UK National Health Service, European Office – Official response

EU Consultation on Legal Proposals on Information to Patients

The **National Health Service** (**NHS**) is the largest publicly funded health care system in the world providing the majority of healthcare in England. The NHS is committed to the principle of universal access to healthcare which is free at the point of use. Every 36 hours the NHS sees over one million patients who make use of a wide range of health services ranging from primary care, in-patient care, long term health care, ophthalmology and dentistry. The NHS is a major employer in Europe with 1.3 million people on its payroll.

This response has been coordinated by the NHS European Office[1] in consultation with NHS organisations.

Summary
The NHS supports efforts to ensure that patients can access understandable, objective, high quality, non-promotional and balanced information about the benefits and the risks of medicines. Our experience is that this requires partnership working between a range of stakeholders including the pharmaceutical industry. We think the UK's present risk-based approach to regulation is working well, and therefore think legislation should provide flexibility for these arrangements to continue. We agree that the ban on direct-to-consumer advertising should remain in place. We are concerned that it would be difficult in practice to distinguish between 'advertising' and 'pushed' information and therefore think that "pushed" information should be prohibited or, if allowed, be subject to very strict oversight by national regulators.

Detailed response

Introduction
The NHS believes that patients should be fully involved in their care and that decisions about an individual's treatment should be made in partnership by the patient and their clinician. As part of this, the NHS supports efforts to make understandable, objective, high quality, non-promotional and balanced information about treatment options, including pharmaceuticals, available.

We agree that the pharmaceutical industry has a role to play in providing information about their products to patients and the general public. In particular, the producer will often be the most expert source of information on outcomes of clinical trials, potential side effects or contra-indications for their product, and it is important that patients can access this information.

However, information about pharmaceuticals is only one aspect of the range of information relating to a condition. Patients should be able to access information about the causes, prevention, symptoms, diagnosis, and the full

[1] The NHS European Oftice was launched in September 2007. It represents the English National Health Service. Its role is to inform the NHS of EU issues and to ensure that the NHS contributes positively to EU developments.

range of potential treatments (not just pharmaceutical options) in order to help them manage their condition together with their clinician.

In view of this, we see industry as only one of many sources of information to patients, and we consider that action in this area should form part of a wider, strategic approach to the provision of health information. The risk of looking at information to patients on pharmaceuticals in isolation is that patients are unable to develop a balanced view on the options available. This may lead to them 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 resources.

Current approach in the UK
Our experience is that a multi-stakeholder approach works best in providing information to patients. An example is the Medicines Information Project[2], which is developing a structured source of information aimed at patients and the public linking medical conditions, treatment options and individual medicines. To do this, the project brings together representatives from:

- Voluntary health organisations (patient groups)
- UK Medicines Information Pharmacists
- The nursing profession
- Royal Pharmaceutical Society
- Royal College of General Practitioners
- PECMI (promoting excellence in consumer medicine information)
- Proprietary Association of Great Britain (PAGB)
- NHS Direct
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Datapharm Communications
- Department of Health
- Association of the British Pharmaceutical Industry (ABPI)
- National Pharmacy Association Ltd (NPA)

Another relevant piece of work currently in development in the UK is the Department of Health's Information Accreditation Scheme[3]. Under the scheme, organisations that have been certified against a national standard for quality information will be able to use a recognisable quality mark on health and social care information that they provide. The aim of the scheme is to provide reassurance to patients and the public that information on health and social care is from a reliable source. The scheme is currently entering a pilot phase, aiming to launch in 2009.

These examples demonstrate that, in the UK, information to patients is constantly developing. It is important that legislative proposals in this area do not cut across or constrain the good work that is going on.

[2] As referred to in Annex II of the Commission Staff Working Document SEC(2007) 1740, see: http://medguides.medicines.org.uk/mip.aspx
[3] See http://www.dh.gov.uk/en/Healthcare/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation/index.htm

Initiatives to provide additional information on medicines such as the examples given above are underpinned by the work of the Medicines and Healthcare Products Regulatory Agency (MHRA), the competent authority in the UK for overseeing information provided to patients on pharmaceuticals.

The MHRA takes a measured approach to monitoring information to patients, depending on a range of factors. For example, information on medicines that are new to market and about which less is known is subjected to a greater degree of scrutiny than information on medicines which are long-established.

The NHS is broadly content with the MHRA's approach in this area, and in general, believes that a proportionate system for monitoring information to patients is needed to avoid excessive bureaucracy or the diversion of resources from patient care. It is important that the EU legal framework provides flexibility for such an approach to continue.

Provisions on advertisement
The NHS agrees that the current rules banning advertising of prescription only medicines to the general public should not be changed.

Scope, content and general principles of the new legal provisions
The NHS agrees that it would be useful to broadly define what information the pharmaceutical industry can provide on their products. However, we would not support a definition that unconditionally permitted all communication not covered by the definition of advertisement. We do not believe such a definition would clarify the present situation nor provide the necessary safeguards to ensure that information is non-promotional.

