Response to
The Scottish Government

No-fault Compensation for injuries resulting from clinical treatment consultation

23rd November 2012

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No-Fault Compensation for injury resulting from medical treatment: Consultation Questions

1. The research team supporting the review reported (Farrell *et al*, 2010[1]) that previous research suggests that when an error has occurred, patients expect doctors to make a meaningful apology, provide an explanation and take steps to prevent the error from recurring. The findings of their research would appear to support the contention that for many, if not most, patients this is the primary aim, rather than a financial award.

2. The Scottish Public Services Ombudsman (SPSO) has published advice in relation to apology[2]. This advice was referenced in the guidance issued to NHSScotland in March 2012 on the handling and learning from feedback, comments, concerns and complaints.

Question 1: What, if any, steps do you feel are necessary or appropriate to ensure that when an error has occurred, patients receive a meaningful apology?

Good practice guidance for community pharmacists includes apologising to a patient or carer when an error has occurred, without necessarily admitting liability.

When a dispensing error has been made in a pharmacy it can usually be quickly and easily identified. Experience shows that appropriate handling of the situation when an error has been made, including an apology, helps facilitate any further complaint management. The NPA supports its members and provides guidance on handling complaints.

Anecdotal evidence indicates that frequently patients are more concerned that the error doesn't happen again than seeking compensation. Prompt handling which addresses this concern is likely to lead to a prompt resolution of the case.

Please see the general comments question for information on the National Pharmacy Association and our experience in handling indemnity claims for community pharmacy.

3. The Review Group considered that the following were essential criteria for a compensation scheme for injuries resulting from medical treatment:

- The scheme provides an appropriate level of compensation to the patient, their family or carers
- The scheme is compatible with the European Convention on Human Rights
- The scheme is easy to access and use, without unnecessary barriers, for example created by cost or the difficulty of getting advice or support
- People are able to get the relevant specialist advice in using the scheme;
- Decisions about compensation are timely
- People who have used the scheme feel that they have been treated equitably
- The scheme is affordable

[1] http://www.scotland.gov.uk/Topics/Health/NHS-Scotland/No-faultCompensation/Volume-II-report
[2] http://www.spso.org.uk/files/2011_March_SPSO%20Guidance%20on%20Apology.pdf

- The scheme makes proportionate use of time and resources
- The scheme has an appropriate balance between costs of administration (e.g. financial or time) and the level of compensation awarded
- Decisions about compensation are made through a robust and independent process
- The scheme has an independent appeal system
- The scheme treats staff and patients fairly/equitably
- A reasonable time limit is set for compensation claims.

Question 2. Do you agree that the principles and criteria set out above are essential in a compensation system?

Yes x ☐ No ☐

2.1 Are there any to which you would attach particular priority or importance? Are there any others you would add?

The current community pharmacy indemnity scheme operated by the National Pharmacy Association Insurance (NPAI) encompasses the principles set out in the criteria above.

On the whole, the current indemnity schemes for community pharmacy work well, resolutions are generally swift causing minimal burden and distress for claimants or pharmacists.
Dispensing errors are fairly easy to identify, what needs to be determined is the level of harm caused by not taking the prescribed medicine and possibly by taking the wrong medicine (Patients often realise they have an incorrect medicine and don't take it).
The number of errors which arise in community pharmacy, are very low compared to the number of complaints from other parts of the NHS and the number of prescriptions dispensed (over 850 million prescriptions are dispensed in England and 90 million Scotland annually).
There has been little increase in the number of claims from community pharmacy despite the increasing numbers of prescriptions dispensed, 4% in 2011/12, and increased pressure on pharmacists. Pharmacists provide a number of services to their patients such as stop smoking, minor ailments, and acute medicine service.
The premium paid by pharmacy owners reflects the low risk and is significantly lower than the premiums paid by other healthcare providers.
The NPAI has its own, experienced, team of legal advisors who support members with their claims and negotiate with claimants. This includes a clear explanation of the process and the likely time to resolution of the claim.
Claims are generally settled swiftly in cases where a dispensing error has occurred. A minor injury claim may take two to three months to settle.
The majority of dispensing errors can be easily identified. Once a mistake has been identified it will be admitted. Causation between the dispensing error and any symptoms /harm then has to be explored and evidence obtained, this may take some time, then loss and damages can be valued.

