Education and Training Committee, 18 November 2010

Proposals to consider changing the Medicines Act 1968 exemptions for sale, supply and administration of medicines

Executive summary and recommendations

Introduction

Currently, medicines legislation limits the sale or supply of pharmacy and prescription only medicines to registered pharmacies. Prescription only medicines can only be sold or supplied in accordance with an appropriate practitioner's prescription.

However, some professions (including paramedics and chiropodists/podiatrists) have exemptions from these restrictions and are therefore allowed to sell, supply or administer medicines to patients. For both paramedics and chiropodists/podiatrists, they are exempt from the requirements on the basis of their HPC registration and/or training they have undertaken.

The Medicines and Healthcare products Regulatory Agency (MHRA) has recently closed an informal consultation on proposals to consider changing the Medicines Act 1968 exemptions for sale, supply and administration of medicines. This includes various proposals to amend or retain different exemptions.

In addition, the MHRA is also considering ways in which the legislation which manages exemptions can be simplified. This includes consideration about whether the process for managing the lists of medicines which can be administered under the exemptions should change.

At this stage, the MHRA is seeking views on their proposals but has not made any firm decisions. The Committee will be updated on any developments in this area.

Decision

This paper is for discussion.

Background information

The Committee has not previously considered a paper on this topic.

Resource implications

None at this time.

Financial implications

None at this time.

Appendices

- Response to the MHRA informal consultation on the Medicines Act 1968 exemptions
- MHRA Review of medicines legislation: informal consultation on the Medicines Act 1968 exemptions for sale, supply and administration of medicines

Date of paper

1 November 2010

1. Background

1.1 The sale and supply of medicines is controlled by the Medicines Act 1968. Under medicines legislation, pharmacy and prescription only medicines (POMs) may largely only be sold or supplied through registered pharmacies. POMs can only be sold or supplied in accordance with an appropriate practitioner's prescription. An appropriate practitioner is a doctor, dentist, supplementary prescriber, nurse, pharmacist or optometrist independent prescriber.

1.2 The law also restricts the administration of parenteral medicines which, if not self-administered, must be administered by a doctor or, in certain circumstances an independent nurse prescriber or a supplementary prescriber.

1.3 There are a range of exemptions from these restrictions which allow certain groups of health professional to sell, supply and administer particular medicines direct to patients. The exemptions are distinct from prescribing which requires the involvement of a pharmacist in the sale or supply of the medicine. They also differ from the arrangements for Patient Group Directions (PGDs) as the latter must comply with specific legal criteria, be signed by a doctor or dentist and a pharmacist and authorised by an appropriate body.

1.4 The Medicines Act exemptions are set out in the Prescription Only Medicines (Human Use) Order 1997 and the Medicines (Pharmacy and General Sale - Exemption Order) 1980. Further provisions relating to persons who may receive wholesale supplies of medicines are contained in the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980.

Exemptions for paramedics

1.5 Under medicines legislation, registered paramedics can administer a range of parenteral medicines on their own initiative for the immediate, necessary treatment of sick or injured persons without the usual requirement for a prescription or directions of a prescriber. There is a list of medicines which can be administered and registered paramedics can also gain stocks of these medicines for administration in the course of a business operated by them.

Exemptions for chiropodists/podiatrists

1.6 Chiropodists/podiatrists also have exemptions to sell or supply from specified lists of POM and P Medicines in their professional practice.

1.7 Chiropodists/podiatrists can only sell or supply POM products if they have successfully completed the necessary training and their qualification is annotated on our Register. Similarly, chiropodists/podiatrists can administer certain parenteral medicines if they have completed the appropriate training in local anaesthetics and been annotated on our Register.

1.8 The training in prescription only medicines and local anaesthetics is now incorporated in all pre-registration education programmes. However, some registrants who qualified a number of years ago or applied via grandparenting may not have completed the necessary training and therefore would not be able to administer or supply these medicines.

