



Department
of Health

Amendments to Human Medicines Regulations 2012 Consultation Responses

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Amendments to Human Medicines Regulations 2012 Consultation Responses

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Executive summary

On 22nd September 2014 a consultation document was published jointly by the Medicines and Healthcare Products Regulatory Agency (MHRA), Public Health England, Department of Health and the Public Health Agency (PHA) /Department of Health, Social Services and Public Safety (DHSSPS). We consulted, on proposals to amend the Human Medicines Regulations 2012 to enable Public Health England (PHE) and the Public Health Agency in Northern Ireland to develop and authorise Patient Group Directions (PGDs).

This proposal is intended to strengthen the health protection response to outbreaks of infectious disease and other incidents through extending the use of PGDs to staff employed by Public Health England (PHE) and Public Health Agency. The aim is to ensure that in the event of an incident or outbreak PHE staff can take the appropriate rapid action to respond or to control the spread of disease. Although supplying/administering vaccines and medicines during incidents and outbreaks will remain primarily an NHS responsibility, enabling PHE and PHA to authorise its own PGDs and specified PHE/PHA health professional staff to supply and/or administer vaccines and medicines under PGDs, will support the Health and Social Care response and strengthen resilience across the respective public health systems in England and Northern Ireland.

Following discussions with key health protection stakeholders, the Department of Health and DHSSPS consider that there is a clear case for Public Health England and the Public Health Agency in Northern Ireland to be able to authorise PGDs. This will enable PHE and PHA staff to supply and/or administer medicines to help ensure the resilience of any response to an outbreak or incident. We therefore propose to add PHE and PHA to the list of authorising bodies specified in Human Medicines Regulations 2012.

Given the expertise and robust arrangements for clinical governance within PHE and PHA we do not believe that enabling PHE/PHA staff to authorise PGDs or to administer medicines under them represents any significant risk. Conversely, not doing so would risk a sub-optimal response to outbreaks, which could lead to serious illness or death.

We are not proposing any amendments to the current legal requirements for signature by a doctor or dentist and a pharmacist or to the particulars the PGD must contain. In addition, we have full confidence that PHE/PHA have the appropriate skills, resources and governance structures necessary to develop and authorise PGDs and to use them safely and effectively.

Consultation Process

The consultation exercise was in accordance with the Cabinet Office Consultation Principles published in July 2012 (Annex A). The consultation process ran from 22nd September 2014 until 31st October 2014. This document provides the responses to the consultation.

The consultation document was published on the MHRA website - www.mhra.gov.uk. The consultation asked 3 questions in relation to the administration of Patient Group Directions.

Number and range of responses

We received 16 responses to the consultation, of which 15 were e-mail and 1 postal. Of the responses:

- 1 was from a NHS Trust
- 1 from a Clinical Commissioning Group (CCG)
- 1 from Acute Hospital
- 1 from Local Pharmaceutical Committee
- 1 from National Pharmaceutical Advisers Group
- 1 from National Ambulance Service Medical Directors
- 1 from National Ambulance Resilience Unit
- 1 from Royal College of Physicians Edinburgh
- 1 from Royal College of Surgeons Edinburgh
- 3 from Pharmacists
- 1 from RCP
- 1 from Royal College of General Practitioners
- 1 from Royal College of General Practitioners (CIRC).
- 1 from Guild of Healthcare Pharmacists

Summary of responses

In this section we have summarised the responses to each of the consultation questions. Not all respondents answered every question, whilst others commented more broadly on the overall content of the consultant document.

Q1: Do you agree with the proposal to include PHE and PHA in the list of authorising bodies under the provisions in medicines legislation to develop, authorise and administer Patient Group Directions? If not, why not?

Every respondent supported the proposals in the MLX letter that Public Health England and Public Health Agency in Northern Ireland should be able to develop and authorise Patient Group Directions. Further comments on this proposal were also given as below:

We agree to have PHE write and authorise PGDs but we feel supply should remain with the existing infrastructure. We question whether the 14 centres will be local enough to serve each region in a timely manner. For example a regional centre in Birmingham would have to travel to Stoke on Trent via the busiest stretch of the M6 which is frequently gridlocked. Local services would be able to respond much quicker. (Local Pharmaceutical Committee)

Yes, the College would agree with this, in exceptional circumstances only. It should not be seen to replace existing usual mechanisms via the NHS. We would appreciate it if further clarification was available as to how it is proposed to ensure this will be by exception only and will not become routine. (Royal College of Physicians)

There appears to be some confusion with the involvement of the Public Health Agency (PHA) in Northern Ireland. The title implies it only applies to Public Health England but paragraph 5 on page 1 implies PHA is involved. This is further confirmed by the proposal paragraph 20 and 23. It is unclear whether Northern Ireland is covered by the proposal.