For more complex cases, where perhaps it is unclear that an error has been made and or whether another party e.g. a doctor is also responsible, for example a prescribing error which wasn't noticed by the pharmacist, investigation is required and the claimant will be kept informed as to progress.

Pre-action protocols in England govern the handling of personal injury /clinical negligence claims with potential cost penalties if the protocols are breached. Time frames are likely to be twenty-one days to acknowledge claim, and three months to investigate the claim and communicate a decision on liability.

If liability has been admitted but the case cannot be quantified for a period of time an interim payment may be made.
Making changes to the system, for example by including insurance for community pharmacy in the proposed no fault system, could make settling claims more problematic and increase costs as a result of additional steps being placed in the process. There is also the possibility that the value of claims could increase.
Changes to the system would cause an increased administration burden on contractors and their insurers.
Customer good will could be reduced if claims take longer to be processed.

4. The Review Group identified a number of issues it believed were relevant to the likely success of any system and agreed that the following criteria were desirable, and considered and highlighted the importance of the wider issues detailed below:

Desirable

- The public in general trusts the scheme to deliver a fair outcome
- The scheme does not prevent patients from seeking other forms of non-financial redress, including through the NHS Complaints system
- The scheme encourages transparency in clinical decision-making
- The scheme contributes to rehabilitation and recovery.

Question 3: Do you agree that these criteria are desirable in a compensation system?

Yes x☐ No ☐

3.1 Are there any others you think are desirable and should be included?

Wider issues

- The scheme contributes to:
  - organisational, local and national learning
  - patient safety
  - quality improvement

- Lessons learned can be used to influence organisational risk management in the future
- The scheme encourages and supports safe disclosure of adverse events
- The scheme does not put barriers in place for referral to regulators of any cases which raise grounds for concern about professional misconduct or fitness to practise.

Question 4: Do you have views or ideas on how a compensation scheme could more effectively contribute to the wider issues identified above?

We don't believe the compensation scheme, in respect of community pharmacy is likely to improve its contribution to the wider issues above.

Currently community pharmacists have to keep a record of any near misses or errors which occur. Staff should carry out a critical review of all errors, identify causative factors and change procedures to prevent a reoccurrence. Near miss logs should be analysed to look for patterns and trends and remedial action is put in place where possible.

The Patients Rights Act Scotland which was implemented in 2012 covers community pharmacy and pharmacists have to report complaints to the NHS. This enables learning's to be disseminated to a wider audience.

Community Pharmacists comply with the guidance included in "A guide to good practice in the management of controlled drugs in primary care - Scotland' published by The Accountable Officer's Network (Scotland) in March 2012. This guidance contains procedures to minimise dispensing errors concerning controlled drugs, including guidance and legislative requirements for all pharmacy processes involving Controlled Drugs. The NHS board Accountable Officer/CD team must be notified of all significant events, near misses, incidents and concerns involving CDs that occur within the pharmacy.

5. When considered the Review Group's suggested essential principles and criteria against other schemes and the Swedish model came out on top. Based on this the Review Group offered:

Recommendation 1 - that consideration be given to the establishment of a no-fault scheme for medical injury, along the lines of the Swedish model, bearing in mind that no-fault schemes work best in tandem with adequate social welfare provision.

Question 5: Based on the background information on the system in operation in Sweden given in Annex A would you support the approach suggested in Recommendation 1?

Yes ☐ **No** ☐

If not, why not and what alternative system would you suggest?

