

# briefing

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## Information to patients

Empowering the individual or advertising by another name?

### Key points

The NHS response:

- agrees that the ban on direct to consumer advertising (DTCA) of prescription only medicines should remain in place
- supports efforts to ensure that patients who seek it can access good quality, trustworthy, non-promotional information about their medicines alongside wider health and disease information
- does not support the provision of unsolicited ('pushed') information
- argues that national authorities should be able to set flexible regulatory arrangements to suit circumstances in their country, including detailed requirements on information and mechanisms and structures for monitoring.

Advertising of prescription only medicines to the general public is banned throughout Europe, but the question of what information pharmaceutical companies can provide to patients and the public has been the subject of a long-running debate at European level. In response to this, the European Commission has said it will make proposals later this year to revise the laws governing information to patients. This *Briefing* provides an overview of the recent consultation on these issues and the NHS response to this.

The laws governing the information that pharmaceutical companies can provide to patients and the public about prescription only medicines are set in Europe, as part of the wider framework of legislation controlling the conditions under which pharmaceuticals can be sold in the European Union (EU).

Under the current regime, as well as the ban on direct to consumer advertising (DTCA), pharmaceutical companies are strictly limited in the information they can provide to patients and the public.

But the lack of clarity about precisely what is and isn't allowed has led to different European countries adopting different approaches<sup>1</sup>.

In addition, it is clear that patients and the public are proactively seeking out information about medicines, in particular by searching on the internet. However, at present, it is very difficult for individuals to determine whether information is balanced, and from a trustworthy and reliable source. Furthermore, as DTCA is allowed in the United States, patients

1. The European Commission has prepared a detailed account of European provisions relating to advertising and information and examples of current practices in different European countries: [ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007\\_12/comm\\_native\\_sec\\_2007\\_1740\\_1\\_en\\_documentdetravail.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_12/comm_native_sec_2007_1740_1_en_documentdetravail.pdf)

who search for information about a medicine on the internet will often access websites aimed at US residents that include promotional information.

In view of this, there has been extensive debate over a number of years, particularly in the European Parliament, about changing the rules. Whilst there seems to be a general consensus in favour of retaining the ban on DTCA, views on the provision of information are diverse. Some argue for minimal restrictions to maximise patients' access to information, whilst others are concerned that insufficient regulation would effectively open the door to advertising by another name. As a way forward, the European Commission was asked to present a report on current practices in the provision of information to patients, and following this, if appropriate, make proposals to amend the legal framework.

The European Commission's report<sup>2</sup> concluded that whilst the ban on DTCA should remain, there was a need to improve information to patients because of the wide variations in access to information and the variable quality of the information that is available. Consequently, a public consultation<sup>3</sup> was launched on ideas to form the basis of future legal proposals in this area.

## The NHS response

The NHS European Office has submitted a response<sup>4</sup>, prepared in consultation with NHS organisations, to the European consultation. The

following section sets out the main ideas in the consultation paper and the NHS response to these.

### Defining what is and is not allowed

The consultation document states categorically that the ban on DTCA should be maintained. The NHS fully supports this.

In terms of defining information, the consultation document proposes that communication not covered by the definition of advertising<sup>5</sup> should be regarded as information, and that criteria should distinguish what information is and is not allowed. Although these criteria are not specified, it suggests that allowed information might include information about scientific studies, prevention of diseases such as vaccines, accompanying measures to medical treatments and prices.

The NHS response raises concerns about whether such a definition, based on the content of information, could provide the necessary safeguards against advertising, and suggests that a more workable approach might be to set out the kind of information that can be provided based on the situation where it is used. For example, information for patients who have been prescribed a medicine might contain different elements to information that formed part of wider health promotion resources.

Whether the definition is based on content or purpose, it is likely that the line between advertising and information will still sometimes be

ambiguous. In view of this, the NHS response argues that it is essential that the national authorities responsible for regulating information to patients (in the UK, the Medicines and Healthcare products Regulatory Agency) have sufficient scope to interpret and enforce the framework effectively.

### Types of information and ensuring quality

The consultation document proposes that a distinction should be made between cases where information is passively received ('pushed' information) such as through TV and radio programmes and printed media, and information that an individual actively searches for ('pulled' information), for example, on the internet or by contacting a pharmaceutical company.

The NHS response agrees that there is an important difference here. Without a very burdensome and costly regulatory regime, it would in practice be very difficult to ensure that 'pushed' information did not stray into advertising. The NHS response therefore takes the view that it would be preferable not to permit 'pushed' information.

The NHS response does, however, support the general principle that pharmaceutical companies should be able to provide 'pulled' information on prescription only medicines to patients and the public who actively seek it. The response notes that this information is most likely to be useful for patients if it is developed in collaboration with patient, professional and regulatory stakeholders and is linked to wider disease information.

The consultation document is clear that whatever information is allowed, it will need to meet specific quality criteria to ensure that it is

2. [ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007\\_12/inf\\_to\\_patients\\_com\\_2007\\_862\\_en.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_12/inf_to_patients_com_2007_862_en.pdf)

3. [ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008\\_02/info\\_to\\_patients\\_consult\\_200802.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802.pdf)

4. The NHS response is available on the NHS European Office website: [www.nhsconfed.org/europe](http://www.nhsconfed.org/europe)

5. Advertising of medicinal products is defined in Article 86 of Directive 2001/83/EC: [eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:EN:PDF)

understandable, objective, high-quality and non-promotional<sup>6</sup>. But this will only be meaningful if the mechanism for monitoring information is effective. The consultation document suggests that regulatory bodies should be notified, but there should not be any validation of information, either before or after publication.