It is not clear why Wales and Scotland will not have equivalent health bodies also authorized. The 4 scenarios provided in Annex A may involve communities on the boundaries of England and Wales or England and Scotland. How will these situations be dealt with and managed?

It would be prudent to develop template PGDs for emergency use and make these available for consultation with national primary care and community nursing representation to ensure resilient PGDs. (Royal College of General Practitioners)

The text is open to different interpretation. It states “it will generally be nurses who are administering/supplying medicines in accordance with the PGD”. Does this mean there may be cases where it is not nurses who are working to the PGD? If this is the case, what other groups are being considered and are the necessary safeguards in place to ensure this additional group are suitably trained/ skilled to undertake the supply and administration of medicines, and are they covered within existing PGD legislation as a group that can work to PGDs? If the PGDs are forced onto other organisations e.g. NHS Trusts, will they be in a format that the receiving organisation can alter the content as we assume that in such a situation the receiving organisation would need to take over the responsibility for the PGD? The text could be interpreted as PHE being ‘above’ the PGD legislation and therefore able to nominate anyone to

work under a PGD. This would be unacceptable. It would also be unnecessary as there is already legislation in place that allows the Government, in an emergency, to relax all the rules and regulations surrounding medicines to open up supply routes.

Although it may be outside the scope of the consultation, there is no mention as to how the medicines will be procured or made available for the PGD to work. The scenarios presented outline mass outbreaks as an example, so if the PGD is to prove effective and useful, we would suggest that there would be a need for rapid access to the medicines for the staff to supply and administer. This is obviously an implementation issue, but if it is not thoroughly considered the PGD would not be of use if the staff do not have the medicines to give. (Guild of Healthcare Pharmacists).

The intention is that the PHA in Northern Ireland will be covered by the proposal to be added to the list of authorising bodies under the provisions in medicines legislation to develop, authorise and administer Patient Group Directions.

Wales and Scotland will not have equivalent health bodies also authorized due to the different nature of their health protection services.

As regards developing template PGDs for emergency use and making these available for consultation with national primary care and community nursing representation to ensure resilient PGDs, PHE has already developed PGDs for Emergency planning e.g. potassium iodide/iodate, ciprofloxacin and doxycycline. Future development would be dependent on other factors, such as resources.

To enable the PGD to work, it is the intention that we are going to amend legislation to allow PHE/PHA to obtain wholesale supplies of medicines.

As for who will administer medicines, professional staff must only include those who are already allowed under legislation to supply or administer under a PGD. This covers many but by no means all PHE/PHA staff.

Q2: We would welcome information on any instances where you believe that there will - or could be - any adverse effect on equality issues under any of the following:

- **competition assessment;**
- **small firms impact test;**
- **legal aid;**
- **sustainable development;**
- **carbon assessment;**
- **other environment;**
- **health impact assessment;**
- **race equality;**
- **disability equality;**
- **gender equality;**
- **human rights;**
- **rural proofing.**

All respondents could see no adverse effects of this change to the legislation. Comments were:

Competition assessment – would impact on existing supply chains for any medication required. Carbon and Environment – there would be an impact if additional resources are deployed when local supply chains and staff are available. Rural proofing – If there are only 14 centres nationwide, travel time to rural areas would be long. Existing local services would be able to respond faster. (Local Pharmaceutical Committee)

As long as the PGDs are composed of a range of ethnic groups and genders this should mitigate against inequalities. We can foresee that individuals with disabilities may have difficulty in being part of the rapid response team either through mobility issues; visual impairment or hearing impairment but they may well be able to assist with the logistics and communication necessary for PGDs support at base. (Royal College of Surgeons Edinburgh).

Q3: You are invited to comment on the proposed changes to medicines regulations governing the use of PGDs.