We need clarity on how the system would be funded and how it would work with existing insurers? We note that in Sweden the hospitals have set up their own insurance company.
Most errors relating to dispensing by community pharmacy are relatively easy to determine. Causation may be harder to determine. We note that the Swedish scheme requires the health care providers to carry liability insurance. Under current regulation owners of community pharmacies (and other providers of primary care) must carry appropriate levels of liability and public indemnity insurance. The NPAI insurance covers the actions of employed and locum staff. To include community pharmacy in a national scheme would appear to add complexity and delay to an already efficient system.
We note that in Sweden the handling of a number of small (dental) claims put a burden on the system. The majority of pharmacy claims are small and may include ex gratia payments as gestures of goodwill. The NPAI are well versed in handling these claims and do so swiftly and efficiently. If community pharmacy was included in a national scheme the speed and efficiency would be lost and costs would rise.
If a levy system is adopted how would costs/ levies be apportioned across the healthcare system? We are very concerned that costs and the burden on pharmacies would rise considerably as pharmacy claims are a very small proportion of claims arising from the provision of health care.

If a levy system is adopted who would collect the levies?

We are concerned that a tariff system, if it is to be fair, could drive up costs. The indemnity insurance provided by NPAI assesses each claim on its own merits. It is therefore able to keep costs proportionate to settlements made.

We note that under the New Zealand system if a claimant leaves the country then any ongoing payments stop. We feel that this is unacceptable especially for Scotland where people are more likely to move across the border to live.

The 'no win no fee' culture which drives up legal costs is not present in Scotland so legal fees are lower here than the rest of the UK.

As only a minority of cases relating to community pharmacy are referred to solicitors or council legal fees are not the significant cost they are for other parts of the NHS.

Recommendation 2 - that eligibility for compensation should not be based on the 'avoidability' test as used in Sweden, but rather on a clear description of which injuries are **not** eligible for compensation under the no-fault scheme.

Question 6: Would you support the approach in Recommendation 2? This would mean for example that where treatment carries a known risk and the patient has given consent to that treatment it would not be eligible.

Yes ☐ No x ☐

If not, why not?
This recommendation gives cause for alarm where medicines are concerned.

All medicines have the potential to cause side effects and it is impractical to give patient detailed information on every side effect and the likelihood of it occurring to any particular patient. Prescribers and dispensers will make an informed decision based on their knowledge of the medicine and the patient as to the level of information given. Pharmacists have a legal obligation to include with all dispensed medicines a Patient Information Leaflet (PIL), produced by the manufacturer, which includes information as to the action and side effects of the medicine as agreed with MHRA.
When a patient visits their GP consent is assumed and not asked for on every occasion. The doctor should always have an informed discussion with the patient before prescribing a new medicine; in practice this may be very brief. It is well documented that patients only recall a limited amount (30%) of information after a consultation with a doctor.
The act of a patient handing over a prescription to a pharmacist for dispensing demonstrates consent to the treatment.
Unlike GPs pharmacists do not have patient lists and do not have access to patient records. They therefore rely on their knowledge of the medicine and information from the patient when counselling patients about their medicines. Additional counselling provided by pharmacists, in addition to handing out the leaflet, is to improve patient understanding and compliance and not to gain consent.

If yes, what other injuries would you consider should not be eligible?

6. The Review Group was of the view that any recommended changes to a no-fault system should cover all healthcare professionals including those not directly employed by the National Health Service. The group believed that fairness dictated that all patients whether treated by the NHS or privately should have access to an improved system if possible. If this proved impossible, the group nonetheless believed that there were benefits that could be obtained by a move to no-fault for NHS patients. The group's preference was that **all** patients should be covered by the no-fault scheme and offered:

> **Recommendation 3 -** that the no-fault scheme should cover all medical treatment injuries that occur in Scotland; (injuries can be caused, for example, by the treatment itself or by a failure to treat, as well as by faulty equipment, in which case there may be third party liability)
>
> **Recommendation 4 -** that the scheme should extend to all registered healthcare professionals in Scotland, and not simply to those employed by NHSScotland.

