MLX 388: PROPOSALS FOR AMENDMENTS TO HUMAN MEDICINES REGULATIONS 2012 TO ENABLE PUBLIC HEALTH ENGLAND TO DEVELOP AND AUTHORISE PATIENT GROUP DIRECTIONS

Introduction

1. We are writing to consult you, in accordance with section 129(6) of the Medicines Act 1968, on proposals to amend the Human Medicines Regulations 2012 to enable Public Health England (PHE) to develop and authorise Patient Group Directions (PGDs).

2. 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). 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 to authorise its own PGDs and specified PHE health professional staff to supply and/or administer vaccines and medicines under PGDs, will support the NHS response where necessary, and strengthen the resilience of the public health system.

3. This consultation abides by the principles set out in the Cabinet Office's revised guidance for Government departments and other public bodies: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255180/Consultation-Principles-Oct-2013.pdf

Application to England, Wales, Scotland and Northern Ireland

4. This consultation letter has been produced jointly by the Medicines and Healthcare products Regulatory Agency (MHRA), Public Health England and the Department of Health and the Public Health Agency (PHA) /Department of Health Social Services and Public Safety (DHSSP).As the proposals are limited in scope and the use of PGDs is well-established, we think a six week consultation period is proportionate.

5. Although medicines legislation applies throughout the United Kingdom, the proposed changes, if adopted, would relate solely to PHE's and PHA's responsibilities.

Background to Current Proposals

Medicines Legislation

6. Under medicines legislation, all medicines are classified according to three legal categories – prescription only (POM), pharmacy (P) and general sale list (GSL). The general rule is that POM and P medicines can only be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist. POMs are subject to the additional requirement that they must be sold or supplied in accordance with an appropriate practitioner's prescription. An 'appropriate practitioner' is a doctor, dentist, or other independent or supplementary prescriber. GSL medicines can be sold from a wider range of premises such as supermarkets, provided that those premises can be closed to exclude the public (i.e. they are lockable) and the medicines are pre-packed.

7. PGDs provide an exemption from these restrictions. A PGD is a written instruction for the supply or administration of medicines to groups of patients who meet the criteria specified in the PGD. Medicines legislation requires that a PGD must be authorised by a doctor (or, if appropriate, a dentist) and a pharmacist, both of whom should have been involved in developing the direction. Additionally, the PGD must be authorised by the relevant appropriate body and contain certain particulars, set out in legislation. PGDs can only be used by certain groups of registered and regulated health professionals such as nurses, pharmacists and paramedics. Organisations using PGDs should designate a senior person responsible for ensuring that only competent, qualified and trained health professionals work under PGDs. The National Institute for Health and Care Excellence (NICE) has published medicines practice guidelines for organisations and individuals developing, authorising and using PGDs.
http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp?domedia=1&mid=30199FE8-BE3E-2637-C7ABAC559ECCED96

8. Currently, PGDs can be used in the NHS, including private and voluntary sector activity funded by the NHS, and also in specified independent organisations. PGDs are an important mechanism in delivering the required capacity and enabling the effective delivery of services in the NHS. Since their introduction in 2000, PGDs have been widely used in the NHS to deliver clinical services, including provision of immunisations or chemoprophylaxis following exposure to infectious disease.

Public Health England

9. PHE is an executive agency of the Department of Health. It became operational on 1 April 2013 and took over many of the functions previously undertaken by the Health Protection Agency. PHE is the expert national body dealing with all aspects of public health, employing around 6,000 staff, of whom

about 300 are nurses and 350 doctors, within the clinical ring-fence. These are based primarily in the 14 PHE centres and the combined London Region and Centre). It is intended that it will generally be nurses based in these centres, who will be supplying or administering medicines under a PGD, should it be necessary for PHE staff to do this. Additionally, PHE will ensure appropriate pharmacist resources for the development of PGDs.

10. One of the core functions of PHE is to ensure that there are effective arrangements in place nationally and locally for preparing, planning and responding to health protection concerns and emergencies, including the future impact of climate change[1]. To ensure a speedy, safe and effective response in these situations, the Department of Health considers it essential that PHE is able to authorise PGDs for use by its staff, to supplement and add resilience to the NHS response.

11. In the event of a public health incident, members of the public may need access to medicines (such as antibiotics or anti-viral agents, immunoglobulins or antitoxins) to:

- treat an infectious disease or a toxic agent;
- reduce the risk of an individual contracting a disease following contact with an infectious agent, or;
- reduce the risk of further transmission of an infectious agent.

