Appendix 4

Best practice guidance on the sale of medicines for pain relief

- **Don't sell more than two packs in any one transaction**
- **Don't use offers that encourage the sale of more than one pack**

What is best practice?

Sales:
Sales of medicines for pain relief should be restricted to a maximum of two packs in any one transaction.

Explanation:
This limit is a reasonable balance between meeting a customer's immediate need for pain relief while helping to minimise stockpiling and accidental or impulsive overdose.

Tools to implement this best practice include:

- Till bars to prevent purchase of more than two packs.

- Regular training for staff on the restrictions, the reason for them, and how to respond to customers who want to buy larger quantities.

- Notices on shelving for customers and in the payment area for staff to raise awareness.

Offers:
Promotional offers on medicines for pain relief should not directly encourage the purchase of more than one pack.

Explanation:
Multi-buy offers such as 'buy one get one free' or 'buy 2 for £xx' may encourage consumers to purchase more packs than they currently need. The customer may stockpile excess packs, which pose a danger for accidental or impulsive overdose.

Please note: This guidance does not prevent reduced price offers on single packs.

Why are these restrictions needed?

Medicines for pain relief on general sale are effective and acceptably safe when used according to the label instructions. But there is evidence to show that people sometimes use large quantities of these medicines impulsively. Restricting the availability of pain relief medicines for purchase and in the home is effective in reducing the number of hospital admissions and deaths from accidental or impulsive overdose.

What does the law say?

The maximum pack size for pain relief medicines in a general sale outlet is 16 tablets or capsules. A pharmacy may sell larger packs containing up to 32 tablets or capsules under the supervision of a pharmacist. It is illegal to sell more than 100 tablets or capsules of either paracetamol or aspirin in any one retail transaction.

Where can I get further advice and information?

The Medicines and Healthcare products Regulatory Agency (MHRA) has developed this guidance with stakeholders representing large and small retailers, pharmacists, trading standards offices and the pharmaceutical industry. It applies to all solid dose (oral tablet or capsule) medicines for pain relief sold without pharmacist supervision. Additional restrictions apply to certain products available only from pharmacies.

Further advice on these voluntary restrictions is available from your trade association, local trading standards office or from MHRA Customer Services at info@mhra.gsi.gov.uk.

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Appendix 5

Reporting to the public on medicines: Advice for journalists and patient organisations

Health issues always hit the headlines and access to health information is important in empowering people to make informed decisions about their health care. Articles often draw attention to a prescription only medicine (POM) or results from trials on new products still in research. Yet the advertising legislation prevents these medicines being advertised to the public and the law applies to 'any person' - not just pharmaceutical companies. So what do journalists and patient organisations need to do to ensure they stay within the law when writing about medicines? Reporting information fairly and accurately while ensuring a balanced view is represented is paramount. Paying attention to these will help ensure the ban on advertising prescription medicines does not become an issue. The bottom line is - keep it factual and balanced to keep out of the advertising controls.

Background – what the law says

There are a number of legal safeguards on advertising medicines intended to protect public health. These apply to materials which fall within the definition of an 'advertisement', which broadly speaking is anything "designed to promote the prescription, supply, sale or consumption" of a medicine.

The safeguards include a ban on advertising medicines which have not been granted a marketing authorisation and on advertising prescription only medicines to the public. They also state that advertisements must present medicines objectively, without exaggerating their properties and that advertisements must not be misleading.

The key point is that these controls (and the penalties for breaches) apply to **any person** who promotes a medicine - not just the manufacturer. This can potentially include newspaper or magazine articles or information disseminated by a patient organisation.

How is the advertising law interpreted

A judgment from the **European Court of Justice**[1] has provided clarification of the advertising law. The Court held that under European law "dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising …, even though the third party in question is acting on his own initiative and completely

[1] Details of Case C421/07 (Reference for a preliminary ruling from the Vestre Landsret, Denmark: Criminal proceedings against Frede Damgaard) are available at: http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=&nomusuel=damgaard&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher

independently, *de jure* and *de facto*, of the manufacturer and the seller of such a medicinal product".

The Court reaffirmed that any person could be viewed as promoting a medicine and proof of a commercial link to the sale of the product was not required. The Court went on to advise that the national courts were best placed to decide on individual cases, balancing the right to free speech against the potential for damage to public health that the law is designed to protect.

So what does this mean in practice?

Implications for journalists

Provided they are intended to inform rather than promote medicines, articles discussing potential treatments won't fall within the scope of the legislation on advertising medicines[2] – the legal restrictions don't prevent balanced factual reporting. But articles should not actively encourage readers to seek a particular product from their healthcare provider and must take care not to exaggerate the potential benefits. It can be hard for a healthcare provider to explain to a patient who has read about the latest 'wonder drug' that it is not in fact suitable for them or not yet available.

Articles discussing healthcare issues, particularly medicines, ought to be factual, well balanced and accurate. Readers who may be suffering from a distressing and disabling condition are entitled to balanced and accurate information that does not raise false hopes or unnecessary worries about their treatment.

Implications for patient organisations

Patient organisations have a clear and important role in providing information on medical conditions and advice on the therapeutic and other management options available. Most have robust procedures to ensure they retain their independence from pharmaceutical companies who may contribute to their support. Even if information provided about treatment is supported by an educational grant from a pharmaceutical company, if editorial control is with the charity and it can demonstrate independent procedures, the material would not be deemed to be promotional. As explained above, patient organisations should not actively encourage people to seek a particular product from their healthcare provider.

Charities take great care to ensure the advice they issue is in line with current clinical evidence and best medical practice, and of course they always have the best interests of members at heart. They often have a reference group including healthcare professionals who are specialists in the area to ensure materials are factual and balanced, and will be able in future to demonstrate quality by certification under the Information Standard[3].

[2] Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 as amended).
[3] For further information see http://www.theinformationstandard.org/.

Implications for other information providers
If you are an independent provider of information about medicines, the principles are the same. Keep the information factual and balanced, and do not directly encourage readers to seek a particular product.

Further information on regulation of the promotion of medicines in the UK is available in the MHRA Blue Guide[4] or from the MHRA Advertising Standards Unit, email advertising@mhra.gsi.gov.uk.

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[4] The MHRA Blue Guide, *Advertising and promotion of medicines in the UK*, available at:

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007552&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB