage stock levels. Accordingly, the supply will be processed and delivered in 98% of the time within 24 hours.

To put things into perspective, for Lyrica in the period from 1 January to 31 December 2014, there were a total of just 41 escalations to the Medical Director for supply beyond the standard additional 2

packs. This amounted to a total of 171 packs, and includes two orders of 25 packs for supply to prisons via Lloyds Pharmacy. For the same period Pfizer processed 1.585 million Lyrica orders and supplied 3.07 million packs. **These Medical Director escalations equate to 0.0026% of all Lyrica orders processed and 0.0056% of all Lyrica packs.**

In times of MSF, we prioritise requests to ensure fair and equitable access to supply for immediate patient use (so that we can avoid surplus stock sitting in some pharmacies that might be needed for immediate use elsewhere).

Lyrica's pain patent

I would begin by stressing that the situation with regard to Lyrica's second medical use patent for pain (the "pain patent") is a legal situation rather than a clinical one.

Pfizer recognises that the Lyrica pain patent is a complex matter and at the time where there was an absence of central guidance on this matter, we had been recommending that pharmacists take steps to ensure the appropriate product is dispensed when presented with a generic prescription for pregabalin. This might involve, amongst other things, the pharmacist contacting the prescriber to establish the indication. We entirely appreciated that this could create an administrative burden for pharmacy staff, but as we have consistently maintained, central NHS guidance would provide the optimal solution for all concerned, since it would allow pharmacists to dispense the appropriate medicine without further enquiry.

We also believe that whilst there may be no NHS contractual obligation on pharmacists to establish the indication for which the treatment is prescribed, this principle does not account for the unusual legal (rather than clinical) situation presented with regard to Lyrica's pain patent.

However, and as you have recognised on your website (for which we are grateful), the position changed on 26 February 2015 when the High Court of Justice in London ordered National Health Service England (NHSE) to issue central guidance for prescribers and pharmacists on how to deal with the position surrounding Pfizer's patent covering the use of pregabalin for the treatment of pain.

In line with the measures sought by Pfizer to help prevent infringement of the pain patent, NHSE issued guidance on 27 February 2015 for prescribers via Clinical Commissioning Groups (CCGs) and pharmacists via NHS Business Services Authority (BSA) that directs the prescription and dispensing of Lyrica, by brand name only, when pregabalin is used for the treatment of neuropathic pain. The NHSE guidance issued on Friday 27 February requests that the CCGs and NHS BSA distribute the notice on or before Friday 6 March 2015. On 6 March 2015, guidance was also issued in Wales by All Wales Chief Pharmacists Committee. We continue to liaise with the relevant authorities in Northern Ireland and Scotland.

Whilst we are still waiting to see the results of this central guidance, we are pleased that the High Court Order will provide much-needed clarity for prescribers and pharmacists and, importantly, help protect pharmacists from unwittingly infringing the pain patent.

Appendix HPR 08/05/15

Briefing on the Report of the Francis Review: Freedom to speak up

Introduction

Sir Robert Francis' independent review aims to create an open and honest reporting culture in the NHS England by providing advice and recommendations to ensure that NHS staff in England feel safe to raise concerns, confident that they will be listened to and the concerns will be acted upon.

The review was set up as a result of the disquiet of the way NHS organisations deal with concerns raised by NHS staff and the way some of those who raised complaints are treated. The report points out that NHS staff must be able to raise their concerns about things they are worried may be going wrong without any fear that they will be victimised or bullied or be badly treated when they do so and confident that effective action will be taken. Concerns of the staff are important and, if addressed correctly, can make a profound contribution to patients' safety and care.

The findings of the review show that there is a serious issue within the NHS and the handling of the complaints made by the staff. In particular, the 2013 NHS staff survey showed that only 72% of the respondents were confident that it is safe to raise complaints. It is also stated in the report that there are shocking accounts of the way some people have been treated when they raised their concerns. It is emphasised that such treatment is not acceptable and has no place in a service which values, as the NHS must, its workforce. The NHS has a moral obligation to support and encourage staff to speak out and to raise concerns.

There was a remarkable consistency in the pattern of reactions described by staff who raised concerns in the past (whistleblowers) and who spoke to the Review about their experiences and the way they were treated. They have also provided convincing evidence that they raised serious concerns which were rejected and were met with a response which focussed on disciplinary action against them rather than any effective attempt to address the issue they raised.

