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## Pharmacists' Defence Association Response to 'A National Guardian for the NHS' Consultation

| representing **your** interests |

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## About the Pharmacists' Defence Association

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

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

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

## Executive Summary

The Freedom to Speak Up review was commissioned in June 2014 and examined the culture of whistleblowing in the NHS. The resultant report was published in February 2015 and recommended the introduction of an 'Independent National Officer' and network of 'Freedom to Speak Up Guardians'.

The 'Consultation on the implementation of the recommendations, principles and actions set out in the report of the Freedom to Speak Up review' was commissioned in March 2015, which asked questions about these roles and proposed that the 'Independent National Officer' be hosted by the Care Quality Commission. Following that consultation, the CQC is consulting further on the introduction of 'A National Guardian for the NHS', whose broad purpose will be to improve NHS whistleblowing culture.

The PDA fully supports the introduction of the National Guardian function and particularly welcomes the fact that Local Freedom to Speak Up Guardians will be accessible at least to some pharmacists working in a hospital setting. We do, however, have a number of serious concerns with the proposed approach. Broadly, these fall in to two areas:

- key elements of the current proposed structure, position and independence of the function are fundamentally flawed
- we are keen to ensure community pharmacy is in scope

### Our recommendations are:

- The most frequently used medical intervention in the NHS is medicine and the most frequently used point of access to NHS services is pharmacy. It is imperative that The National Guardian function includes community pharmacy – specifically the management of concerns raised by community pharmacists – within its scope.
- A radical rethink is required as to the host, positioning and independence of the National Guardian. It would be in the interests of the public both from a cost and a healthcare safety perspective to do that now rather than in the future. The initial Freedom to Speak Up consultation needs to be revisited after further careful consideration. The Health Select Committee must investigate these issues urgently.

- A clear timeline must be set out detailing which healthcare bodies, professions and organisations are to be included in the remit of the National Guardian. The remit must include the community pharmacy sector from the outset.
- The National Guardian must, through oversight of the management of concerns:
  - promote mechanisms for dealing with concerns at the appropriate level
  - ensure issues are thoroughly investigated without omitting difficult issues
  - ensure rights of appeal are clearly set out to whistleblowers
  - ensure appeals genuinely re-examine the issues and are not treated as a rubber-stamping exercise
- Local Freedom to Speak Up Guardians must be able to comment and provide advice about ongoing processes
- The functional positioning of the National Guardian and therefore its guiding principles need to be revised to ensure it is truly independent of the CQC, Monitor, TDA and NHS England. It must not concern itself with political issues so that it remains free to raise and document any issue it sees fit.
- The National Guardian function should have separate funding identified and manage its own budget.
- Local Freedom to Speak Up Guardians should be aligned geographically and have a wider focus on all NHS healthcare professions. Dedicated independent leads should be mandatorily aligned to (but not employed by) certain organisations such as NHS trusts and large multiple pharmacy chains.
- A distinct and explicitly-defined function of the National Guardian must be to actively share advice and learning publicly and nationally, in relation to better management of whistleblowing processes as well as common themes identified in whistleblowing allegations.
- The National Guardian should have a separate independent legal team with access to legal teams within the CQC, Monitor, TDA, NHS England and relevant healthcare regulators such as the GPhC.

## Introduction

The PDA fully supports the introduction of the National Guardian function, and particularly welcomes the fact that Local Freedom to Speak Up Guardians will be accessible at least to some pharmacists working in a hospital setting. We do, however, have a number of serious concerns with the proposed approach.

### Whistleblowing in Pharmacy

The function has the potential to make healthcare staff far more comfortable in coming forward with their concerns. It could help to remove the fear – and reality – of adverse consequences for doing so. It should share learnings and improve whistleblowing cultures. It must highlight common themes and trends to the public at a national level, related to both the *nature* of the concerns raised and their management – ultimately resulting in better patient care and safety.