Rationale

12. Currently, the NHS generally responds to these sorts of incidents by providing supplies of any required medicines from a number of potential sources, such as by GP prescription, staff from community trusts working on site, attendance at A&E or attendance at NHS clinics using NHS-authorised PGDs. CCGs might be expected to have a role in coordinating the response.

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/259756/DH-PHE_FRAMEWORK_AGREEMENT_FINAL_VERSION_FOR_PUBLICATION_accessible.pdf

13. In general, if it is necessary to provide medicines, DH believes that it is preferable for the NHS to do this, but we recognise that there are exceptional circumstances where the NHS is unable to provide the required response and where PHE needs to supply and /or administer medicines. This is likely to be the case in large-scale and high-risk situations where a complex and speedy

response is required, and where the NHS organisations may not be able to respond sufficiently rapidly.

14. In these sorts of circumstances, there may be various logistical complications:

- large numbers of people involved with many different GPs;
- it may be time consuming to contact such large numbers of GPs;
- the GPs may not be readily available to prescribe;
- some of those involved may not be registered with local GPs because they are foreign tourists or UK residents away from home;
- GPs may not be willing to prescribe for individuals who are not their patients;
- there may be complex local arrangements for out-of-hours primary care.

15. Additional complications may also arise:

- the high numbers of individuals involved in an outbreak or incident may make using CCGs for outbreak response impractical as they may have very few suitably trained staff available to respond, particularly when rapid individual assessments are required or, out-of-hours;
- A & E services may already be overwhelmed treating casualties;
- there may not be sufficient time to organise additional community clinics;
- there may not be sufficient local NHS staff to respond;
- there may be a lack of expertise within the local NHS about highly specialised or novel infectious diseases such as a new type of influenza. In these circumstances, GPs and other prescribers are unlikely to be willing to prescribe as they may feel that it is outside their competence. In unusual situations, the expertise may lie with infectious disease doctors, of whom there are few, and with PHE staff.

16. In any of these circumstances, coordinating an NHS response would be very difficult and time consuming, leading to potential delays, but PHE staff would

already be on site to undertake health protection risk assessments and to provide advice on the public health response. Specific examples are described at Annex A.

Clinical Governance Arrangements

17. PHE is establishing a Quality and Clinical Governance Framework that underpins all its functions: service delivery, leadership and workforce development. Further detail on these arrangements is provided at Annex B.

18. PHE will have an agreed and ratified process for the development and authorisation of PGDs, which will comply with the legislation. This includes ensuring that all PGDs contain a statement of the records that are to be kept for audit purposes, and that PHE will carry out audits on a regular basis. PHE will also comply with the recommendation contained in guidance, which advises that PGDs should be reviewed every 2 years. Reviews will include clinical governance arrangements and an assessment of whether the PGD remains the most effective way of providing the relevant interventions. Before an eligible healthcare professional can use a PGD, he/she must have been assessed as competent to do so, and have signed the PGD documentation.

Guidance

19. PHE will comply with the legislation governing the development, authorisation and use of PGDs and follow NICE medicines practice guidelines.

Proposal

20. Following discussions with key health protection stakeholders, the Department of Health and DHSSPS considers 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 medicines regulations.**

21. Given the expertise and arrangements for clinical governance within PHE we do not believe that extending PGDs to PHE staff represents any significant risk. Conversely, not doing so would risk a sub-optimal response to outbreaks, which could lead to avoidable serious illness or death.

22. 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 expect PHE to have the appropriate skills, resources and governance structures necessary to develop and authorise PGDs and to use them safely and effectively.

23. **We welcome views on this proposal.**

i. **Do you agree with the proposal to include PHE and PHA in the list of authorising bodies under the provisions in medicines legislation relating to Patient Group Directions? If not, why not?**

Impact Assessment

24. We have completed a screening assessment and were advised by the Better Regulation Team that this consultation does not require a full Impact Assessment.

Equality

25. We have completed a screening assessment. We do not believe that the proposal contained in this consultation would have any adverse effect on any equality issue as they are aimed at ensuring outbreak control services can be provided to anyone who needs them on public health grounds. **We would welcome information on any instances where you believe that there will - or could be - any adverse affect 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.

