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Date 25 April 2008

Dear Colleague

PUBLIC CONSULTATION – LEGAL PROPOSAL ON INFORMATION TO PATIENTS

Please accept my apologies that this response from the UK Government to the Commission consultation on a legal proposal on information to patients did not meet the deadline for comment. I do hope the Commission will be able to take account of the views of the UK.

The UK Government and its Medicines and Healthcare products Regulatory Agency (MHRA) consider the provision of high quality information for patients about medicines and other treatments to be a public health priority. We welcome the progress made by the Commission in taking forward the commitment in Article 88a of Directive 2001/83/EC to deliver a report to the European Parliament on current patient information and to consult on legislative proposals.

Set out below is the UK Government response to the Commission's *Legal proposal on information to patients*. In preparing this response MHRA has consulted other UK Government departments, patient and industry stakeholders and the Patient Information Expert Advisory Group of the Commission on Human Medicines. This group includes representatives of patient organisations and health professional stakeholders.

Also relevant is the response we sent on 29 June 2007 to the previous consultation on the Article 88a report, which set out the UK vision for a future strategy for patient information. We wish to reiterate many of the points made in that response and a copy is attached for ease of reference.

Main points

The UK Government acknowledges that there is a need for a framework for understandable, good quality, objective, reliable and non promotional information about medicines. The report put before the European Parliament on 20 December 2007 demonstrated the wide differences in information provision across the EU and moves to harmonise the framework under which Member States operate are welcomed. However, these should only be taken forward in so far as they provide

additional opportunities and not to restrict existing practices in some member states that have been found to be beneficial to patients.

The UK Government's position is that the proposals are broadly acceptable, but we have three main concerns.

Firstly, it is not possible to develop a clear definition, based solely on the content of the information, of what is non-promotional information about medicines in order to distinguish clearly between advertising and information. The UK Government, along with UK stakeholders we met, believe that the purpose of information rather than its source is the key factor when considering if information is advertising or information. We permit industry to communicate with patients at certain times, for example post prescription and through disease awareness campaigns, and these are greatly valued by patients. The example in the UK of allowing industry to communicate with patients in certain circumstances could serve as a useful model for the rest of Europe.

Second, as advertising is a matter of national competence, national bodies are best placed to make decisions on what is and is not advertising, based on national guidance, past examples and national law. The regulation of advertising (currently a matter of national competence) works well and these systems should be expanded to meet the new proposals, supported by the flexibility to use self regulation.

Third, the scope of the proposals is limited in only applying to non-statutory information that is provided by industry. This is a missed opportunity on two counts – failure to further improve statutory information and failure to put the proposals for industry into a wider context. The specific legal proposals for industry information should be set in the context of an information strategy for patients across Europe to promote the provision of information about health and disease and encourage health literacy in the EU. The quality principles which could apply to all health information regardless of the provider and should be supported by further work to develop accreditation schemes to verify the quality of information provided and tools to promote health literacy. Initiatives relevant to this in the UK include the DISCERN instrument[1] which has been developed by an organisation in the UK to help patients to judge the quality of information provided, the Department of Health Information Prescriptions project and the Information Accreditation Scheme, both of which we cited in our reply of 29 June 2007. We would be happy to provide further information about each of these schemes.

We would also refer you to the information in our response of 29 June 2007 about further changes to statutory Patient Information Leaflets (PILs) proposed in the 2005 report *Always read the leaflet*[2] that were the result of extensive research in the UK. These included headlines, benefit information, better risk communication, changes of the order and signposts to other information sources in patient information leaflets. The opportunity of legislative change could be used to clarify issues around copyright of patient information to enable greater consistency of patient information and to require publication of risk management plans aimed at patients.

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[1] See http://www.discern.org.uk/.

[2] See http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=12398&noSaveAs=0&Rendition=WEB.

Provisions on advertising

The UK Government strongly supports the maintenance of the current ban on direct to consumer advertising for prescription only medicines to the general public. There was consensus for this among all stakeholders we consulted.