It might instead be more practical 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.

Whatever definition is in included in EU legislation, it is essential that national competent authorities have sufficient scope to interpret and enforce the framework effectively. In view of this, detailed requirements, reflecting factors such as how health systems are organised, should be determined at national level by the competent authority working together with stakeholders.

The Commission's consultation document suggests that comparisons between medicinal products should not be allowed. The NHS agrees that in general, the industry should not be allowed to provide information that compares different products. However, it can be difficult for patients and clinicians to translate information on average risks into an assessment of the comparative risks and benefits of different treatment options for an individual. Consideration should therefore be given as to how information can be presented in a way that enables patients, together with their clinicians, to compare products, taking into account their personal circumstances.

The Commission's consultation paper suggests that information provided by the pharmaceutical industry should be compatible with and should not contradict or go beyond approved summaries of product characteristics (SPC) and patient information leaflets (PIL). In general, we would support this, but note that experience from the Medicines Information Project is that information drawn from SPCs and PILs can themselves present inconsistencies, for example, different brands of the same medicine giving different information on use and contraindications. Consideration should be given to how ensure consistency for example, the use of expert opinion through resources such as the British National Formulary (BNF).

Although information on over-the-counter medicines (OTC) is not considered as part of this consultation, it is also worth being aware of the risk of inconsistent or contradictory information being made available on medicines which are available both OTC and as prescription only medicines (POM), or for medicines that are moved from POM to OTC.

Type of actions, content and monitoring of information
We agree that a distinction should be made between cases where a patient is passively receiving information ("pushed" information) such as through TV and radio programmes and printed media, and information that a patient actively searches for ("pulled" information), for example, on the internet or by contacting a pharmaceutical company.

In our view, it is very difficult to clearly define the distinction between advertising and "pushed" information. In view of this, if "pushed" information is allowed there is considerable risk of frequent breaches to the ban on direct to consumer advertising. Even a very burdensome system of regulatory assessment of all "pushed" materials prior to their use may struggle to prevent this, given the lack of agreement on what constitutes advertising. We have not seen any analysis showing that there is a benefit to patients or the general public from the provision of such "pushed" information specifically on pharmaceuticals, as opposed to more general health information. In the absence of any such evidence, our view is that "pushed" information aimed at patients and the general public should not be permitted, or if it is allowed, a very cautious approach taken, with national competent authorities able to restrict such information as appropriate to the circumstances of their country.

We agree that industry should be able to provide information on prescription medicines to patients and the public who actively seek it ("pulled" information), for example through Internet searches. However, as set out above, our experience is 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.

We consider that detailed requirements in relation to information to patients, including content and monitoring arrangements should be set out in a code of conduct developed at national level under the oversight of the competent authority. This would allow national competent authorities, working together

with the industry and other stakeholders, to determine the appropriate balance between pro-active monitoring by the regulator, co-regulation and self-regulation to suit national circumstances.

On the issue of specific requests from citizens for information on a product, our experience from NHS Direct[4] is that monitoring complaints alone is not adequate as a method of monitoring overall quality. Undertaking regular audio call review or review of written requests underpins the development of a high quality service. This could be carried out by providers on a primarily self-regulatory basis to nationally agreed standards and reported to the regulator.

Quality criteria
The NHS would support the use of the core quality principles developed by the Information to Patients Working Group of the Pharmaceutical Forum as the basis for quality standards. We would particularly highlight the need to consider accessibility of information for different groups. This is not simply a question of making information available through a variety of channels or in different languages. Our experience is that patients will require information in different formats to meet a range of needs.

Structure for monitoring and sanctions
The NHS is concerned that the structure proposed in the Commission's consultation document, consisting of an EU Advisory Committee, National Competent Authorities and National Co-Regulatory Bodies, is potentially too burdensome and rigid for purpose. In particular, we do not see a need for an EU-level body. It is not clear what added value this would provide, given that mechanisms already exist at EU-level for exchange of information in this area.

The UK competent authority, the MHRA, already works in partnership with industry, other interested public authorities and other stakeholders through a number of established committees such as the Patient Information Expert Advisory Group and initiatives such as the Medicines Information Project. Although similar in some ways to the proposals for national co-regulatory bodies, we do not see a need to formalise this partnership working with a specific legal base and consider that doing so could limit future developments.

We recognise that situations differ in different member states and therefore it may be useful for member states to adopt different models for regulation at national level. We consider that the legislation should provide for national competent authorities to determine arrangements for regulation at national level, including the form, functions and legal status of any co-regulatory bodies, partnerships or other mechanisms with a role in the process. We are concerned that attempts to harmonise member states' arrangements too closely would be counter-productive. In particular, rather than enhancing the range and quality of information available to patients, a 'one-size-fits-all' model risks resulting in a lowest common denominator approach, undermining existing projects which are already providing value to patients.

[4] NHS Direct is a telephone, e-health and interactive television health information service accessed by over 2 million people every month, see: www.nhsdirect.nhs.uk