Comments

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

CIRCULATION OF PROPOSALS

27. This consultation letter is being sent in hard copy to those organisations listed. A copy of the consultation is also available on the MHRA website - www.mhra.gov.uk and replies are welcome from all interested parties.

How to respond

28. A reply can be e-mailed to: part3@mhra.gsi.gov.uk or sent by post to: Paul Jenkins, Public Health Policy and Strategy Unit, Department of Health, 79 Whitehall, SW1A 2NS. **Comments must arrive no later than 31 October 2014.** Comments received after this date will not be taken into account. The MHRA and DH will not enter into any correspondence concerning these proposals.

29. The response to the consultation will then be brought to the Commission for Human Medicines (CHM) for their consideration and final recommendations will then be made to Ministers. Subject to the agreement of Ministers, we plan to implement the changes by Statutory Instrument. Statutory Instruments are available from the Stationary Office and may also be viewed on http://www.legislation.gov.uk

Responses: Confidentiality and Disclaimer

30. The information you send us may be passed to colleagues within the Government or related agencies. Furthermore, information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

31. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on us.

Please ensure that your response is marked clearly if you wish your response (whole or in part) and name to be kept confidential. Confidential responses will be included in any statistical summary of numbers of comments received and summary of views expressed.

32. The Agency's Information Centre at Buckingham Palace Road will supply copies of responses on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Information Centre by prior appointment (telephone 0203 084 6351).

Annex A

EXAMPLE SCENARIOS DESCRIBING CIRCUMSTANCES WHERE ENABLING PUBLIC HEALTH ENGLAND TO DEVELOP ITS OWN PGDS WOULD HELP ENSURE AN EFFECTIVE RESPONSE AND STRENGTHEN THE RESILIENCE OF THE PUBLIC HEALTH SYSTEM

1. Scenario 1

1.1 An avian influenza outbreak occurs on a poultry farm at a weekend, involving large numbers of workers, some of whom live locally and are registered with different GPs, some are on short term contracts and are not registered with local GPs, and some are not registered at all. Local NHS organisations are already dealing with large numbers of ill and anxious patients and do not have the capacity to help.

1.2 *What needs to be done?*
All the staff of the poultry farm needs to be assessed and provided with anti-viral medicines to reduce the risk of them getting infected or ill and of passing on the virus.

1.3 *Why is it difficult?*

- Those who are registered with GPs are registered with a number of different GPs so it will be time consuming for NHS staff to contact each of the practices. In some cases the GPs will not be readily contactable; many of the staff of the poultry farm are from out of the area or from overseas and are not registered with local GPs;
- Local GPs are unwilling to prescribe as they are not familiar with the use of antiviral medication in this circumstance;
- At a weekend the local CCG is unable to provide suitably trained staff in adequate numbers;

- The out-of-hours service may already be overstretched and is unable to respond.

1.4 *Why would a PHE PGD be helpful?*

There is the potential for the response to be delayed if the NHS is left to respond alone. A PHE PGD would allow named PHE staff that are already on site, and who are suitably trained and have the expertise, to assess and supply the antiviral medication immediately.

2. Scenario 2

2.1 A child on a large traveller site is diagnosed with diphtheria. There are several hundred people on the site, many of whom are saying they will leave for other sites now that the diagnosis is widely known.

2.2 *What needs to be done?*

From a public health perspective, it is important to treat close contacts of the case quickly, so as to protect them and to reduce the risks of further spread.

2.3 Why is it difficult?

This scenario presents several challenges in ensuring an effective response:

- It is unusual – cases of diphtheria are rare in this country;
- The numbers of people affected, including children, who are potentially more seriously affected by the disease;
- The probability that their vaccination status is uncertain or incomplete so making interventions more important;
- The mobility of the group affected, resulting in a higher risk of the outbreak spreading to the wider population and greater difficulty in dealing with all those affected before they leave;
- Urgency – in terms of the need to provide treatment/ prophylaxis to a large number of people in a short period of time;
- The probability that they are not registered with GPs;
- Local NHS organisations are likely to be unable to find enough community nurses to run clinics on the site in order to take throat swabs from people, issue antibiotics and give vaccinations as needed within the required timescale;
- As with the avian influenza scenario above, there may not be enough local prescribers who are available and willing to prescribe any necessary antibiotics or vaccines, especially as this is a clinical condition with which they are not familiar.