(As explained in the Cabinet Secretary's foreword we acknowledge that further work is needed to help in our understanding of the volume, level and cost of compensation claims handled by the Medical Defence Unions and private healthcare providers. We will seek to explore this further with the relevant stakeholders during the consultation period.)

Question 7: Do you support the view that, if introduced, a no-fault scheme should cover all clinical treatment injuries (e.g. private healthcare and

independent contractors) and all registered healthcare professionals and not just those directly employed by NHSScotland?

Yes ☐ No x☐

If not, why not?

We do not support this view. As stated elsewhere in this document the number of claims received by insurers against community pharmcists is very low in comparison with other health care providers and the number of prescriptions dispensed.

The confidential information supplied as appendix a gives an overview of the number of claims against community pharmacy in Scotland over the last 3 years and the range of value of those claims. We also include an indication of the time taken to handle these cases and associated legal costs.

We believe that the cost and efficiency of handling claims against community pharmacy is unlikely to be improved and therefore community pharmacists should be excluded from the scheme. In Wales all primary care providers were excluded from their 'Right to Redress' scheme.

7.1 What, if any, difficulties do you foresee in including independent contractors (such as GPs, dentist etc) and private practice?

There was no representation of community pharmacy on the review group. The NPA as the major provider of insurance for community pharmacy considers this to be an omission. For the reasons given above we believe that those working in primary care should be excluded from the scheme.
See question 5 for our comment with regard to the Swedish system and dental claims.
As stated earlier we believe that the adoption of the proposed system will increase costs relating to community pharmacy claims, introduce delays for patients and pharmacists and increase the burden on community pharmacists.
The NPA welcomed the opportunity to discuss the issues with Sandra Falconer and is willing to discuss the matter further with the Scottish Government Justice Department.

7.2 What are your views on how a scheme could be designed to address these issues?

Question 8: The intention is that if introduced the no-fault system will not be retrospective. However, consideration will need to be given to when and how we could transfer to a new system and how outstanding claims could be handled if/when a no-fault system was introduced. What are your views on how outstanding claims might be handled?

7. The Review Group did not favour the use of a tariff system for compensation, as it felt that this would not address individual needs and it was unlikely that people would buy into a system where compensation was based on a tariff. The group therefore offered:

> **Recommendation 5 -** that any compensation awarded should be based on need rather than on a tariff based system;

Question 9: Do you support the approach in Recommendation 5?

Yes x☐ No ☐

If not, why not?

9.1 What are your views on the assumption that the level of payments will be similar to those settled under the current system?

The NPA currently assess claims on the basis of need. Claims for damages are usually based on the exacerbation of symptoms from not taking the correct medicine, and in accordance with the law relating to personal injury and clinical negligence claims.

There is a real concern that costs will increase for pharmacy insurers beyond those that are currently paid and proportionate to the settlement of claims of pharmacy in the proposed no fault system.

8. The Review Group was satisfied that a no-fault scheme established as they describe would be fully compatible with the requirements of the European Convention of Human Rights, based in particular on the need – as in Sweden and New Zealand – to build in appropriate appeals mechanisms, with an ultimate right to appeal to the courts on a point of fact or law. In addition, retention of the right to litigate will ensure that those for whom the no-fault system is felt to be inappropriate will still be able to raise claims using this route. The group recommended:

> **Recommendation 6 -** that claimants who fail under the no-fault scheme should retain the right to litigate, based on an improved litigation system
>
> **Recommendation 7 -** that a claimant who fails in litigation should have a residual right to claim under the no-fault scheme
>
> **Recommendation 8 -** that, should a claimant be successful under the no-fault scheme, any financial award made should be deducted from any award subsequently made as a result of litigation
>
> **Recommendation 9 -** that appeal from the adjudication of the no-fault scheme should be available to a court of law on a point of law or fact.

Question 10: Do you support recommendations 6 – 9 as proposed by the Review Group?

Yes ☐ No x ☐

If no, why not?

We disagree with recommendation 7; if there is no liability or causation established then claimants should not be allowed a residual claim.