2. Managing the list of medicines

2.1 As outlined above, both chiropodists/podiatrists and paramedics are able to sell, supply or administer certain medicines as a result of training and their HPC registration. Both professions are can only administer medicines taken from the list managed by the MHRA.[1]

2.2 The MHRA also manage the process by which the list of medicines is amended. The MHRA make changes to the list only where there is a clear case for doing so. This is because the purpose of the list of medicines is not to allow health professionals to administer any medicines; instead the list is kept short to limit it to those medicines which are absolutely essential for practice. In addition, the medicines that feature on the list must be those which are already included in the necessary training.

2.3 Any change to the exemptions requires an amendment to medicines legislation. As a result, there is a statutory requirement to consult interested organisations and to consider advice from the Commission on Human Medicines before making a change.

MHRA proposals

2.4 The consultation process and requirement to change legislation means that it can take a considerable amount of time and resources to change the list of medicines.

2.5 In their recent informal consultation, the MHRA argued that the current process caused a delay in responding to changes in professional practice. They proposed that they should consider stepping away from the current system where lists of medicines are written into legislation.

2.6 Instead, they proposed that the health professionals who could sell, supply or administer medicines should be written into legislation. It would then be up to the relevant statutory regulator to decide which medicines would be available to particular health professionals, depending upon what was necessary for practice.

[1] The list of medicines for paramedics can be found here:
http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/Paramedics/index.htm
The list of medicines for chiropodists/podiatrists can be found here:
http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/Chiropodists/index.htm

2.7 The MHRA argued that this would allow amendments to be made faster by removing the requirement to change legislation. They stated that they believed this would bring benefits for patient care.

2.8 The MHRA is therefore considering giving us the power to maintain and amend the list of medicines which can be sold, supplied or administered by our registrants.

2.9 It is important to remember that legislation would have to be amended if the MHRA decided to implement their proposals. It is therefore likely that this change (if progressed) would not be implemented before 2012.

3. Our considerations

3.1 The Executive has had an initial meeting with the Department of Health to discuss some of the issues outlined in this paper.

Response to the informal consultation

3.2 We responded to the informal consultation by the MHRA and a copy of our response is appended to this paper.

3.3 In our response we stated that we believed there would be advantages to the proposals made by the MHRA. For example, amendments could be made in a more timely fashion to follow developments in practice and would also bring benefits for patient care.

3.4 However, we also raised a number of points of concern. If the decision was made to transfer maintenance of the list of medicines, we would need to develop governance systems which would allow us to manage those lists. By governance arrangements, we mean developing a process to allow us to manage these lists which could draw on the relevant expertise of the professions, prescribing and medicines more broadly and which did not present a disproportionate burden on our resources. This would have both financial and resource implications.

3.5 In addition, the MHRA has developed considerable expertise in the field of medicines regulation which is vital when making decisions about whether the list of medicines should be amended. We believe it is important that both the expertise and governance arrangements are available to regulators.

3.6 Arguably, exemptions work best within NHS systems. This may be because the MHRA is an executive agency of the Department of Health and there is therefore a clear link with practice in the NHS, although the exemptions can be translated to practice outside the NHS as well. As we regulate individuals working within a profession, rather than a sector or service, any approach to exemptions would need to reflect differences in access to medicines across both the public and private sector.

3.7 At present, the MHRA takes responsibility for managing these lists across all the professions which fall within the remit of exemptions. This ensures

consistency in decision making and in the processes which support those decisions. If the responsibility was passed to the different regulators, those regulators would need to take a consistent approach to how decisions were made about amendments.

Impact on the HPC

3.8 As outlined above, at this stage the MHRA is undertaking only an informal consultation on their proposals and no firm decisions have been made. It may be helpful however, to explore the impact of a decision to move management of the lists to the regulators.

3.9 At the moment, the MHRA receives requests to amend the list of medicines from relevant organisations, for example professional bodies. If responsibility was passed to us, we would need to develop the necessary governance arrangements to manage the list and respond to requests to amend the list.

3.10 The governance arrangements would be necessary to ensure that we had access to sufficient expertise so that we could make the appropriate decision about whether or not to amend the list of medicines. This expertise could be provided through a working group or similar.