2.4 *Why would a PHE PGD be helpful?*

In a scenario like this, PHE staff would already be on the ground to assess the situation, assess the public health risk and provide advice on managing the incident. PHE doctors and nurses from PHE centres could be mobilised to provide the required response. A PGD would be a particularly useful mechanism as it would allow nurses to administer antibiotics or vaccines to individuals who, following assessment, they felt would benefit and who meet the criteria described in the PGD. This is a far more flexible approach than prescribing for individuals who meet these criteria as this would need all these people to be seen by a doctor and to have an individual prescription.

3 Scenario 3

3.1 A new pandemic strain of influenza has just arrived in the UK. There is a high attack rate amongst young people, particularly those of school age, with an associated increase in hospital admissions and some deaths. A decision is taken to try to slow the spread by issuing antivirals to affected schools, of which there are several in the area.

3.2 *What needs to be done?*
Antivirals need to be supplied to students in all the local schools affected.

3.3 *Why is this difficult?*
The scenario involves large numbers of students, all registered with different GPs and it will be time consuming for the NHS to contact the number of GPs necessary; some of whom may not be available. The NHS is already struggling with the number of influenza cases and cannot release enough staff to support the preventive response and to run additional clinics.

3.4 *Why would a PHE PGD be helpful?*
There is likely to be a delayed response if it is left to the NHS to coordinate the response. PHE staffs that have the expertise in such situations could be deployed to add resilience to what the NHS is already doing. PHE staff could set up clinics in the affected schools and, working to a PHE PGD, would be able to assess the individual students and supply the required antivirals.

4 Scenario 4

4.1 There have been several cases of meningococcal meningitis in a large tower block in student accommodation on a university campus. The decision is taken to offer prophylaxis to all living in the block, which has several hundred people in it. However, not all students at risk turn up to the clinic.

4.2 *What needs to be done?*

There is a need to visit all rooms in the student accommodation to offer prophylaxis.

4.3 *Why is it difficult?*

The student medical services are already stretched coping with the outbreak and routine clinics. They do not have access to additional suitably trained staff. It will be time consuming contacting those students who did not attend the clinic. In addition, they may not have presented if they did not understand the need for the prophylaxis. It will therefore also be time consuming, once they have been contacted, to explain the benefits of receiving the medication and this will require suitably trained healthcare professionals.

4.4 *Why would a PHE PGD be helpful?*

PHE staffs have the necessary expertise and are well versed and trained in explaining to contacts the benefits of prophylaxis. PHE staff could be used to add resilience to the NHS response by visiting the student accommodation to trace contacts that did not attend the clinic and could provide the necessary medication using a PHE PGD.

ANNEX B

MLX 388: PUBLIC HEALTH ENGLAND: DUTIES IN RELATION TO HEALTH PROTECTION, STRUCTURE AND CLINICAL GOVERNANCE ARRANGEMENTS

Public Health England's (PHE) key statutory duties on behalf of the Secretary of State for Health include the following:

1. Section 11 of the H&SCA 2012[2] states 'The Secretary of State must take such steps as the Secretary of State considers appropriate for the purpose of protecting the public in England from disease or other dangers to health'.

    - As a Category 1 responder under the Civil Contingencies Act 2004 (CCA) in respect of emergency planning, the response and resilience functions for public health. For the avoidance of doubt, these duties under the CCA shall be delegated from the Secretary of State to officials in Public Health England who are responsible for emergency planning, resilience and response, such that those officers operate as if Public Health England itself were a category 1 responder under the CCA; and
    - The Public Health (Control of Disease) Act 1984 gives the Secretary of State powers in relation to port health.

PHE Structure

2. Please refer to **Annex C** for a diagram.

PHE Regions

3. PHE has four regions that are coterminous with the four regions of NHS England and Department for Communities and Local Government resilience hubs, covering London, the South of England, Midlands and East of England and North of England. For each of these areas the PHE regions:
    - ensure that Public Health England's emergency preparedness, resilience and response plans are in place;
    - ensure that high-quality public health and healthcare advice, including for screening, immunisation and specialised services commissioning, is available to NHS England;
    - assure the quality and consistency of all services delivered by PHE Centres (see below), ensuring that they are responsive to local government;
    - offer professional support to Directors of Public Health in local authorities.