The PDA Union deals with hundreds of whistleblowing cases each year and is contacted on a daily basis by pharmacists raising issues that directly impact on patient safety. It deals with many cases where pharmacists have raised issues with their line manager and then found themselves downgraded at their performance review or had their capability to do their job called in to question.

The PDA recently conducted a survey of its members. At the time of writing it had received 2,779 responses.

- 93% of respondents believed that at least some of the time there were not enough suitably qualified and skilled staff for the safe and effective provision of the pharmacy services provided. 22% said this was the case most or all of the time.
- 77% of respondents found that at least some of the time they were in a position whereby commercial incentives or targets had compromised the health, safety or wellbeing of patients and the public, or the professional judgement of staff. 26% said this was the case most or all of the time.
- 85% of respondents reported that at least some of the time they had found themselves in positions where they believe financial cutbacks imposed by their main employer had directly impacted upon patient safety. 38% said this was the case most or all of the time.

Comments from the survey included:

- ‘Running around multi tasking, trying to avoid mistakes. We don’t come across as safe. Having spoken out more than once, I have been threatened by area manager to button it. Nobody wants to whistleblow as they fear detection and disciplinary’
- ‘Where staffing is such an issue, there are obviously safety concerns, but there are ethical issues for me with the company as well – for example having what I believe to be inappropriate products on weekly deals, and giving staff incentives to sell them. When I raised concerns and said I didn’t agree with us selling a product in such a way... I was told by my area manager that Superintendent’s had given it the OK, and that was that’
- ‘Patient safety concerns not taken seriously, area managers do not respond at all to emails raising concerns’
- ‘Concerns fall on deaf ears, and any issues raised are turned back on the concerned party as either a performance or capability issue’
- ‘With so many pharmacists looking for work it makes it very hard to raise concerns about safe working levels in the dispensary. The response seems to be ‘Maybe you are not suited to the job’
- ‘I feel that as a locum I should be able to provide feedback to the employer, but fear of losing bookings means that I cannot afford to be critical or express any concerns of patient safety due to reduction in staffing levels’
- ‘Patient safety and wellbeing has just become ‘lip service’ in the company, as how can patient safety be... the companies major concern, when we are bombarded by emails every day with tables naming pharmacists who have and have not achieved their targets and shaming those who have not’
- ‘Intend raising concern even though it will put my livelihood at risk’
- ‘Patient care and safety are not the main concern money is’

- 'If you raise a concern then you are told to be incompetent which is a direct threat to your job. Only lip service to the patient safety and in reality it's money, money and more money'
- 'Raising concerns about lack of sufficiently qualified staff, availability of cover when staff are absent etc is met most of the time with silence or worse pharmacists are made to feel they are working inefficiently by management'
- '[Name removed] pharmacies are extremely understaffed and it is a serious patient safety concern'

## Community Pharmacy and the National Guardian Role

Primary care may be defined as the 'first point of contact in the healthcare system'<sup>(4)</sup> or alternatively 'all healthcare taking place outside acute and mental health trusts'<sup>(5)</sup>. We are unsure what definition has been adopted within the consultation document.

Community pharmacy is an integral part of primary care. According to the consultation document, it is proposed that the National Guardian will not initially review cases of staff raising concerns in primary care, but that it may do so over time; however, there is no specific mandate for this and no timeframe has been set out. The document does state 'we do propose to include in the scope independent healthcare providers who deliver NHS services covered by the standard contract'. Since it is not set out explicitly, we are unsure of what is meant by 'independent healthcare providers who deliver NHS services covered by the standard contract' and, specifically, whether this includes pharmacy contractors. By 'pharmacy contractors' we mean organisations (and staff thereof) who deliver pharmacy services under contract to the NHS such as community pharmacies. We are left uncertain as to whether community pharmacists and/or the community pharmacy sector will be included in the remit of the National Guardian from the outset or at all. We are also left uncertain whether pharmacists providing services under contract in a hospital setting, i.e. those working for a pharmacy contractor based within a hospital, would benefit from access to a Local Guardian.