3.11 It is likely that we would have to consult publicly on any amendments to the list of medicines. It is therefore important that any processes we develop do not place an overly large burden on our resources. One way of managing this might be by asking for amendments to the list on a yearly basis.

4. Discussion

4.1 The MHRA has not yet finalised their proposals in this area. It is therefore possible that the process for managing and maintaining the lists of medicines may not change.

4.2 At this stage therefore, the Committee is not invited to make any decisions on this topic, but is invited to discuss the issues associated with the MHRA’s proposals.

4.3 The Committee is invited to consider the points we raised in our response to the informal consultation. The Committee is also invited to consider any other points of relevance to this issue, including the processes we would need to develop to manage the lists if the responsibility was passed to us.

To Interested Organisations

Date: 4 October 2010

Dear Sir or Madam

REVIEW OF MEDICINES LEGISLATION: INFORMAL CONSULTATION ON THE MEDICINES ACT 1968 EXEMPTIONS FOR SALE, SUPPLY AND ADMINISTRATION OF MEDICINES

As many of you will know, we are undertaking a review of the legislation. As part of this review, we have been looking at the provisions which allow health professionals and others to sell, supply and/or administer medicines by way of exemptions from the usual Medicines Act restrictions. We have already written to organisations and representative bodies informally to seek their views on their specific exemptions. We are now writing more widely to seek further views on future provisions for the exemptions again, on an informal basis.

The Medicines Act exemptions are set out in the Prescription Only Medicines (Human Use) Order 1997 and the Medicines (Pharmacy and General Sale - Exemption Order) 1980. Further provisions relating to persons who may receive wholesale supplies of medicines are contained in the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980.

The attached document sets out the current legal provisions for exemptions together with initial proposals for retention, removal or amendment. The proposals take account of comments received from the earlier exercise as well as our preliminary views. We welcome your views on these proposals. (For clarification, the document does not include Patient Group Directions as these will be considered separately. Exemptions for podiatrists are also not covered. This is because we are preparing a formal consultation letter on proposals to update their exemptions.)

As well as the specific proposals set out in the attached, we are considering ways in which the legislation can be simplified. Those health professionals who are covered by exemptions are generally allowed to access specific lists of medicines, particularly POMs. Any changes to the lists can only be made after a statutory consultation process leading to amendment of legislation. This process is lengthy and resource intensive. It results in delay in responding to changes in professional practice and access to medicines and timely treatment for patients. We are considering a move away from the present system of legally specifying lists of medicines and any conditions attached to those exemptions. Instead, we could designate in law the health professionals able to sell, supply and administer medicines. However, the choice of medicines available to those health professionals would be determined by the relevant statutory regulatory body as appropriate to professional practice. This would mean that updates to the lists would no longer require the current consultation process and amendments to the law with the resultant delay in effecting changes. We believe this could benefit patient care.

The concept of seeking to ask regulatory bodies to take responsibility for those medicines which their registrants can access and to maintain the lists themselves is at an early stage. It needs to be further explored with the bodies concerned and we appreciate that some may feel better placed than others to adopt this approach. In the meantime though, we would like your views on this

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proposal. Please note, that as this is an idea for further discussion and consideration, the attachment has been drafted on the basis that the lists are retained under statutory control. Also, unless otherwise stated, references to retaining an exemption includes retention of any attached conditions.

We would be grateful if your views could reach us by 1 November. As the Agency is moving to new offices during this period, can I ask that responses are sent by e-mail to Part3@mhra.gsi.gov.uk If you wish to contact me, I will be available on 0207 084 2392 until 15 October or e-mail anne.ryan@mhra.gsi.gov.uk.

Yours faithfully

Anne Ryan
MHRA Policy Division

LIST OF CURRENT EXEMPTIONS AND PROPOSALS FOR RETENTION, REMOVAL OR AMENDMENT

1. **Persons selling or supplying medicines to universities, other institutions concerned with higher education or institutions concerned with research**

This applies to the sale or supply of all medicines subject to conditions. We have interpreted this provision quite widely to cover, for example, a company wishing to obtain a medicine for testing or comparing purposes provided no supply or administration to humans was involved. **We propose to amend** the provision so that sale or supply of a medicine for research purposes is extended to other settings where research is carried out. This will be subject to the conditions that no administration to humans is involved and there is no onward sale or supply.