1. Scope content and general principles of the new legal provisions

The UK Government agrees that any material not covered by the definition of advertising should be considered as information and that clear criteria should distinguish the information that is allowed. However, we do not consider that this can be done on content alone. Rather than attempt a workable definition of information, we suggest that the legislation should define specific categories of acceptable information that could be promulgated by industry. This should include the following:

- Disease awareness materials, including those that provide a balanced overview of the available treatment options in the context of wider management of the condition. This ties in with work undertaken by the Pharmaceutical Forum and the UK has also developed guidance on acceptable practices to ensure materials are non-promotional[3].
- Materials with a recognised patient support purpose for onward dissemination by a healthcare professional as part of a medical consultation.
- Post-prescription support materials that could be accessed through information in the PIL or via a healthcare provider.

It is possible to define purposes that benefit patients and are non-promotional building from the existing definitions given in Article 86(2) of Directive 2001/83/EC.

The legislation should also specifically permit the development of public private partnerships with independent supervision to provide information about the whole range of medicines available rather than the products of a particular company. One successful example of information of this type produced in the UK is Medicines Guides and the Pharmaceutical Forum has identified other successful approaches in other member states.

Industry and patient stakeholders we met with felt strongly that patients wanted to have information so they could compare medicines and other treatment options, in particular at different stages of a long term condition. Current proposals would not address this and we agree that companies should not be permitted to provide comparative information (although they could as part of comprehensive information on all published clinical studies include all those, both positive and negative, that provided comparative information). There is a need for comparative information about medicines and treatments and this might be the sort of area where a partnership model might best be employed.

The UK Government agrees that information from industry should not contradict or go beyond the information in the Summary of Product Characteristics (SPC). The

[3] See http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007555.pdf.

only exception could be provided by public private partnerships as described above where the overseeing bodies may define acceptable additional authoritative sources of evidence that may supplement the information in the SPC.

2. Type of actions, content and monitoring of information

The UK Government agrees that a distinction should be made between "push" and "pull" mechanisms but not just for monitoring. The types of information that may be pushed by industry should be limited to those outlined in the answer above. Other than those, industry should be allowed to provide information to patients who "pull" towards it, including providing the range of factual information as defined in the consultation on a company website, but not to actively "push" information to the public.

2.1. Information passively received by citizens

We do not consider it appropriate for industry to use TV, radio or print media to communicate information on prescription medicines other than for disease awareness campaigns. Companies may provide factual information in line with the principles above to independent media producers provided no financial support is provided and editorial independence is maintained.

Public private partnerships may have a role here to provide information on the range of therapeutic options in the context of disease awareness materials, without focussing on the products of a single company.

Given these restrictions, the materials could be monitored as for 3.2 below.

2.2. Information searched by citizens

We agree that information specific to a medicine may be made available on the company website in a format that can be downloaded or provided in alternative formats on request and that this may be monitored by the relevant authorities as proposed. Information that industry puts on its websites should not be subject to case-by-case validation approval by the regulator. The regulatory approach should provide for flexibility in the mechanisms of monitoring and requirements should be proportionate to the perceived risks.

It is important that companies be allowed to include their website address on medicine packs or in the PIL. This will signpost patients on how to access further information about the medicine if they wish.

2.3. Answering requests from citizens

We agree that replies to enquiries should be monitored based on complaints only and do not consider that there is a role for further regulation in this area. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry in the UK already sets standards for this; for example, a company would not provide information which would interfere in the relationship between a health professional and a patient.

3. Quality criteria

The UK Government welcomes the quality criteria developed by the Pharmaceutical Forum. Our stakeholders told us that patients want access to a variety of information

sources and consider every provider has an agenda and all information has a bias. They want to be able to make a decision based on assessment of different information sources. The large increase in internet access in the past 10 years had had a huge impact on patients' ability to access information.