The GPhC said in its response to the Freedom to Speak Up review that 'a culture of openness, honesty and learning within the environments in which pharmacy services are provided, as well as being able to raise concerns, is critical in making sure that patients receive safe and effective care' but also said 'as we have understood the proposals there

would be no requirement for registered pharmacies to have Local Freedom to Speak Up Guardians in place'<sup>(6)</sup>.

A number of PDA members with whistleblowing experience have expressed dismay that it may not be within the scope of the National Guardian function to consider staff concerns from community pharmacists, initially or eventually. The community pharmacy sector, beneath its surface, is desperate for the support that the National Guardian could offer.

Below we have provided some NHS figures which highlight the importance of community pharmacy in providing care to patients. The statistics demonstrate that, in order to safeguard the public, it is vital to have effective oversight of concerns related to the safety of community pharmacy patients.

- 978.3 million prescription items were dispensed by community pharmacies in England in 2014/2015<sup>(1)</sup>
- 1.6 million people visit a pharmacy each day<sup>(2)</sup>
- 84% of the adult population visit a pharmacy each year<sup>(2)</sup>
- The average adult visits a pharmacy 16 times a year<sup>(2)</sup>
- As at March 2013, there were 38,867 registered pharmacists in England, who each have a statutory duty to report concerns<sup>(3)</sup>
- As at the 31st of March 2015, there were 11,674 community pharmacies in England<sup>(1)</sup>

## External Context for Community Pharmacy

The European Court of Justice, in its determination C-531/06 – and in joined cases C171/07 and C172/07, May 2009, effectively concluded that non-pharmacists do not provide the same safeguards as pharmacists in the operation of a pharmacy and that member states may therefore take the view that 'the operation of a pharmacy by a non-pharmacist may represent a risk to public health'. Furthermore, it was said that 'there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator [, which] could make it difficult for them to oppose instructions given by him'<sup>(7)</sup>.

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

Since 2009, corporatisation of pharmacy in the UK has increased markedly. Over 50% of community pharmacies in the UK are part of major chains, and at least 40% are owned by groups with their headquarters outside the UK and whose executive directors at their highest level are almost exclusively non-pharmacists. Hospital pharmacy services are being contracted to the same chains. Non-GPhC registrants operating pharmacies remain unchecked with respect to the weakness of the whistleblowing culture they create; the utilization of whistleblowing helplines, for example, and management of concerns raised is subject to corporate control and decision-making. These changes have accentuated the tensions between corporate and professional imperatives; external oversight of corporate whistleblowing cultures from the Local Freedom to Speak Up Guardians would be immensely helpful. It is extremely important that pharmacy professionals are supported to raise concerns.

Pharmacy's regulator, the GPhC, is principally concerned with the fitness to practice of individual registrants and the inspection of registered pharmacy premises. It does not operate a whistleblowing helpline, nor does it have the incentive or mandate to do so. It is unable to regulate non-registrants (i.e. those who are not pharmacists or technicians) who may be responsible for the design and operation of any whistleblowing policy. It could hold the Superintendent of a pharmacy or pharmacy chain to account for any failure through fitness to practice mechanisms, but to do so takes a considerable amount of time, often more than a year, which could be a disincentive to raising concerns. In addition, whistleblowers would likely find themselves giving evidence against an individual rather than addressing a systemic issue. There is no co-ordinated dedicated external oversight of the whistleblowing culture or the operation or success of whistleblowing policies in the pharmacy sector.

Whistleblowing involves raising concerns about alleged malpractice, typically with a focus on issues that affect others. Through the introduction of the National Guardian function, there is a huge opportunity to shine a light on the issues affecting public healthcare provision. Some of the issues will be localised, but some will be systemic and of great national importance. The function should highlight issues raised with the way healthcare is provided to the public, and by doing so allow the public to make more informed choices about healthcare services.

