Reforms of s12(1) of the Medicines Act 1968: the requirement for a face to face consultation

Introduction

1. This informal discussion paper is one of a series prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) which explores possible reforms of section 12(1) of the Medicines Act 1968 and its associated provisions. S12(1) is the legislative provision used by herbal practitioners, and some others, carrying out a business in which they prepare unlicensed herbal medicines to meet the individual needs of patients identified in consultation. The MHRA welcomes dialogue with interested parties on these ideas. The paper is intended to help focus such discussions. The MHRA's expectation is that this work will help prepare the way for a subsequent formal public consultation.

The current position

2. Section 12 of the Medicines Act 1968 exempts herbal remedies, under certain conditions, from the requirement for a product licence and various other provisions of the Medicines Act[1]. The provisions of s12(1) are used by practitioners to prepare and supply unlicensed herbal remedies to meet the needs of individual patients identified in consultation. The requirements relevant to the issue of the conduct of the consultation are set out in s12(1)(b):

   "*The person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.*"

3. The MHRA has become aware in recent times that, notwithstanding the above provision, certain businesses have established on line consultation services offering diagnosis and treatment recommendations in relation to unlicensed herbal/traditional medicines. In MHRA's view, the wording "in that person's presence" clearly require a face to face consultation and therefore without a face to face consultation online consultation and similar activities would not fall within s12(1). (Whether or not the activity was exempt under other legislative provisions, eg s12(2), would depend on the specifics of the case.)

[1] Section 12 is an exemption from the licensing provisions in the Medicines Act 1968, and is only relevant to medicinal products which in the first place fall outside the scope of Directive 2001/83/EC (eg products which are neither prepared industrially nor prepared using an industrial process).

The issue

4. The issue is whether the existing requirement for a face to face consultation should be maintained under a reformed s12(1) scheme. In MHRA's view it is relevant to consider in particular (a) wider developments in health care; (b) public health issues associated with the conduct of consultations in herbal medicine; and (c) the maturity of the herbal medicine profession as regards professional self regulation.

5. Strictly, the question is not whether herbal practitioners are permitted to engage in online consultations, rather it is whether the herbal medicines made up and supplied by a practitioner in response to a consultation should be exempt from the requirement from a product licence and various other provisions. In practice, the linkage between the two is very close since MHRA believes that the requirement for a face to face consultation for the activity to come within the s12(1) exemption should only be lifted if it is clear that remote consultations and similar practices are fully consistent with the best professional practice.

Wider developments in health care

6. Doctors are not in law restricted to holding consultations face to face. There is recognition that there are certain circumstances in which remote consultations may be acceptable and necessary in the interests of good patient care. With changing technology and other developments in healthcare, there may in future be new situations in which the practice is acceptable. Extracts from GMC guidance are at **Annex A**. This permits remote prescribing but makes clear the onerous responsibilities on the doctor if the practice is to be professionally acceptable. As regards supplementary and independent prescribers, such as pharmacists and nurses, there is again no specific legislative requirement that consultation has to be face to face. However, recent extensions of prescribing rights have taken place within strong safeguards of professional accountability and it may be doubtful that there would be many situations envisaged in which routine remote prescribing by supplementary or independent prescribers would be regarded as acceptable professional practice.

Public health issues with the conduct of consultations in herbal medicines

7. A thorough and professionally competent consultation is crucial if the health of the patient is to be improved rather than put at risk by a herbal practitioner. In a consultation the patient looking for the practitioner to make an exercise of professional judgement as to whether, and if so what, medication may be suitable. In this situation it will be necessary for the practitioner to consider a wide range of issues, including symptoms, previous medical history, other medication or treatment the patient may already be receiving. Taking, using and retaining patient notes will be no less important than it is for other healthcare professionals.

8. Factors that are specifically relevant to consultations carried out by herbal practitioners include:

- usage of herbal medicines extends far beyond "the worried well". A proportion of patients visiting herbal practitioners are like to have serious and/ or long term medical conditions; many are likely to have symptoms which may well be minor but could be indicative in a minority of cases of a serious medical condition. Some clinics also are known positively to encourage patients to come for treatment of serious conditions. The MHRA has, for example, seen numerous clinic leaflets and advertisements in the TCM sector suggesting that therapies can help with a wide range of serious conditions. In any case, irrespective of any advertising, etc, some herbs in various herbal traditions have a reputation for treating serious conditions and some patients will be aware of this

- patients will often already be receiving treatment and medication from a doctor or other healthcare professional; the possible interactions between a prescribed medicine and any herbal medicines that may be supplied by a herbal practitioner may well be unknown or unclear

- the patient's GP or other doctor may or may not be aware that the patient is also seeing a herbal practitioner and the patient may or may not be willing to tell the doctor that he/she is taking herbal medicine

- the patient may not previously have sought professional advice on a potentially serious condition. A competent and prudent practitioner carrying out an effective consultation may recognise the need to advise a patient to consult their GP as soon as possible

- a key element of the practice of herbal medicine is its holistic approach to the patient; it must be doubtful if some forms of remote prescribing can easily be made consistent with a holistic approach.