The document refers generically to PHE staff. Only one of the scenarios refers to nurses being the staff member using PGD. I would support the proposal if the range of staff allowed to use the PGD remain the same as now, ie nurse, pharmacist, etc, but not an HCA. How would the people excluded by a PGD be captured eg if ill on the day and requires deferral? (NHS Trust)

I support these changes completely, they are appropriate and sensible to assist the emergency preparedness of the UK to significant disasters or terrorist incidents. (National Ambulance Resilience Unit)

We feel that it is a good idea to write and authorise PGD's centrally but it would be beneficial to work with existing services rather than bypassing local talent and expertise. Working with LMCs and LPCs would ensure that local GPs and pharmacists were able to deliver the supply aspect of the proposal in a timely manner. For example during the avian flu pandemic, pharmacy was deployed successfully to supply medication quickly before local centres were set up. We were able to be flexible by moving staff to the branches supplying the medication to ensure that there was no impact on the day to day services. This showed that the existing infrastructure was able to respond much faster than a central set up. (Local Pharmaceutical Committee)

We are in agreement that the ability of PHE to support the rapid issue of vaccines and drugs in response to large population outbreaks of disease would be facilitated by PHE PGDs rather than relying on local solutions. The Scenarios suggested reflect the most likely scenarios where PHE PGDs would allow rapid administration or distribution of vaccines or medication in populations at risk of contracting disease requiring prophylaxis or requiring treatment after contracting disease PGDs could be used for distribution of antidotes or antitoxins in response to terrorist chemical attacks or accidental exposure to toxins. Consideration should be given to the logistics around distribution of medicines and whether the PHE NHS arrangements described on page 15 are in place following NHS re-organisation The PGDs may cover multiple supply sources and the quantities and labelling of the medicines need to match the PGD and labelling must meet Medicines Act requirements PHE may require wholesale dealing licence provisions Consideration should be given to the lessons learnt and difficulties experienced in the Swine Flu Pandemic around medicines distribution. Consideration should be given to how PHE writes the PGDs in relation to the resources required , availability of a pharmacist and who would sign off the PGDs. PHE may learn from the difficulties experienced by parts of NHSE in the writing, signing off PGDs in relation to vaccines. The dissemination of the PGDs should be via a link to the PHE website.

The time frame from writing to sign off and distribution should be considered as this may be longer than might first be anticipated and this is important if it is time critical in a health emergency. The emergence of Ebola highlights the possibility of a requirement to use an unlicensed vaccine if this becomes available. The use of unlicensed products (as opposed to

use outside the terms of the product licence) is outside the original provisions set out in the original directive HSC 2000/026. There may be issues around liability and as PHE is an executive agency of the DoH, the Department of Health may wish to consider these issues. (Pharmaceutical Advisers Group).

The manner in which PGDs will be drawn up is unclear within the consultation document. It may be that this has not yet been decided until consensus is reached as to whether it should be permitted at all. However we have concerns about the way in which these PGDs may be implemented. For instance, will PGDs be drawn up at a national or regional level? Our preference would be for nationally-agreed PGDs to be in place for clarity & to reduce confusion between regions.

The speed with which PGDs are likely to be developed is also of concern. Is it PHE's intention to have a library of PGDs – covering a vast range of possible public health emergencies – ready to roll out in the event of an emergency arising? This would be a lengthy task for whoever was responsible for the development of the PGDs & would require a rigid system of review to ensure they all remained up-to date & fit for purpose.

Alternatively, if PGDs are developed as soon as an emergency arises, will there be sufficient safeguards in place to ensure all key personnel required for the PGD development are readily available & are given sufficient time to review the PGD carefully to ensure its clinical safety & appropriateness? In both instances there will be the issue of public health personnel administering medication under a PGD that they are unlikely to be familiar with. We assume safeguards will be put in place regarding staff training & recording any untoward incidents etc. The option to extend the use of pharmacies in the administration of PGDs merits further consideration, in our opinion. Pharmacists have a wealth of experience with PGDs & should be included wherever possible.

Indeed, we see this consultation as being an ideal opportunity to create national public health PGDs, such as for emergency hormonal contraception, smoking cessation & minor ailments, to improve clarity & consistency of service provision up & down the country.

Procurement of medication/treatment is another aspect of this consultation that we feel requires further discussion. The majority of pharmacies do not have wholesale dealer licenses so are only able to make small volumes of supplies as wholesale transactions. It is likely this would not be enough to meet PHE's requirements. This would require PHE to obtain stocks direct from the manufacturer, from pharmaceutical wholesalers (if accounts are in place) or requisitioned from hospital pharmacy stores.