### **Recommendation**

*The most frequently used medical intervention in the NHS is medicine and the most frequently used point of access to NHS services is pharmacy. It is imperative that The National Guardian function includes community pharmacy – specifically the management of concerns raised by community pharmacists – within its scope.*

## **Independence of the National Guardian**

The PDA finds the proposed approach frightening and sadly ironic. Whatever your views on the state of the public healthcare system, NHS England, Monitor, TDA and the CQC have presided over it, and the National Guardian is being introduced to contribute to the 'culture change that is needed throughout the system'. Although the intentions of those organisations may be wholesome, they should not regard themselves as benevolent and must be in a position to be challenged properly by the Guardian. Broadly speaking, the National Guardian's role is to improve the whistleblowing culture in the NHS. The approach set out – specifically that the National Guardian's authority will come from the aforementioned organisations – will intrinsically suppress concerns which are in conflict with the interests and modus operandi of those organisations. There would be a clear conflict of interest for the Guardian in highlighting concerns related to wider systemic issues relevant to their respective functions. Further, it will provide no support for employees of those organisations to raise concerns themselves in any meaningful way.



A further irony is that the conflicts of interest described in the consultation document are apparent, but appear to have been ignored. The document fails to address the concerns that the CQC ought to have with 'hosting' the National Guardian or 'locating the role' within its organisation. For example: 'Local Guardians will be appointed by the Chief Executive of their organisation to act in a genuinely independent capacity' and 'the National Guardian will operate independently of CQC, only reporting to our Chief Executive'. It is even being considered that the National Guardian use CQC branding (page 11). The fact that this is even being considered points to a total lack of independence. Blindness to these conflicts is exactly the type of approach which would be challenged by a whistleblower. The lack of independence is so stark that another current consultation being lead by the Royal Pharmaceutical Society refers to the National Guardian as a 'Care Quality Commission National Guardian'<sup>(14)</sup>.

It is sad and telling, but at least honest, that the current approach 'has advantages over creating a new body that would require new legislation and incur greater costs' (explained in the consultation document). It should be remembered that it is events such as the Stafford Hospital scandal that has ultimately lead to the introduction of the National Guardian. The scandal involved patient deaths as a result of poor care, attributed at least in part to financial considerations<sup>(10)</sup>. We seriously question whether the wider public has truly made an informed decision that it wants a lower cost option.

### **Recommendation**

*A radical rethink is required as to the host, positioning and independence of the National Guardian. It would be in the interests of the public both from a cost and a healthcare safety perspective to do that now rather than in the future. The initial Freedom to Speak Up consultation needs to be revisited after further careful consideration. The Health Select Committee must investigate these issues urgently.*

## **Other External Context**

The PDA noted that a new chair was recently appointed to the CQC. At his pre-appointment hearing on the 1st of December 2015, he was asked by the Health Select Committee how he would ensure people were not afraid to whistleblow. He said he needs to 'understand properly whether there really is a problem'<sup>(19)</sup>. Given the massive press coverage of the difficulties facing whistleblowers and the controversy around whistleblowing the CQC has experienced itself, the PDA is alarmed that this remains a question in his mind. The PDA takes the view that executive officials appointed to such high level positions really should know better and ought to take the time to apprise themselves of the issues at hand. It does usefully further demonstrate that the position of the National Guardian relative to the CQC will not be a suitable arrangement from a public safety perspective. It also shows that the National Guardian needs to remain entirely independent of the CQC, must be able to hold the CQC to account through the issues it brings to the attention of the public and must help it to learn. Although the new chair's comment indicates that it will be beneficial for the CQC to learn from the Guardian, ignorance of the issues cannot be used to justify hosting it.

We also have concerns about the recruitment process used. The advert for the National Guardian role was placed in a national newspaper<sup>(18)</sup> from the 13th to the 28th of September 2015 with interviews to be held on the 27th of November 2015. The consultation process ran from the 17th of September to the 9th of December. We would question how a suitable candidate was selected when it was not yet known how the Guardian would operate; it is difficult to imagine that the successful candidate simply presented themselves as a blank canvas waiting to be informed by the consultation responses. If the candidate simply acquiesced to the way the CQC believes the role should be delivered, as evident from the consultation document, then the public interest has not been served by this consultation.