9. These factors do not mean that it would be impossible ever to achieve an effective and fully professional consultation online or by similar means. However, the range and complexity of the issues involved do underline the extent of the challenge that would be involved.

The maturity of the herbal medicine profession

10. An important issue in this context is the maturity of the herbal medicine profession on issues relating to professional self regulation. Is there for example clear evidence across the range of practitioners using s12(1) that consultations are consistently held in a fully professional and thorough manner? The direct and indirect evidence on this is not wholly encouraging, particularly in relation to parts of the TCM sector. The MHRA is aware of reports of some practitioners unable to communicate effectively with patients on account of language difficulties. In other cases practitioners have sourced adulterated products from unreliable sources

despite the known issues with adulteration; also clinic leaflets have claimed that traditional medicines have no side effects. Poor practices of this kind in parts of the sector do not promote confidence that the time is right for relaxation of the consultation requirements.

Conclusion

11. The MHRA considers on the basis of the above considerations:

- it is possible that at some point in the future it might be realistic to consider further the case for lifting or modifying the requirement that the consultation under s12(1) should be face to face, subject to rigorous safeguards as to professional guidance and accountability being in place; but

- for the foreseeable future lifting the requirement for a face to face consultation under s12(1) would neither be in the interest of public health nor would it help the profession as it seeks to strengthen and consolidate good professional practice.

12. The MHRA therefore considers that we should plan on the basis that the existing requirement for a face to face consultation requirement will be maintained under the reformed s12(1) scheme.

Issues for discussion

- ***Do you have comments and views on this assessment?***

MHRA Dec 2006

Good Practice in Prescribing Medicines (2006)

May 2006

Our booklet Good Medical Practice (2001) sets out in paragraphs 1 to 3 and 21 the principles that doctors must follow when prescribing medicines.

The guidance below explains how these principles apply in situations that doctors often meet, or find hard to deal with. We propose to review this guidance regularly to ensure that it is up to date and relevant to problems doctors face, and reflect any legal differences across the UK countries. We will publish updated versions on our website. Printed copies are available on request.

The GMC expects doctors to comply with the standards of good practice set out in our guidance. You must be prepared to explain and justify any decision not to follow this advice on good practice in prescribing.

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Remote prescribing via telephone, email, fax, video link or a website

38. From time to time it may be appropriate to use a telephone or other non face-to-face medium to prescribe medicines and treatment for patients. Such situations may occur where:

    d. You have responsibility for the care of the patient

    e. You are deputising for another doctor who is responsible for the continuing care of a patient or

    f. You have prior knowledge and understanding of the patient's condition/s and medical history and you have authority to access the patient's records.

39. In all circumstances, you must ensure that you have an appropriate dialogue with the patient to:

    d. Establish the patient's current medical conditions and history and concurrent or recent use of other medications including non-prescription medicines;

    e. Carry out an adequate assessment of the patient's condition

    f. Identify the likely cause of the patient's condition

g. Ensure that there is sufficient justification to prescribe the medicines/treatment proposed. Where appropriate you should discuss other treatment options with the patient

h. Ensure that the treatment and/or medicine/s are not contra-indicated for the patient

i. Make a clear, accurate and legible record of all medicines prescribed.

40. If you are not providing continuing care for the patient, do not have access to the patient's medical records, or are not deputising for another doctor, you must follow the advice above and, additionally you must:

. Give an explanation to the patient of the processes involved in remote consultations and give your name and GMC number to the patient

a. Establish a dialogue with the patient, using a questionnaire, to ensure that you have sufficient information about the patient to ensure you are prescribing safely

b. Make appropriate arrangements to follow the progress of the patient

c. Monitor the effectiveness of the treatment and/or review the diagnosis

d. Inform the patient's general practitioner or follow the advice in paragraph 9 if the patient objects to the general practitioner being informed.

41. Where you cannot satisfy all of these conditions you should not use remote means to prescribe medicine for a patient.

42. If you prescribe for patients who are overseas, you should also have regard to differences in a product's licensed name, indications and recommended dosage regimen. The Medicines and Healthcare products Regulatory Agency issues guidance on import/export requirements and safety of delivery, which you might also need to consider. You should ensure that you have adequate indemnity cover for such practice. You may need to be registered with a local regulatory body in the country in which the prescribed medicines are to be dispensed.