With regard to recommendation 9; we believe that appeal should be available to a court of law on a point of law only, unless the point of fact is perverse there should be no appeal under this heading.

10.1 Do you have any concerns that the Review Group's recommendations may not be fully compatible with the European Convention of Human Rights?

Yes ☐ No ☐

If yes, what are your concerns?

9. The Review Group offered suggestions for improvement to the existing system and these are reproduced in Annex B. The group recommended:

> **Recommendation 10 -** that consideration should be given to our analysis of the problems in the current system, so that those who decide to litigate can benefit from them.

10. It is proposed that the suggested improvements will be taken forward as part of the forthcoming consultation on the Courts Reform Bill later this year by the Scottish Government Justice Directorate. In particular the Scottish Civil Courts Review[3] recommended that pre-action protocols should be made compulsory and it is considered that this would assist in resolving many of the areas identified by the Review Group In addition, Sheriff Principle Taylor's Review of Expenses and Funding of Civil Litigation in Scotland[4], which is due to report at the end the year will consider a range of issues.

Question 11: Do you agree with the Review Group's suggestions for improvements to the existing system?

Yes ☐ **No** ☐

11.1 Do you have any comments on the proposed action in relation to these suggestions?

11**.** The Review Group also considered whether or not the establishment of a scheme specific to neurologically impaired infants should be created (in the event that a general no-fault scheme is not introduced). Members considered that this group of patients arguably represents a special case and certainly accounts for the most significant sums awarded in compensation and legal costs. The Group were of the view that this was worthy of consideration.

[3] http://www.scotcourts.gov.uk/civilcourtsreview/
[4] http://scotland.gov.uk/About/taylor-review

Question 12: Would you support the establishment of a scheme specific to neurologically impaired infants if a general no-fault scheme is not introduced?

Yes ☐ No ☐

12.1 What are your views on the Review Group's suggestion that the future care component of any compensation in such cases could be provided in the form of a guarantee of delivery of services (both medical and social care) to meet the needs of the child, instead of by way of a monetary sum?

General Comments

We would welcome any further general comments you may wish to offer here.

We think it is important that the Scottish Government sets out the evidence base that a no fault compensation scheme is required for community pharmacy: it is not clear on what basis the Government has assessed that the current arrangements which apply in community pharmacies are inadequate.

Before taking these proposals forward we would expect the Scottish Government to undertake a full impact assessment to identify the potential costs for community pharmacy and other NHS providers. Only then can the cost-benefit be identified.

Community pharmacy should be excluded from the proposed 'no fault compensation scheme' for the reasons stated throughout the consultation document. Pharmacy insurers provide an efficient and effective service for claimants and pharmacy owners. In addition the majority of pharmacy claims are of low value. Including community pharmacy in the scheme would increase the complexity adding additional costs and bureaucratic burden to our pharmacy owners for no apparent gain.

The National Pharmacy Association (NPA) is the trade body which represents the entire spectrum of community pharmacy owners in Scotland and the UK. We count amongst our members nationwide pharmacy multiples, regional chains and independent pharmacies accounting for the majority of Scottish pharmacies. This spread of members, our Scotland and UK-wide geographical coverage, and our remit for NHS and non-NHS affairs means that we are fully representative of the community pharmacy sector. In addition to being a representative voice and the main provider of indemnity and public liability insurance, we provide members with a range of commercial and professional services to help them maintain and improve the health of the communities they service.

The NPA through NPAI are the main insurer for community pharmacy providing a complete package of insurance for pharmacy owners which includes professional indemnity, public liability, product liability and legal expenses. The insurance package covers all pharmacy staff employed at the insured premises and any locum pharmacists who may work there.
The NPA has been providing insurance since 1899

Over the last few years pharmacists have become better at handling complaints. In complying with NHS regulation all pharmacies have a process in place for dealing with complaints. After a heartfelt apology patients often only need reassurance and an explanation of what the pharmacist is doing to prevent a reoccurrence of the error.

We are grateful for your response. Thank you.