PHE Centres

4. PHE Centres and the combined London Region and Centre developed from the 25 previous Health Protection Units of the Health Protection Agency. The Centres' main areas of work are to:
    - deliver services and advice to local government, the NHS, other local organisations and the public, and work in partnership to protect the public against infectious diseases, minimise the health impact from hazards, involving the national centres when appropriate;
    - make an effective contribution to the emergency preparedness, resilience and response system.[3]

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[2] http://www.legislation.gov.uk/ukpga/2012/7/section/11/enacted

Clinical Governance

5. The Secretary of State (SofS) has a duty to exercise his public health functions in relation to England with a view to securing continuous improvement in the quality of services provided to individuals for, or in connection with:
   (a) the prevention, diagnosis or treatment of illness, or;
   (b) the protection or improvement of public health.

   (Section 11 of the H&SCA 2012)

6. PHE supports SofS in fulfilling this duty. In doing so, PHE shall have regard to NICE quality standards and other relevant standards, including those relating to information.

7. PHE is establishing a Quality and Clinical Governance Framework that underpins all its functions: service delivery, leadership and workforce development. The framework will ensure a focus on:
   - continuous quality improvement;
   - outcomes based approach;
   - requirements to meet CQC registration standards;
   - learning from the lessons from the Mid Staffordshire Public Inquiry and implementing relevant recommendations from the Inquiry report;
   - using its serious incident policy to identify learning and ensure robust arrangements are in place to prevent recurrence.

8. PHE's aim is to have in place an effective clinical and health protection governance framework which includes:
   (a) clear lines of responsibility and accountability for the overall quality of services to patients, populations and communities;
   (b) effective mechanisms for quality assurance and clinical and health protection audit;
   (c) clear standards for services, and systems for demonstrating that these standards are met;
   (d) a comprehensive programme of continuous quality improvement in all its activities;
   (e) policies and procedures for the management of clinical and health protection risk;
   (f) policies and procedures for reporting and managing clinical and health protection incidents, including critical incident reporting, complaints procedures and reports detailing lessons learnt reports;

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[3] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131907.pdf

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131882

(g) clear statements on clinical and health protection governance requirements in all relevant contracts with third parties;
(h) a confidentiality framework, which complies with the principles set out in the Caldicott Committee Report on the Review of Patient-Identifiable Information (1997), revised guidance in the form of The Caldicott Guardian Manual (2010), and the Data Protection Act (1998);
(i) a mechanism which ensures that clinical and health protection delivery and practice within the Agency are based on the best available evidence;
(j) ongoing plans for staff education, training and development to ensure that the Agency has a well-trained and competent workforce which meets the requirements for continuous professional development of bodies such as the royal colleges and professional institutes. This should include processes for:
(i) the appraisal and revalidation of medical staff;
(ii) the supervision and management of training programmes for medical trainees in both microbiology and health protection, including external trainees seconded to the Agency;
(iii) comparable appraisal and training facilities for non-medical staff, such as healthcare scientists and environmental scientists;
(iv) effective and supportive measures where poor performance has been found.

9. In discharging its responsibilities, PHE will commit to providing the necessary resources in terms of an appropriate process for developing and authorising PGDs and providing information to patients and GPs. PGDs developed by PHE will be signed off by the appropriate clinical governance lead, such as the area Medical Director. PHE will have doctors, pharmacists and nurses who will take responsibility for the development of PGDs.

Training and Development

10. PHE will have delegated authority to develop its own training and development strategies, particularly around continuing professional development (including revalidation that is essential for clinical staff, who are subject to the standards set by regulatory bodies).

Supply

11. The Association of Directors of Public Health, Department of Health, Faculty of Public Health, Local Government Association, NHS England and Public Health England have formally requested the Co-Chairs of Local Health Resilience Partnerships (LHRPs) to provide assurance about the details of local health protection arrangements in the context of emergency planning and response. This includes the funding arrangements for medicines required in such circumstances.

12. Under normal circumstances, PHE provides leadership, technical expertise and co-ordination of the response to incidents and outbreaks. NHS providers lead the delivery of the response to incidents and outbreaks in hospitals as advised by the

incident management team. They would normally fund and supply vaccines and medicines as appropriate. The proposals we are consulting on would allow PHE to authorise PGDs (if this were needed and appropriate). PHE could (as it does now) mobilise its staff to provide additional capacity for supply and/or administration of vaccines and medicines under PGDs. In situations of emergency or requiring a large scale response, where it is difficult for the NHS to respond in a timely manner, PHE may therefore authorise PGDs for the supply of medicines. In such circumstances, local agreements between PHE and the NHS are in place to provide PHE with access to NHS stocks of vaccines and medicines.