The UK Government believes strongly that quality criteria could serve as a useful tool to be applied to all providers of information, not just industry. We recommend that the Commission consider widening the scope of the criteria and partnering them with a Europe-wide accreditation scheme. This could build on the Department of Health's Information Accreditation Scheme[4] currently being developed in the UK. This accredits a company's information production system and not individual pieces of information.

4. Proposed structure for monitoring and sanctions

Regulation of advertising across Europe is a national responsibility and the existing legislation in Article 97(4) provides for the option of self regulation in individual member states. In the UK there is already a robust self regulatory system for the control of information to patients. This has been proven to be effective and we consider that it provides a model template for proposed legislation regulating non-promotional information from the pharmaceutical industry. More widely, recent initiatives by EFPIA in the development of new Codes of Practice for industry suggest that self regulation can have a part to play across the EU.

There was broad support among UK stakeholders for adopting a flexible approach in legislation at an EU level which would allow for co-regulation or self regulation as agreed at a national level depending on local traditions and competences rather than a rigid definition of co-regulation imposed in an identical fashion on all member states.

The UK Government view is that the need for any additional European regulatory body has not been clearly justified, given that such a body has not been deemed necessary for advertising.

5. Concluding remarks

The UK Government's position is that the proposals are broadly acceptable when set within the long standing position on direct to consumer advertising. The provision of non-statutory information about medicines by industry should be more clearly defined. The UK would like to see the concept of information "pulled" by patients, and strict definitions on the types of information that may be "pushed", clearly reflected in the proposals. Regulation of the provision of information is best achieved at a national level. The UK model of regulation of advertising works well and could serve as a model for adoptions more widely across Europe, underpinned by a European quality standards framework.

More widely, the lack of any proposals to further enhance statutory information is a missed opportunity. In particular, the legislative proposals ought to be placed within a broader strategy for information to patients, including improvements to statutory

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[4] See http://www.dh.gov.uk/en/Healthcare/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation/index.htm.

information and the development of quality principles for the assessment of information from all providers and measures to promote health literacy across the EU.

Yours sincerely

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Vigilance and Risk Management of Medicines Division
MHRA

Annex 1 – Response to previous consultation

European Commission
Enterprise and Industry Directorate-General

020 7084 2267 ✉ 14-207

020 7084 2293

Date 29 June 2007

Dear Colleague,

INFORMATION ON MEDICINES FOR PATIENTS – CONSULTATION ON THE REPORT UNDER ARTICLE 88a OF COUNCIL DIRECTIVE 2001/83/EC

The UK government and its Medicines and Healthcare products Regulatory Agency are very supportive of access for patients to high quality information about medicines and other treatments. We have taken particular interest in the work of the Pharmaceutical Forum in this regard and feel that it would now be timely to put forward for your detailed consideration the advice we have received from our expert advisory bodies. My purpose in writing now is to communicate to you our views on the very welcome report presented under article 88a of Council Directive 2001/83/EC [the directive] and our thoughts on how an information strategy might look.

We consider that any future strategy should be based on the concept of the statutory Patient Information Leaflet as the cornerstone of information for patients. This is because the PIL is authoritative – based on evidence, regularly updated, tested by users of the medicine and available with the medicine. The information strategy should at all times "signpost" medicines users to the PIL.

In the UK the statutory information on some marketed medicines is available via the internet. The majority of this electronic provision is through the websites of pharmaceutical companies and more recently through the electronic medicines compendium. http://www.medicines.org.uk/ The MHRA as the competent authority in the UK does not currently provide all statutory information via our website although some information is made available through that route.

Non-statutory information about medicines is widely available through the internet sites of patient support organisations, the pharmaceutical industry, and the National Health Service.

We recognise that there is a need for high quality information on medicines and disease areas to be provided for patients in a consistent manner to European citizens. The UK Government, therefore, fully supports this endeavour. Access to medicines

information should be both via the internet and through more conventional means. A proposed strategy to take this forward is set out below.

A FUTURE STRATEGY FOR INFORMATION TO PATIENTS

The strategy for the provision of patient information to all in the European Union should be based on three pillars in line with the work already underway in the Pharmaceutical Forum.

- improvement of quality of statutory patient information
- accreditation of non statutory medicines information based on quality criteria
- promulgation of the concept of "information partners" together with better access to statutory information

A fundamental aspect of any information strategy is that it should not permit the promotion or advertising of medicines directly to patients and consumers unless such promotion is consistent with the current legislative framework. The prohibition on advertising of prescription medicines directly to patients should remain in place.

For some time now the UK has afforded patient information a high profile and convened a Working Group of the Committee on Safety of Medicines in 2003 to advise on improvements to patient information. With their help we have identified several further improvements that can be made within the current legislative framework and developed guidance for companies in the UK. Details of the advice can be found in the publication "Always read the leaflet – getting the best information with every medicine" which is available at http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=12398&noSaveAs=0&Rendition=WEB . A copy of this report is attached to this response. Please contact me if further copies would be helpful.

An expert advisory group on patient information under the auspices of the Commission on Human Medicines, (CHMEAGPI) has taken over from the previous group and they have considered in particular what a strategy for patient information could encompass going forward. This three pillar approach is described in detail below and covers statutory information, non-statutory information and information partners and access.

1. Improved quality of statutory information

The statutory information provided pursuant to Title V of Council Directive 2001/83/EC should be the foundation of any future information strategy. This is the main source of medicines information for all patients. The measures relating to Title V included in Directive 2004/27/EC, particularly the requirement for consultation with target users, provide a critically important opportunity to ensure that the leaflets provided with the medicine are useful to patients. We see this statutory patient information leaflet (package leaflet) as a fundamental aspect of any information strategy which should be available to all patients in a timely manner, including before treatment is started, to help patients make sound treatment choices. This information resource should be of high quality and should provide signposts to other sources of information which may be provided in the other strands of any information strategy developed.

The new statutory provisions for patient information leaflets which concern the order of the information and the need to consult patients to ensure their views are taken into account (articles 59(1) and 59(3) of the directive) are going some way to raising quality standards. However, we believe that more could be done through legislative amendment and the development of regulatory guidance to boost the quality and usefulness of this information. Specifically we believe it would be useful to agree across Europe the following:

- High level information quality principles
- Common principles on risk communication
- The inclusion of "headlines" which set out key issues about the medicine
- Information on benefit or efficacy of the medicine
- Signposting to other related sources of information
- A less prescriptive order to the information

Quality principles

In the UK in taking forward quality improvements in patient information we have been working on a series of quality criteria which can be used to evaluate the statutory information presented by marketing authorisation holders and provide a quality rating. We would recommend such a system for use in the development of tools to support an information strategy for all.

Risk communication

One of the most criticised aspects of statutory information is the lack of good risk communication tools within the leaflet. There is a growing recognition among regulatory bodies that a set of common principles on risk communication is needed to increase the quality of the statutory patient information. Much work on this has already been done in the UK and we would welcome the opportunity to share this with others working in the field. Better risk communication will enable patients to take more robust decisions about their medicines through a greater understanding. Separately the summaries of product characteristics will also require suitable updating to maximise the way in which risk communication is achieved with patient information leaflets.

Headlines

Many medicines contain large amounts of information which patients need to assimilate in order to fully understand their medicine, how to take it and the risks associated with it in normal use. Including at the beginning of the statutory information those key messages for safe use in the form of headlines will serve to remind patients of these. This has been considered in some detail by the UK regulatory body and we would welcome the opportunity to share this with others to help drive up quality. Examples of best practice in this area will be forwarded separately.

Benefit information
In addition, setting the medicines information in the context of the disease being treated we believe, is an important mechanism for helping patients to balance the risks and benefits of a particular medicine. For some medicines, particularly those for chronic use, we see the inclusion of some disease-related information within the statutory information as beneficial to patients in terms of concordance. This has been considered in some detail by the UK regulatory body and again we would welcome the opportunity to share this with others to help drive up quality. Examples of best practice in this area will be forwarded separately.

Signposting
Another important aspect linked to this would be the ability of the leaflet to signpost patients to other sources of information via third party information providers such as voluntary organisations. The ability to cite web addresses would be an advantage in this modern internet age.

Order of the information
Although the main headings within the statutory patient information are logical, beyond that there should be more flexibility on how best to set out the necessary information for safe use of the medicine. The legislation should provide the framework and the detail should be provided in guidance.

Quality Review of Documents templates
Separately our CHMEAGPI has undertaken a survey of those companies who currently provide a service to the pharmaceutical industry in connection with the new legal obligation to ensure that all leaflets reflect the results of consultation with target patient groups (article 59(3) of Council Directive 2001/83/EC) to gauge their views and experience with this new requirement. The report of this is available from http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2030408&RevisionSelectionMethod=Latest. A key message from this work is the high level of criticism of the template provided by the Quality Review of Documents group which most companies are expected to use when drawing up their patient information leaflet. There is a view that use of such a template may stifle innovation in information provision and the emerging evidence suggests that use of the suggested wording is confusing and unhelpful to patients. Although the use of templates can be beneficial in ensuring the correct information appears in the correct order we urge you to consider the role of such a document in the light of the available evidence.

2. Accreditation scheme for non-statutory information
Although the statutory medicines information is in our view the foundation of the strategy for patient information we recognise that the patient information leaflet cannot address all the needs of patients and that there is a need for a wide variety of sources of information for patients at different times. Individual patients' needs are most likely to be able to be met if there is a range of diverse sources of information supported by quality principles to enable them to make informed choices about their condition and the treatments available. These sources may include patient organisations, the National Health Service, the national competent authority and others.

Patients' needs can be diverse – information for children and young people, information for the visually impaired, information for carer-givers, information for psychiatric patients – all require different handling and these groups in particular should be consulted on what best meets their needs. The UK in the publication "Always Read the leaflet – getting the best information with every medicine" looks at the tools which could be used to help particular groups of patients have access to important information about the medicines they use. This is available from our website at http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2018041&RevisionSelectionMethod=Latest and we commend the recommendations in this report to you.

Source/imprimateur of the information

As part of evaluating the quality of the information they find, patients will need to be able to identify the source so that they can make a judgement of how far to trust what is provided to them. The heritage of the information will need careful consideration if it is to be widely disseminated. Who should provide such information is a matter of debate. The pharmaceutical industry clearly has much information about the medicines they market but it is extremely difficult for them to participate without offending the DTCA ban. Voluntary sector organisations such as patient support groups within particular disease areas are known to be trusted by patients and they also have a track record of researching the information that patients want and ensuring that these needs are met. We consider that better use of these organisations should be made in both the development and dissemination of non-statutory information. Where appropriate, collaboration with other information providers within set parameters could be considered.

Core quality principles

We very much support the work of the Pharmaceutical Forum in the area of non-statutory information for patients. A set of core quality principles which all information providers could follow would be useful. The information developed could then be tailored at national, local and individual level to provide meaningful information for each patient.

We believe the provision of information on disease areas particular for chronic conditions is a valuable resource for patients. This can discuss in addition to the disease progression, the treatments which are available and provide a balanced perspective on the merits of these. The UK has already developed guidance for the pharmaceutical industry in this area which helps to ensure that the information they provide is useful for the patient and not promotional. Key aspects of this guidance are that the information should be accurate, up-to-date, able to be substantiated, comprehensive, balanced and fair, accessible, and the source of the information should be transparent. Details are available from our website. http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=632&noSaveAs=0&Rendition=WEB

Accreditation of the non-statutory information

We do not believe that this type of information should fall to be regulated by the competent authority. Rather, this information should be subject to self-regulation underpinned by a set of quality principles such as those developed by the Pharmaceutical Forum. An accreditation scheme for information providers being developed in the UK may be a useful model to consider. This scheme aims to improve the quality of public, voluntary and commercial information and will provide a tool to explain good quality principles and guide those who produce the information. Such a scheme will accredit information providers rather than individual pieces of information and the principles that it embodies could be more widely applicable across the community. Given the diversity in national practices, we suggest that implementation of such a scheme should be managed at the national level.
Details are available at
http://www.dh.gov.uk/en/Policyandguidance/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation/index.htm