## **The Consultation Document**

As a general principle, we recommend that questions in a consultation such as this should be asked in an entirely neutral manner. Commencing questions with 'do you agree' could lead to acquiescence bias<sup>(11) (12)</sup>. This may mean that the responses obtained will not truly represent respondents' views.



# Questions

## 1. Do you agree with the proposed scope for the National Guardian?

No

### Please explain your answer

It is a fundamental flaw within the proposals not to ‘initially review cases of staff raising concerns in primary care’, even if the remit of the National Guardian is extended over time. The rationale provided for this within the consultation document is that:

- it would risk shifting ownership of the problem away from frontline providers
- it would not support the creation of a learning culture
- the potential resources required for the office of the National Guardian are hard to predict accurately until it is operational
- starting with concerns raised by staff in NHS trusts and NHS foundation trusts only will allow the National Guardian to gain a better understanding of the resources needed

The PDA believes this rationale does not logically support the position and is flawed even in itself.

- It is entirely unclear how including primary care in the Guardian’s remit would shift ownership of the problem away from frontline providers. Primary care providers, including pharmacists, are also on the front line.
- It is unclear how reviewing whistleblowing cases in primary care from the outset would not support the creation of a learning culture. The PDA believes it is clear though that if primary care was to be excluded, even initially, this would be detrimental to improvements in learning culture in those working environments.
- Regardless of whether primary care is included from the outset, it will remain difficult to predict the resources required to bring it in to scope. If primary care was brought into scope in the future, this problem would remain the same. It would however be more difficult to ‘undo’ the structure of the network established at this stage; if Local Guardians were employed by and focused solely on NHS Trusts and Foundation Trusts, a structural review would likely be needed in order to expand their role.

In order to establish the Local Freedom to Speak Up Guardian network effectively, to create the right focus, balance and remit, it is essential that the function starts as it means to continue. If its focus is to improve the whistleblowing culture throughout the NHS, its ways of working and Terms of Reference of its associated board would be better defined through a more holistic focus at its inception. We are particularly keen to ensure that the community pharmacy sector is in scope from the outset.

### Recommendation

*A clear timeline must be set out detailing which healthcare bodies, professions and organisations are to be included in the remit of the National Guardian. The remit must include the community pharmacy sector from the outset.*

## 2. Do you agree that these principles are the rights ones?

No

### Please explain your answer

We are concerned about the wording and nature of principle d (‘The National Guardian will not second-guess or interfere with ongoing processes locally or nationally’). We believe there will be instances where it is appropriate for the National Guardian to comment on or provide advice about an ongoing process. This principle must not prohibit that being done if necessary. It must be made clear that doing so would not constitute ‘second guessing’ or ‘interference’.

### Recommendation

*The National Guardian must, through oversight of the management of concerns:*

- *promote mechanisms for dealing with concerns at the appropriate level*
- *ensure issues are thoroughly investigated without omitting difficult issues*
- *ensure rights of appeal are clearly set out to whistleblowers*
- *ensure appeals genuinely re-examine the issues and are not treated as a rubber-stamping exercise*

It may be necessary to comment on the process followed in an investigation, without necessarily commenting on the outcome. Steps may need to be taken during an ongoing investigation to improve the process. These steps would be taken by those conducting the investigation rather than by the National or Local Guardian, but contemporaneous input from the Guardian may be helpful or even vital.

**Recommendation**

*Local Freedom to Speak Up Guardians must be able to comment and provide advice about ongoing processes.*

We are also concerned about the nature of principles (a) and (e). It is stated in the consultation document that ‘the National Guardian must be independent of both providers and national bodies’ (page 10). The recommendations of the National Guardian may conflict with the interests of one of the four national arms-length bodies (the CQC, Monitor, the TDA and NHS England) – for example if a recommendation meant that additional funds were needed at a national level. This may lead to indirect pressure on the National Guardian not to make such recommendations in the first place, pushing certain issues below the surface and out of the public eye. The Guardians must not concern themselves with such issues and must make public their recommendations, whether politically controversial or not.

**Recommendation**

*The functional positioning of the National Guardian and therefore its guiding principles need to be revised to ensure it is truly independent of the CQC, Monitor, TDA and NHS England. It must not concern itself with political issues so that it remains free to raise and document any issue it sees fit.*

**3. Do you agree that the proposed arrangements will be enough to effectively ensure the National Guardian’s independence, and provide effective governance?**

No

**Please explain your answer**

If the National Guardian is appointed by the CQC, the individual would naturally be indebted to the CQC for their appointment and would be conscious that this would be due for review every 3 years. It is proposed that CQC resources would be used by the National Guardian, including the provision of legal advice, ‘analysis to support themed reviews’ and administrative tasks such as forwarding FOI requests. The CQC’s call centre will be shared with the National Guardian, rather than the Guardian having its own ‘private premises’ for the whole of its function.

The consultation document states that out of 106 responses, 56 (out of 75 that gave a view) were in favour of the role being hosted by the CQC. It was actually proposed in the consultation documents for the ‘Consultation on the Implementation of the Recommendations, Principles and Actions set out in the Report of the Freedom to Speak Up review’ that the Guardian be based at the CQC, and as such this would be subject to acquiescence bias from the respondents. The question asked was ‘Do you agree that the Care Quality Commission is the right national body to host the new role of Independent National Officer, whose functions are set out in principle 15 of the Freedom to Speak Up report?’ No alternative was suggested, so the lack of consensus as to an alternative among those who disagreed should not be surprising. The PDA’s view is that it is also wrong and misleading to simply state the number of responses received. The numbers say nothing of the quality of those responses and the merits / validity of the points raised by those who disagreed.

We take the view that the National Guardian ought to be accountable to parliament with scrutiny from the Health Select Committee, and must be independent from the four arms-length bodies. A concern may be reported to the CQC which requires management and oversight from them. The National Guardian may need to comment on aspects of the CQC’s response or handling of the concern and may be reticent to do so given that the CQC will be hosting the function.

Separate funding should be identified for the National Guardian. Identifying the funding as an element of the CQC's budget may mean that the National Guardian will be liable to direct or subtle indirect interference from the CQC. The CQC might, for example, take the view that the amount spent by the Guardian on healthcare professions for which it has no oversight was too high, leading it to question and challenge that amount. For the funding level and prioritisation to be appropriate, it should not be managed by a regulator whose oversight does not extend to each of the professions for which resources and funding would be required.

**Recommendation**

*The National Guardian function should have separate funding identified and manage its own budget.*

According to the consultation document, The Freedom to Speak Up review recommended that:

- 'the National Guardian must be independent of both providers and national bodies' (page 10)
- 'expenditure that relates to the National Guardian's role and activity must be appropriately managed... and be subject to the Chief Executive's ultimate oversight'
- 'it is the independence of judgement of the National Guardian that is critical' and later 'the National Guardian's decisions over which cases to review, and their recommendations regarding those cases must be entirely free from interference from other CQC executive staff or other national bodies. They remain accountable to the Chief Executive of CQC for the overall delivery of their role and functions'

The PDA finds the conflicts worryingly obvious here and they arise even within adjacent sentences (see last bullet point above). The National Guardian cannot be independent if it is 'hosted' by and/or financially accountable to the CQC.

Further evidence of the lack of independence of the National Guardian exists in the CQC public board paper dated 29th July 2015. It states 'There needs to be a formal arrangement with Monitor, TDA and NHS England that governs their... expectations in terms of input into the delivery of the role'<sup>(17)</sup>. If the four arms-length bodies are to have formal input into the delivery of the National Guardian's role, it cannot be independent.