2. **Persons selling or supplying medicines to any of the following:**

a public analyst appointed under section 27 of the Food Safety Act 1990(a) or article 36 of the Food (Northern Ireland) Order 1989(b),

an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990,

a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989,

a person duly authorized by an enforcement authority under sections 111 and 112,

a sampling officer within the meaning of Schedule 3 to the Act.

This applies to all medicines subject to conditions. Following contact with the Food Standards Agency, **we propose to retain** the provision.

3. **Persons selling or supplying medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(a), the National Health Service (Scotland) Act 1978(b) and the Health and Personal Social Services (Northern Ireland) Order 1972(c), or under any subordinate legislation made under those Acts or that Order.**

Applies to all medicines subject to conditions. **We propose to retain** the provision.

4. **Persons providing a poultry vaccination service. persons selling or supplying poultry vaccines, persons selling or supplying medicinal products to veterinary surgeons and veterinary practitioners**

We propose to retain these provisions subject to advice from the Veterinary Medicines Directorate.

5. **Registered Midwives**

Registered midwives can sell, supply and administer a specific range of POM medicines. They can also sell or supply all P and GSL medicines in the course of their professional practice. **We propose to retain** the provision.

6. **Registered Optometrists/Additional Supply Optometrists**

Subject to conditions, registered optometrists can sell or supply specified POMs. They can also sell or supply all P and GSL medicines in the course of their professional practice. Additional Supply Optometrists can sell or supply the same range of medicines as optometrists. They can also, subject to conditions, sell or supply a wider range of POMs. The POMs to which these exemptions apply may also be sold or supplied by a person lawfully conducting a retail pharmacy business on the presentation of an order signed by a registered ophthalmic optician or Additional Supply Optometrist. **We propose to retain** these exemptions.

7. **Dispensing Opticians**

Dispensing Opticians can sell or supply over the counter preparations of Chloramphenicol for the treatment of bacterial conjunctivitis. **We propose to retain** this provision.

8. Persons selling or supplying medicines to the British Standards Institution.

9. **Holders of product licences, marketing authorisations, homoeopathic registrations and manufacturer's licences**

This provision allows holders of these licences, authorisations etc to sell or supply medicines to a pharmacist to enable him or her to prepare an entry relating to the medicine in question in a tablet or capsule identification guide or similar publication. **We propose to retain** this provision.

10. **Pharmacists selling or supplying to persons to whom cyanide salts may be sold.**
The exemption only applies to the sale of Amyl Nitrate and is subject to conditions. Amyl Nitrate is used in cases of cyanide poisoning. However, it is no longer recommended as an antidote by the Health and Safety Executive (HSE). HSE do not require employers to keep supplies although they would not object if a particular employer, having conducted a risk assessment, decided to maintain a supply. As the treatment is not recommended, **we propose to remove** this provision.

11. **Holders of manufacturer's licences where the licence in question contains a provision that the licence holder shall manufacture the medicinal product to which the licence relates only for a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.**

The exemption extends to the supply and administration of P and GSL medicines for external use. **We propose to retain** the exemption.

12. **Royal National Lifeboat Institution and certified first aiders of the Institution.**
Those covered by the provisions can supply all medicines subject to conditions. An initial response from the RNLI states that it is likely they will want to maintain the exemption. **We propose to retain** the exemption.

13. **The owner or the master of a ship which does not carry a doctor on board as part of her complement.**
This covers supply of all medicines with conditions. The Maritime and Coastguard Agency has confirmed they wish to keep the exemption which they believe works well. **We therefore propose to retain** it. The MCA has also informed us that under the Merchant Shipping Act 1995, a ship includes every description of vessel used in navigation.

14. **Persons authorized by licences granted under the Misuse of Drugs Regulations to supply a controlled drug. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only.**
The exemptions only apply to drugs specified in the licences/group authorities. Groups covered by the latter include paramedics. **We propose to retain** these exemptions.

15. **Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.**
The provision allows for supply of POM and P medicines subject to any conditions set out in the enactment as well as supply of GSL medicines. **We propose to retain** the exemption.

16. **Persons operating an occupational health scheme.**
The provision allows for sale, supply or administration of all medicines in the course of an occupational health scheme subject to conditions. **We propose to retain** the exemption, updated to remove the reference to state enrolled nurse.

17. **The operator or commander of an aircraft.**
The exemption allows supply and administration of all medicines for the immediate treatment of sick or injured persons on the aircraft subject to conditions. It does not cover sale of any medicine. From time to time, we have been asked to consider amending the legislation to allow for the sale of medicines, specifically GSL, on aircraft. We do not consider that there is a strong case for an amendment. The Agency's view is that medicines legislation is based on the assumption that medicines are not like most other commodities. It is designed to ensure minimum standards of safety and quality. The current exemption provides for patient care by enabling the supply of medicines to passengers in need. **We therefore propose to retain** the provision in its current form.

18. **Persons employed as qualified first-aid personnel on offshore installations**.
The exemption allows for supply of all medicines subject to conditions. **We propose to retain** it.

19. **Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.**
We are unclear about the history or the rationale behind this exemption but we imagine its use must now be limited as it covers only those undertaking such practice over 28 years ago. The British Society of Acupuncturists take the view that the extension of needles into the field of injections of whatever type, introduces new tiers of risk from the use of hollow needles. The Society supports the removal of the exemption. Our understanding is that osteopathy involves manipulative therapies rather than routine administration of injectable medicines. We have not

come across any information to suggest that naturopaths are involved in such administration either. In the circumstances, **we propose to remove** the exemption.

20. **Registered paramedics**
This exemption allows paramedics to administer a range of parenteral medicines on their own initiative for the immediate, necessary treatment of sick or injured persons. The Joint Royal Colleges Ambulance Liaison Committee (JRCALC), which acts as a national focal point for ambulance issues, considers the exemption is necessary but raised issues about how the legislation addresses the application of the Committee's clinical guidelines across NHS, and independent ambulance service providers as well as individual paramedics. They were concerned that the process of adding new drugs to the exemption list was too slow and thought a new system might be better. JRCALC suggested a formulary which would allow paramedics not only to administer certain drugs but also to obtain then from a pharmacy if they were privately employed. JRCALC also consider that paramedics should be able to supply medicines such as painkillers and antibiotics so they can provide care at first point of contact by leaving a course of drugs with the patient. **We propose to retain** the exemption but we will also be exploring the rationale for extending the current arrangements for paramedics.

21. **Persons employed or engaged in the provision of lawful drug treatment services**
This allows people involved in drug treatment services to supply Water for Injection (WFI) subject to a limit of 2ml per ampoule. **We intend to retain** the exemption. However, we have had a number of enquiries relating to the sale or supply of WFI for use other than as an injection, for example, to inflate a balloon in a catheter. **We are considering** exempting WFI from prescription control when it is intended for non-medical use.

22. **The Armed Forces**
The exemption, which was implemented last year, allows members of the Armed Forces to supply and administer medicines in emergencies and situations where the usual levels of medical support are not available. **We propose to retain** the exemption.

23. **British Red Cross Society and certificated first aid and certificated nursing members of the Society**
The exemption allows for supply of P and GSL medicines subject to conditions. Similar exemptions are in place for the St John Ambulance Association and Brigade, St Andrew's Ambulance Association and Order of Malta Ambulance Corps. **We propose to retain** these exemptions.

24. **Mountain rescue**
The provision applies to the supply and administration of all medicines in the course of mountain rescue services by people who hold a first aid certificate issued by the Mountain Rescue Council in England and Wales or its Northern Ireland equivalent. (The Scottish mountain rescue service planned to adopt the Mountain Rescue Council certificate.) **We plan to retain** the exemption.

25. **Persons carrying on the business of a school providing full time education and Health Authorities**
These exemptions apply to the supply of P medicines containing sodium fluoride for dental use. The Department of Health has informed us that these exemptions are still relevant so **we propose to retain** them.

26. **Prison officers**
This exemption allows prison officers to supply GSL medicines to inmates. **We propose to retain** it.