The Review concluded that there is a culture within many parts of the NHS which deters staff from raising serious and sensitive concerns and which has negative consequences for those who are brave enough to raise them. The main reasons that members of staff are reluctant in raising their concerns is the fear of the repercussions that speaking up would have for an individual and for their career and the futility of raising a concern because nothing would be done about it. The Review identified a need for a culture in which concerns raised by staff are taken seriously, investigated and addressed by appropriate corrective measures and sets out twenty principles which should guide the development of a consistent approach to raising concerns through NHS, whilst leaving scope for flexibility for organisations to adapt them to their own circumstances.

Legal Context

The Review indicated that there is a confusion around the term "whistleblowing" – the term means different things to different people – but the legislation does nothing to remove this confusion - it does not even mention the term "whistleblowing" at all.

The Employment Rights Act 1996, as amended by the Public Interest Disclosure Act 1998, provides that a worker who makes a protected disclosure has the right not to be subjected to any detriment by his employer for making that disclosure.

However, this legislation has been limited in its effectiveness; it provides a series of remedies after detriment, including loss of employment, has been suffered. It is also limited in its applicability as it

applies only to "workers" and therefore provides no protection against, for example, discrimination in recruitment.

Experience of employees

The majority of the people who wrote to the Review reported bad experiences and also lack of support and confidence in the process. Many referred to disciplinary action and victimisation; bullying and oppressive behaviour were also mentioned, both as a subject for a concern and as a consequence of speaking up. The review found that there are problems at a number of stages including deterrents to speaking up, poor handling of concerns that are raised and vindictive treatment of the person raising the concern.

Experience of employers in receiving and handling public interest concerns

Two approaches were taken by the employers who received and handled public interest concerns; some took a strict procedural approach when concerns were raised and others took a less rigid approach which focused on resolving the issue. The latter approach, though, was still at a formative stage. Employers who received public interest disclosures, accepted that many disclosures are made in good faith but they were concerned that some disclosures are made in order to protect the person raising them from performance action or disciplinary processes they face for entirely unrelated matters.

The Review identifies five overarching themes; in particular, that there is the need for culture change, improved handling of cases, measures to support good practice, particular measures for vulnerable groups and extending the legal protection.

The Report sets out twenty principles and actions which should guide the development of a consistent approach to raising concerns throughout the NHS. A summary of these principles and actions are set out below.

Culture change

Principle 1 – Culture of safety

The Review notes that every organisation involved in providing NHS healthcare should actively foster a culture of safety and learning in which all staff feel safe to raise concerns. In order to achieve this change, boards must devote time and resource and also ensure that progress in creating and maintaining a safe learning culture is measured, monitored and published on a regular basis.

Principle 2 – Culture of raising concerns

Raising concerns should be part of the normal routine business of any well-led NHS organisation. Policies and procedures for dealing with staff concerns should not distinguish between reporting and incidents and making protected disclosures. Every NHS organisation should have an integrated policy and common procedure for employees to formally report incidents or raise concerns. Also, responsibility for policy and practice should rest with the executive board member who has the responsibility for safety and quality, rather than human resources. It is also recommended that investigation of the concern should be the priority, and any disciplinary action associated with it should not be considered until the facts have been established.

Principle 3 – Culture free of bullying

It was pointed out that there needs to be an examination of the causes of bullying behaviour and for honest and direct feedback to individuals about the impact of their behaviour. The Review recommends also that everyone in leadership and managerial positions should be given regular

training on how to address and how to prevent bullying and regulators should consider evidence on the prevalence of bullying in an organisation as a factor in determining whether it is well-led. Any evidence that bullying has been covered up should be taken into consideration when assessing when someone is a fit and proper person to hold a post at director level in an NHS organisation.

Principle 4 – Culture of visible leadership

All employers of NHS staff should ensure and be able to demonstrate that staff have open access to senior leaders in order to raise concerns, informally and formally.

Principle 5 – Culture of valuing staff

Employers should show that they value staff who raise concerns and should consider and implement ways in which the raising of concerns can be publicly celebrated.

Principle 6 – Culture of reflecting practice

A recommendation that there should be opportunities for all staff to engage in regular reflection of concerns in their work is made by the Review. All NHS organisations should therefore provide the resources, support and facilities to enable staff to engage in reflective practice with their colleagues and their teams.

Better handling of cases

Principle 7 – Raising and reporting concerns

The Review emphasises the need for all NHS organisations to have structures to facilitate both informal and formal raising and resolution of concerns. In particular, it is stated in the report that staff should be encouraged to raise concerns informally and also that NHS organisations should have a clear process for recording all formal reports of incidents and concerns.