28% of respondents to a CQC staff survey in 2013 claimed that its culture was 'bullying'<sup>(16)</sup>. In 2012 the CQC-commissioned 'Project Ambrose' to be carried out by Grant Thornton; the report was published in 2013. The report led to significant press coverage and highlighted a 'number of weaknesses in governance arrangements, leadership culture and handling of concerns raised'<sup>(15) (20)</sup>. The PDA understands that the CQC may have learned from these events. However, these are recent events in the CQC's history and the standard of proof of having taken action as a result should be high for a regulator, given the pivotal role in upholding public confidence in the NHS. A survey in 2015 revealed that only 33% of CQC staff responded positively to the question 'I believe that changes are effectively implemented in CQC' and only 65% answered positively 'I feel that CQC is committed to an environment which is free from bullying and harassment', the rest remaining neutral or answering it negatively<sup>(21)</sup>. Therefore the PDA believes that it would only be proper and in the public interest for the CQC to distance itself entirely from hosting the National Guardian.

**4. How should communications from the National Guardian be branded?**

A sentence on page 11 of the consultation document reads 'CQC must also ensure that the function is established in a way that safeguards its independence from CQC and the other arm's length bodies.' Bearing in mind that the National Guardian is to be independent, it should have independent branding.

**5. Do you agree with our proposal that the National Guardian should build a strong network of local FTSU Guardians?**

**Yes**

**Please explain your answer**

Local insight and knowledge will enable oversight of individual cases and ensure local enhancement of whistleblowing culture. In addition, the network will be instrumental in forming a cumulative national view on major and common issues, which will be vital to the success of the National Guardian's role in influencing change.

**Do you have additional ideas for how this should be delivered?**

Only having a Local Guardian attached to NHS Trusts is short-sighted and is a fundamental flaw in the current plans.

**Recommendation**

*Local Freedom to Speak Up Guardians should be aligned geographically and have a wider focus on all NHS healthcare professions. Dedicated independent leads should be mandatorily aligned to (but not employed by) certain organisations such as NHS trusts and large multiple pharmacy chains.*

A regional management structure would allow the Guardians to remain independent of organisations.

In the consultation document, a clear conflict exists within the sentence ‘Local Guardians will be appointed by the Chief Executive of their organisation to act in a genuinely independent capacity’. The Local Guardians will not be independent of their organisation if they are appointed by it.

The Chief Executive of the organisation will be managing budget constraints, influenced by regulatory oversight from the four arms-length bodies. He or she will be responsible for other operational elements which may affect the issues raised to and via the Local Guardians. The Chief Executive may influence the views and approach of the Local Guardian. The continued employment of the Local Guardian being dependent on the Chief Executive would not instil a healthy culture and would limit the accessibility of the Local Guardian to staff in other healthcare providers – such as pharmacy staff – meaning that a restructure would be required if the remit of the Guardians was to be extended in future.

Performance metrics must be designed and delivered carefully by the National Guardian to achieve consistency nationally and to reduce the risk that Local Guardians would compete with each other inappropriately in relation to the number of concerns raised. For example, monitoring of performance based on the lowest number of concerns raised would be inappropriate and defeat the objective of having a Guardian.

**6. Do you agree with our proposals that the National Guardian should review how concerns have been handled in individual cases, where serious issues appear to exist?**

Yes

**Please explain your answer**

The proposals in relation to this question seem reasonable.

**Do you have additional ideas for how this should be delivered?**

The proposals in relation to this question seem reasonable, with the caveat that they should not be NHS trust-centric (e.g. ‘individuals should go through relevant NHS trust processes for raising and managing a concern’ (page 15)). We have addressed our concerns with a trust-centric approach in our responses to other questions.

**7. Do you agree with our proposal that the National Guardian should support and advise providers?**

Yes

**Please explain your answer**

Healthcare providers must be supported to learn and improve the whistleblowing culture. This will be to the benefit of whistleblowers and as such should be a function of the National Guardian.