27. **Operators in nuclear procedures**
The exemption applies to certain POMs administered in nuclear procedures in accordance with guidance/protocols required under the Ionising Radiation (Medical Exposure) Regulations 2000. **We intend to retain** the exemption.

27. **Article 7 of the Prescription Only Medicines (Human Use) Order 1997**
This allows for the administration of a specified list of medicines by anyone for the purpose of saving life in an emergency. The list is attached at **Annex A**. **We intend to retain** the list but seek views on whether any additions or removals are appropriate. For example, the list includes Adrenaline 1 in 1000 (1mg in 1ml) but there are now other preparations available which are more suitable for administration to a child. Another example is that the list does not cover medicines used in cardiac arrest. We are interested to have comments on whether the list should be amended to include these medicines. Alternatively, might it be more appropriate to consider a separate provision which would allow persons who hold the Resuscitation Council's Advanced Life Support to administer the medicines in emergency situations involving cardiac arrest?

28. **Regulation 5 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980**
Regulation 5 sets out provisions relating to persons who may be supplied with stocks of medicines. A summary is attached at **Annex B**. **We intend to retain** the current provisions. However, in view of the changes in the structure of the NHS, particularly the split between commissioners and providers we understand that other organisations and companies are entering into contracts to provide NHS services. We are seeking views on whether it would be appropriate for those providers to directly order and receive stocks of any medicines needed to provide the commissioned service. This could be subject to guidance that the commissioning body is satisfied that the provider can safely store and handle the medicines.

Annex A

EXTRACT FROM THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997 (AS AMENDED) : ARTICLE 7 FROM 30 JUNE

Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines

7. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of any of the following medicinal products for parenteral administration-

Adrenaline Injection 1 in 1000 (1 mg in 1 ml)
Atropine Sulphate Injection
Atropine sulphate and obidoxime chloride injection
Atropine sulphate and pralidoxime chloride injection
Atropine sulphate, pralidoxime mesilate and avizafone injection
Chlorphenamine Injection
Dicobalt Edetate Injection
Glucagon Injection
Glucose Injection 50%
Hydrocortisone Injection
Naloxone Hydrochloride
Pralidoxime chloride injection
Pralidoxime mesilate injection
Promethazine Hydrochloride Injection
Snake Venom Antiserum
Sodium Nitrite Injection
Sodium Thiosulphate Injection
Sterile Pralidoxime

where the administration is for the purpose of saving life in an emergency.

Annex B

List of persons who can receive medicines by way of wholesale dealing. (Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 SI No1980/1923 as amended refers)

All medicines

- Practitioners (Doctors, dentists, vets)
- Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968
- Holders of wholesale dealer's licences or persons to whom the restrictions imposed by section 8(3) (wholesale dealer's licences) of the Medicines Act 1968 do not apply by virtue of an exemption conferred by the Act or the provisions of section 48
- Authorities or persons carrying on the business of -

  (a) an independent hospital, independent clinic or independent medical agency, or

  (b) a hospital or health centre which is not an independent hospital or independent clinic.
- Ministers of the Crown and Government Departments and officers thereof
- A person other than an excepted person (in this context a pharmacist) who carries on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of health care by or on behalf of, or under arrangements made by -

  (a) a police force in England, Wales or Scotland,

  (b) the Police Service of Northern Ireland,

  (c) a prison service, or

  (d) Her Majesty's Forces.
- A Health and Social Services Trust established under article 10 of the Health and personal Social Services (Northern Ireland) Order 1991
- A NHS Trust established under section 5 of the NHS and Community Care Act 1990 or section 12 A of the NHS Service (Scotland) Act 1978
- The Common Services Agency for the Scottish Health Service established under section 10 of the NHS (Scotland) Act 1978

Pharmacy medicines

- Any person who requires pharmacy medicines for the purpose of administering them to human beings in the course of a business carried on by him, pharmacy medicines which are for the purpose of being so administered.

General Sale List medicines

- Any person who requires GSL medicines for the purpose of selling, supplying or administering them to human beings in the course of a business carried on by that person.