For supplies to be obtained via wholesale transactions they could only be made as original manufactured packs. If the intended supply for the patient's treatment was for a quantity that did not equate to a complete manufacturer's pack pharmacies would need to be involved in the supply chain, whether that is by pharmacists making supplies from the PGD or, say, hospital pharmacies preparing smaller patient treatment packs.

In conclusion, we agree with PHE & PHA becoming able to develop, authorise & administer PGDs but do feel the role of pharmacies in the implementation of such PGDs should not be overlooked. (Pharmacist)

The scenarios all seem to suggest that the PGDs would be for use by PHE staff only. In our opinion PHE should have a role in producing PGDs that covered additional staff including those working in community pharmacy. There are a variety of Public Health services commissioned from community pharmacy. We believe that an opportunity is being lost by not considering

whether PHE could also be given the responsibility to create template PGDs for community pharmacy services.

Presently, each HWB (or other commissioner) needs to create their own PGD for their service even though the service specifications are normally very similar. This is leading to duplication of effort both on the part of the commissioner and the need for community pharmacists being required to sign multiple PGDs for what amounts to be the same service. This is also, clearly, an expensive process which, with duplication, does not make economic sense. For example, in West Yorkshire a single PGD underpins the EHC service commissioned from 5 different commissioners. It would be helpful if this type of collaborative working were seen on a larger scale using PHE resources at a national level.

We believe that, in collaboration with other bodies, PHE should create national service specification templates and then PHE specifically should be given the responsibility for creating any PGDs which are needed to operate those services.

This is not currently what was envisaged i.e. the plan is to develop PGDs for PHE employed staff only. However, templates could be developed for community pharmacies to adapt/adopt, but to extend the current plans would need further thought and considerable resources.

There is no mention in the consultation of the route by which medicines will be procured to operate the PGDs. (Pharmacist)

The RCSEd has a Faculty of Pre-hospital Care which includes paramedics so we may be able to assist PHE in assuring competence; bestowing qualifications and training this group of registered health professionals. RCSEd Dental Dean would be happy to advise on which group of Dental Practitioners would be suitable to aid in the drafting of the PGDS directions. A robust governance structure will be essential and external members on the biannual review groups is recommended. (Royal College of Surgeons Edinburgh)

Regarding the question of any “library of PGD.s” We would prioritise what we did in advance, and as in any emergency environment also decide what needed to be done urgently.

As for the question of PHE creating national service specification templates and then being given the responsibility for creating any PGDs which are needed to operate those services. This is not currently what was envisaged i.e. the plan is to develop PGDs for PHE/PHA (as appropriate) employed staff only. However, templates could be developed for community pharmacies to adapt/adopt, but to extend the current plans would need further thought and considerable resources

Conclusion and Next Steps

We are grateful to all those who responded to our consultation about the proposed amendments to Human Medicines Regulations 2012.

The consultation responses have been helpful in identifying the different issues that the MHRA needs to consider when developing the amendments to the Patient Group Directions, and associated guidance and the responses have given us a number of valuable ideas about how we can overcome these challenges.

Next steps

This document will inform the development of the amendments to the Human Medicines Regulations 2012 and their future publication.

Guidance is available from the PGD website

<http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/>

Annex A: Cabinet Office Consultation Principles

The key Consultation Principles are:

- departments will follow a range of timescales rather than defaulting to a 12-week period, particularly where extensive engagement has occurred before
- departments will need to give more thought to how they engage with and use real discussion with affected parties and experts as well as the expertise of civil service learning to make well informed decisions
- departments should explain what responses they have received and how these have been used in formulating policy
- consultation should be 'digital by default', but other forms should be used where these are needed to reach the groups affected by a policy
- the principles of the Compact between government and the voluntary and community sector will continue to be respected.

Annex B List of organisations responding

NHS Trust

CCG

Acute Hospital

Local Pharmaceutical Committee

National Pharmaceutical Advisers Group

National Ambulance Service Medical Directors

National Ambulance Resilience Unit

Royal College of Physicians Edinburgh

Royal College of Surgeons Edinburgh

Pharmacists

RCP register

Royal College of General Practitioners

Royal College of General Practitioners (CIRC).

Guild of Healthcare Pharmacists