Whilst an intensive system requiring validation of every piece of information on a case-by-case basis prior to publication would imply a significant, possibly disproportionate, regulatory burden, relying entirely on a system of self-regulation does not seem sufficient.

The NHS response argues that the framework should allow for a flexible approach, determined by national regulatory authorities in consultation with stakeholders, allowing, for example, information on medicines that are new to the market and about which less is known to be subjected to a greater degree of scrutiny than information on medicines that are long-established.

Alongside this, another useful tool may be the validation of information providers, along the lines of the Information Accreditation Scheme<sup>7</sup> currently being developed by the Department of Health.

### Structure for monitoring and sanctions

The consultation paper proposes a monitoring structure with three levels: an EU advisory committee, national competent authorities to oversee the

system in each country, and national co-regulatory bodies, made up of public authorities and a mix of stakeholders, to adopt a national code of conduct and monitor information providers.

In one way, this seems unnecessarily complicated. In particular, it is not clear what added value a European-level body would provide, given that mechanisms already exist for European co-operation and information exchange in this area. On the other hand, the proposed structures could be too rigid for purpose, potentially limiting the future scope of partnership working by formalising in law their status and remit as co-regulatory bodies.

The NHS response again argues for a flexible approach, contending that each country should be able to develop its own regulatory structures reflecting national traditions and arrangements related to information to patients.

### Harmonisation versus diversity in approaches

A key objective for the European Commission is to provide rules that harmonise practices on information to patients throughout Europe. There are good arguments to support adopting a standard approach. It should ensure universal public access to good quality information, avoid potential confusion or conflicting information, and reduce the burden on information providers as they would only have to comply with one set of rules.

However, the reality is that there is very considerable variation across Europe in current practices on information to patients and attempts to introduce one common approach could be counter-productive. Making the same information available everywhere in Europe would not automatically mean that inequalities in access to information were addressed. It is important to avoid a lowest common denominator approach which could undermine existing projects already providing value to patients.

### Conclusions and possible implications for the NHS

Patients increasingly seek out health and disease-related information, including information about prescription only medicines. Pharmaceutical companies already have a role in providing information about their products to patients and the general public. They will often be the most expert source of information on their products, for example, on outcomes of clinical trials, potential side effects or contra-indications, and it is important that patients can access this information.

The forthcoming European proposals on information to patients should be an opportunity to enhance the range and quality of information available to patients, further enabling them to better manage their condition together with their clinician.

But developing a legal and regulatory framework that will ensure that the information patients access is understandable, objective, high-quality, non-promotional and balanced, raises many questions and challenges. Given the current variation in practices it is unlikely that one

6. The core quality principles developed by the Information to Patients Working Group of the Pharmaceutical Forum are set out in Annex B of the *2nd Pharmaceutical Forum Progress Report*: [ec.europa.eu/enterprise/phabiocom/docs/pf\\_20070626\\_prog\\_report.pdf](http://ec.europa.eu/enterprise/phabiocom/docs/pf_20070626_prog_report.pdf)

7. The Department of Health website includes information on the Information Accreditation Scheme: [www.dh.gov.uk/en/Healthcare/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation](http://www.dh.gov.uk/en/Healthcare/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation)

model will work everywhere in Europe and there are risks to existing initiatives involving the NHS if proposals attempt to enforce too rigid a structure.

In addition, information about medicines is only one aspect of the range of information relating to a condition. It is important to avoid the trap of looking at information on medicines in isolation, leaving patients unable to develop a balanced view on the options available. This could lead to patients seeking a treatment that is inappropriate or ineffective for them, with the potential for negative consequences both in terms of their health and the inefficient use of NHS resources. This risk would increase if 'pushed' information on prescription only medicines was allowed.

Patients should be able to access information about causes, prevention, symptoms, diagnosis and the full range of potential treatments (not just pharmaceutical options) in order to help them manage their condition together with their clinician. In view of this, pharmaceutical companies should be seen as only one of many sources of information to patients, and action in this area should form part of a wider, strategic approach to the provision of health information. The NHS can demonstrate many examples of holistic approaches to health and disease information, and is therefore well-placed to continue to

influence the development of proposals in this area.

For further information see:  
[www.nhsconfed.org/europe](http://www.nhsconfed.org/europe)

### Next steps

The European Commission will publish legal proposals later this year which are likely to suggest:

- that the ban on DTCA of prescription only medicines should remain in place
- that pharmaceutical companies should be able to provide more information to patients than they can at present. They may be able to provide unsolicited ('pushed') information as well as responding to requests from patients and the public ('pulled' information)
- that information will need to meet quality criteria to ensure that it is understandable, objective, high-quality and non-promotional
- new structures, involving a range of stakeholders, for monitoring information.

### The NHS European Office

The NHS European Office has been established to represent NHS organisations in England to EU decision-makers. The office is funded by the Strategic Health Authorities and is part of the NHS Confederation.

EU policy and legislation have an increasing impact on the NHS as a provider and commissioner of services, as a business and as a major employer in the EU.

Our work includes:

- monitoring EU developments which have an impact on the NHS
- informing NHS organisations of EU affairs
- promoting the priorities and interests of the NHS to European institutions
- advising NHS organisations of EU funding opportunities.

## NHS European Office

Rue Marie Thérèse, 21, B-1000 Brussels  
Tel 0032 (0)2 227 6440 Fax 0032 (0)2 227 6441  
Email [european.office@nhsconfed.org](mailto:european.office@nhsconfed.org)  
[www.nhsconfed.org/europe](http://www.nhsconfed.org/europe)

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