Principle 8 – Investigations

When a formal concern has been raised, there should be prompt, swift, proportionate, fair and blame-free investigations to establish the facts. The Review suggests that all NHS organisations should devise and implement systems which enable such investigations to be undertaken, where appropriate by external investigators. Also, feedback to the person who raised the concern is critical as the sense that nothing happens is a major deterrent to speaking up. Where suspensions and special leave are being considered, these should only be used where there is a risk to patient or staff safety or concern about criminal wrongdoing or tampering with the evidence. Ideally, the person who spoke up should not be the person who is moved, as this can be send a signal that they have done something wrong.

Principle 9 – Mediation and dispute resolution

The use of expert interventions to resolve conflicts, rebuild trust or to support staff who have raised concerns should be considered at an early stage. As the NHS is a complex service, it cannot be expected to run without professional disagreement or conflict. Therefore, all NHS organisations should have access to resources to deploy alternative dispute resolution techniques, including mediation and reconciliation in order to address unresolved disputes between staff or between staff and management as a result of a report raising concern and to repair trust and build constructive relationships.

Measures to support good practice

Principle 10 – Training

Every member of staff should receive training in their organisation's approach to raising concerns and in receiving and acting on them. The system will work more effectively if there is more training for staff in how to raise concerns and for managers in how to receive and handle concerns. Training should be provided through face to face sessions. More senior members of staff will need additional training in how to handle concerns. Therefore, the Review recommends that every NHS organisation should provide training which complies with national standards, based on a curriculum devised jointly by Health Education England and NHS England in consultation with stakeholders.

Principle 11 – Support

All NHS organisations should ensure that there is a range of persons to whom concerns should be reported easily and without formality. They should also provide staff who raise concerns with ready access to mentoring, advocacy, advice and counselling. The Review suggested that clarity about to whom concerns can be reported and clarity about where to go for support is necessary. In order to achieve this, NHS organisations should appoint a person (a "Freedom to speak up Guardian") to act in a genuinely independent capacity; if some people however do not feel comfortable to seek advice from such a person there should be a range of others where people can go for advice and support. This should include a nominated non-executive director to receive reports of concerns directly from employees and to make regular reports on concerns raised by staff and the organisation's culture to the Board, one or more nominated executive directors to receive and handle concerns, at least one nominated manager in each department to receive reports of concerns and a nominated independent external organisation (such as the Whistleblowing Helpline) whom staff can approach for advice and support. All these people can ensure that the primary focus is on the safety issue, that each case is handled appropriately, investigated promptly and issues addressed. They will also ensure that there are no repercussions for the person who raised the concern.

Principle 12 - Support to find alternative employment in the NHS

Where a NHS worker who has raised a concern cannot, as a result, continue in their current employment, the NHS should fulfil its moral obligation to offer support. When a person leaves their employment, either voluntarily or otherwise, after raising a concern they might find it difficult to find another job. The Review recommended that all NHS organisations should actively support a scheme to help current and former NHS workers whose performance is sound to find alternative employment in the NHS.

Principle 13 – Transparency

All NHS organisations should be transparent in the way they exercise their responsibilities in relation to raising of concerns, including the use of settlement agreements. Transparency about incidents and events, and how the trust has responded to them, sends an important signal to staff that the board welcomes and values them. The Review suggests that all NHS organisations should publish in their Quality Accounts quantitative and qualitative data about formally reported concerns which could be then used by the National Learning and Reporting System (NLRS) to identify safety issues that are common across the NHS. This would be achieved if the NHS system regulators adopt a common approach to data about concerns, with a shared understanding of what good looks like so that there is no disincentive to trusts to be transparent and open.

Principle 14 – Accountability

Everyone should be held accountable for their behaviour and practice when raising, receiving and handling complaints. This applies to those raising concerns as well as to their leaders and managers. The Review recommends that there should be personal and organisational accountability for poor practice in relation to encouraging the raising of concerns and responding to them, for victimisation of workers for making public interest disclosure or for inappropriate use of confidentiality clauses. Trust Boards, CQC, Monitor and the NHS TDA should have regard to any evidence of responsibility for, participation in or permitting such conduct in any assessment of whether a person is a fit and proper person to hold an appointment as a director or equivalent.

Principle 15 – External Review

The Review suggests that there should be an Independent National Officer resourced jointly by national systems regulators and oversight bodies and authorised by them to carry out functions, such as, review the handling of concerns raised by NHS workers and the treatment of the people who spoke up where there is a cause for believing that this has not been in accordance with good practice and advise NHS organisations to take appropriate action where they have failed to follow good practice. Therefore, CQC, Monitor, NHS TDA and NHS England should consider and consult on how such a post might jointly be created and resourced and submit proposals to the Secretary of State as to how it might carry out these functions in respect of ongoing and future concerns.

Principle 16 – Coordinated Regulatory Action

There should be coordinated action by national systems and professional regulators to enhance the protection of NHS workers making protected disclosures and of the public interest in the proper handling of concerns. The Review highlights the lack of any coordination between the various regulators in their approach to whistleblowing and suggested that they should pay more attention to the record of an NHS organisation in respect of how it handles concerns and takes regulatory action where that record is poor and review their procedures and processes.

The Review also suggests that CQC, Monitor, NHS TDA should work together, with the Department of Health, to agree procedures and define the roles to be played by each in protecting workers who raise concerns in relation to regulated activity, and where necessary they should seek amendment of the regulations to enable this to happen.

Principle 17 - Recognition of organisations

CQC should recognise NHS organisations which show they have adopted and apply good practice in the support and protection of workers who raise concerns.

<u>Measures for vulnerable groups</u>

Principle 18 – Students and Trainees

The Review points out that all principles in the report should be applied with necessary adaptions to education and training settings for students and trainees working towards a career in healthcare. The Review heard disturbing but consistent accounts of students with previously good records who suddenly found themselves criticised, if not failed, after they raised a concern. It is suggested that all training for students and trainees working towards a career in healthcare should include training on raising and handling concerns.

Principle 19 – Primary Care

The Review recommends that all principles should apply with necessary adaptation in primary care. In particular, it is suggested that NHS England should include in its contractual terms for general/primary medical services standards for empowering and protecting staff to enable them to raise concerns freely and in consistency with these principle.

Extending the legal protection

Principle 20 – Legal protection should be enhanced

The Review states that some NHS bodies which are not currently prescribed persons to whom disclosures could be made, should be added to the list (i.e. NHS England, CCGs and Local Education and Training Boards) and also welcomes the intention to extend the scope of the legislation to include student nurses and students midwives and suggests that this should go further to include other students working towards a career in healthcare. The Review is particularly concerned because the legislation does nothing to protect people who are seeking employment from discrimination on the grounds that they are known to be a whistleblower and invites the Government to review the legislation to extend protection to include discrimination by employers in the NHS, if not more widely, either under the Employment Rights Act 1996 or under the Equality Act 2010.

Finally, the Review recommends that all organisations which provide NHS healthcare and regulators should implement the principles and actions set out above and the Secretary of State for Health should review at least annually the progress made in the implementation of these principles and actions and the performance of NHS in handling concerns and the treatment of those who raise them and to report to the Parliament.

Appendix HPR 09/05/15

Key Parliamentary Messages

We have agreed to work with Pharmacy Voice on a post-election campaign to promote key messages to both new and returning MPs. This will include work to involve LPCs and to encourage MPs to take part in the work of the All-Party Pharmacy Group (APPG).We hope that the plan will sit alongside the work plan for the APPG which will be developed by politicians after the election.

Our preference is to work within a key theme, such as looking after older people, to give our Parliamentary work focus and to ensure that public interest is maintained while also giving scope to explore a range of important issues such as public health, supporting independence, and managing long term conditions.

To help inform our plan we have pulled together some key messages which we will need to promote to politicians over the next year or so. These are not new and are largely drawn from PSNC's existing plans and vision, as well as the joint manifesto published last year.

Core role and value

- Promote understanding of the value of the supply function that community pharmacies deliver.
- Improve understanding of the pressures on the supply chain and the need to ensure that those pressures are minimised and pharmacies appropriately reimbursed for the work they do to access medicines.
- Improve understanding of the role pharmacies can and do play to improve public health and support people to self-care.

Service development

- Gain support for the extension of community pharmacy services to:
    - Reduce pressure on urgent care and GP practices (EHC; emergency supply; flu vaccination; minor ailments)
    - Support independent living (reablement; post-discharge care)
    - Support medicines optimisation and long-term condition management (development of MURs/NMS; asthma; blood pressure monitoring)
- Improve understanding of the limitations of local commissioning systems and the benefits of national commissioning. Also improve understanding of the need for pharmacy to be included in care pathways.
- Gain support for investment in the community pharmacy network to ensure more patients are able to access a wider range of services and understand what is available to them.

Enablers

- Gain support for the alignment of the GP and pharmacy contracts and for the sharing of patient information between pharmacies and other care settings.
- Develop understanding of the need to ensure regulatory changes are made in a timely fashion and ensure ease of working for pharmacies (to include EPS and red tape).
- Improve understanding of the impact that NHS/regulatory/governmental processes and systems such as pricing have on pharmacies and the need to make those as efficient as possible**.**