Other relevant provisions

- Under medicines legislation, the general rule is that prescription only medicines may only be sold or supplied on a retail basis against a prescription on registered pharmacy premises by or under the supervision of a pharmacist. There are exemptions from these restrictions for certain persons in respect of specific medicines which are contained in Schedule 5 to the Prescription Only Medicines (Human Use) Order 1997 (the POM Order). Under the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, these people may be sold the prescription only medicines relevant to their particular exemption on a wholesale basis.

- Similarly, the general rule for pharmacy medicines is that they may only be sold or supplied by or under the supervision of a pharmacist on registered pharmacy premises. There are exemptions from these restrictions for certain persons in respect of specific medicines contained in the Medicines (Pharmacy and General Sale – Exemption) Order 1980. The Miscellaneous Provisions Regulations allow these people to receive the pharmacy medicines relevant to their particular exemption on a wholesale basis.

- The Miscellaneous Provisions Regulations also contain other provisions which allow wholesale sales in certain circumstances:

  - Homoeopathic products which contain a prescription only medicine and are not for parenteral administration can be sold by way of wholesale dealing to a practitioner provided the product has been diluted to at least one part in a million (6x). They may also be sold to anyone else provided they are diluted to at least one part in a million million.

  - Because of an exemption in the POM Order, registered optometrists can obtain a range of medicines on a wholesale basis for sale or supply in the course of their professional practice. In addition to these arrangements, they may also obtain prescription only medicines containing the following substances for administration:

    Amethocaine hydrochloride
    Lignocaine hydrochloride
    Oxybuprocaine hydrochloride
    Proxymetacaine hydrochloride

  -

25 October 2010

Health Professions Council response to MHRA informal consultation on the Medicines Act 1968 exemptions

The Health Professions Council welcomes the opportunity to respond to this informal consultation.

The Health Professions Council is a statutory UK wide regulator of healthcare professionals governed by the Health Professions Order 2001. We regulate the members of 15 professions. We maintain a register of professionals, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a professional may not be fit to practise. Our main role is to protect the health and wellbeing of those who use or need to use our registrants' services.

Our comments

We welcome this opportunity to respond to the Medicines and Healthcare products Regulatory Agency's (MHRA) informal consultation on the Medicines Act, in particular the exemptions from the restrictions of the Act. An exemption allows a health professional to sell, supply or administer a medicine which would otherwise be limited to independent prescribers.

At the moment, only two of the professions we currently register can administer medicines through an exemption. These are paramedics and chiropodists/podiatrists. Paramedics, for example, can administer a range of parenteral medicines on their own initiative for the immediate, necessary for the treatment of sick or injured persons.

Our registrants who are covered by exemptions are allowed to access specific lists of medicines. Those lists of medicines can only be changed after a statutory consultation process and then amendment of legislation. We note that the MHRA is considering changing this process so that the lists of medicines which could be administered would be held by the regulators. Under this process, the list could be altered without an amendment to legislation.

We believe that there would be advantages to this approach. This would allow amendments to be made in a more timely fashion, in line with developments within a profession and in practice. It would also reduce the regulatory burden for the MHRA, by more closely associating the list of exemptions with the needs of the particular profession.

However, we are aware that the MHRA has developed considerable expertise in the field of medicines regulation. This expertise, alongside strong governance, is vital when making decisions about whether amendments should be made to the list of medicines covered by exemptions. We would want to ensure that both the

expertise and governance arrangements were available to regulators if they were asked to take on these responsibilities.

In addition, exemptions work best within NHS systems. As we regulate individuals working within a profession, rather than a sector or service, any approach to exemptions would need to reflect differences in access to medicines across both the public and private sector.

At present, the MHRA takes responsibility for managing these lists across all the professions which fall within the remit of exemptions. This ensures consistency in decision making and in the processes which support those decisions. If the responsibility was passed to the different regulators, those regulators would need to take a consistent approach to how decisions were made about amendments.

We hope that you find these comments useful. Should you wish to discuss any of our comments then please do not hesitate to contact us.

Yours sincerely,

Charlotte Urwin
Policy Manager