Separately, there is much that can be done to support patients in building skills to find and evaluate data. Providing patients with "power questions" will enable them to review the information provided more critically and assist them in making informed choices. Examples of this have been developed in the UK, for example the DISCERN tool, and we would be happy to share these with the Commission.

3. Improving access and the concept of information partners

We strongly believe that there is a hierarchy of information sources with the statutory patient information leaflet which is available to all patients being of prime importance. Beneath this are many levels of information of varying importance and relevance but all of which will have value in the patient journey.

Patients get information from a wide variety of sources – from families, faith networks, word of mouth, schools and non-health related outlets such as supermarkets. However, any future information strategy should designate the healthcare professionals as the primary source of information about health and medicines. The partnership between the healthcare professional and the patient is essential for enabling the patient to make informed choices.

Many patients now have access to the internet although we recognise that this is not widespread across the Community. Some competent authorities already make the statutory patient information leaflet available via their website (and there is a problem with copyright in some member states) but this is not widespread and there is no compulsion on such bodies to do so. We believe that setting out a regulatory requirement on competent authorities to make statutory information available via their own websites could help to raise availability of this information. This could also promote access to the statutory information through healthcare professionals at the time of prescribing which we believe could be extremely useful in the patient journey.

As important as ensuring that a range of information from authoritative sources is available to patients, is ensuring that patients can find these sources of information. A new initiative being rolled out in the UK is the "information prescription" where at the time of diagnosis the healthcare professional will provide the patient with information about the disease and details of where further information and support

can be obtained. This builds on research which shows that the doctor (or other prescriber or healthcare professional) is often the most trusted source of information. This initiative will provide information about national and local resources which may be internet based or accessible through other providers such as patient organisations. Further information about this can be found at http://www.dh.gov.uk/en/Policyandguidance/PatientChoice/Choice/BetterInformationChoicesHealth/DH_4123091

There is also a need to consider how groups with special needs such as those with sight loss, those with low basic skills and those not proficient in the national language can access information. This could build on the achievements resulting from the legal requirement for the statutory information to be made available in alternative formats for those with sight loss.

New and emerging technologies mean that there are many opportunities to provide information through a wide variety of routes. The internet is clearly one area where patient experience is beginning to be shared through such websites as www.youtube.com but health channels on television, touch-screens in pharmacies and health-centres, clinics and hospitals and dissemination through libraries can all be useful. Nevertheless, any initiatives in this area need to reflect local conditions and can only be guided by broad frameworks at European level and this should be recognised going forward.

It is also important to consider gaps in the current community provision of information; for example the Pharmacovigilance Working Party is currently conducting a survey on safety communications at member state level. The outcome of this survey should inform the information strategy as it develops.

Concluding remarks

To sum up, the UK Government strongly supports the provision of information to patients from a wide variety of sources and recognises that patients value this where it is available. In taking forward a strategy for medicines information provision more widely we believe a three pillar model would achieve the right balance and an improvement for patients. The foundation of medicines information should remain the statutory patient information leaflet and we have put forward key quality improvements which could be supported by regulatory amendments either through statute or guidance. We believe these quality improvements would be both welcomed by patients and meet needs not currently catered for. Widening out the strategy to include measures to promote the availability of non-statutory information underpinned by a set of quality principles with the option of a national accreditation scheme would give patients confidence and trust in the information provided. And engaging fully with healthcare professionals in assisting with the dissemination of this information resource will be essential in creating an open access policy in this area.

We very much welcome the opportunity to share our experiences in this area with colleagues from other member states.

Yours sincerely,

Information for Public Health
Medicines and Healthcare products Regulatory Agency