**Do you have additional ideas for how this should be delivered?**

Whilst they should advise and support providers, it is essential that the Local Freedom to Speak Up Guardians retain their independence from providers. Guardians must be able to identify instances in which individuals or organisations are seeking to use the function for their own ends – for example to obscure a problem through misdirection or falsely embracing support and advice. They should also be provided with tools and guidance to help assess their level of independence.

**8. Do you agree with our proposal that the National Guardian should provide support and challenge to the system?**

**Yes**

**Please explain your answer**

This proposal emphasizes the role of the National Guardian in creating better whistleblowing cultures by supporting employers to get it right and learn from mistakes, but also by challenging them as necessary, both of which would support whistleblowers. The proposal must also mean that the National Guardian has a role in challenging the healthcare system through identification of common themes raised by whistleblowers.

**Do you have additional ideas for how this should be delivered?**

As already stated, to provide effective challenge to the system the National Guardian must be independent of the four arms-length bodies.

**9. Do agree that the four functions described are the right ones to enable the National Guardian to discharge its role, as described in the Freedom to Speak Up review?**

**No**

**Please explain your answer**

The four proposed functions seem appropriate in themselves. We would add, however, that a fifth function, which is distinct from the others and should be stated explicitly, must be added. The Guardian must actively share advice and aid learning publicly and nationally. Its guidance may be tailored for whistleblowers or for organisations. Learning should not be confined to better management of the whistleblowing process and improvement of the whistleblowing culture; Guardians will be in a prime position to provide insights into common themes and major issues raised by whistleblowers, and must do so. This will include insights into their experiences and treatment as whistleblowers, but will also include insights into the subject of their allegations. The Guardians might become aware, for example, that concerns are commonly being raised about working conditions.

A necessary part of having a better whistleblowing culture will be that issues such as this are raised to very high levels – which the Guardians will be in a unique position to do.

**Recommendation**

*A distinct and explicitly-defined function of the National Guardian must be to actively share advice and learning publicly and nationally, in relation to better management of whistleblowing processes as well as common themes identified in whistleblowing allegations.*

**10. Do you have any further views on how the National Guardian should discharge its role?**

**Yes**

As set out in the introduction, it is of paramount importance that community pharmacy be included in the scope of the National Guardian.

We have already said that the National Guardian must be entirely independent from the CQC, and have set out our views in responses to other questions. As such it would need its own legal team. It is proposed in the consultation document that the CQC’s legal team would support the National Guardian. The CQC’s legal team will not have experience in all areas of healthcare. This will limit their ability to function at a level appropriate to the needs the healthcare professions outside of the CQC’s remit.

**Recommendation**

*The National Guardian should have a separate independent legal team with access to legal teams within the CQC, Monitor, TDA, NHS England and relevant healthcare regulators such as the GPhC.*

**11. Do you agree with the assessment of drivers of costs and benefits of the National Guardian and its functions?**

**No**

**Please explain your answer**

There will be costs of consumable items and maintenance / infrastructure of private office space associated with the function, not mentioned in the consultation document. In addition, there will be costs associated with the publication and dissemination of reports. These have perhaps not been mentioned in the report since the costs will be absorbed by the CQC; it is understood that the private office space for the National Guardian will be on the CQC's premises. This would further point to a lack of independence of the Guardian from the CQC.

**Can you provide further examples of likely drivers of costs and benefits?**

With respect to the staffing costs for Local Guardians, it has not been set out whether these are to be charged to the National Guardian or given as incremental budget to the organisations at which they are based. The PDA's view is that the Local Guardians should be charged to the National Guardian's budget, which we have already said should be its own to manage so that it is independent from the CQC.

Healthcare regulators should also benefit from the function, through greater awareness of the issues raised by staff. With the correct approach, this would enable them to discharge their roles and safeguard the public more effectively.



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