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: Reaction to the 'Legal proposal on information for patients'.

Elewijt, April 7, 2008.

Dear Ulla Nähri,

Please find on the following pages my reaction to the proposal on information for patients.

The main conclusion of my reaction is: 'The proposed legislation is in direct conflict with its intended perspective of putting the interests of patients first.'

Before this proposal is implemented, please reconsider the assumptions that have lead to the proposal. At lease five of these assumptions are severely flawed and very problematic.

This proposal will – if implemented – provide patients with even more sub-standard and irrelevant information. This is not the way forward.

Please do not hesitate to contact me if further information is required.

Kind regards,

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Summary:
This text is a reaction to the Public consultation about the 'Legal proposal on Information to patients'.

The proposal is based on a number of assumptions. This response describes five of these assumptions and explains why these are problematic.

The text shows that the following assumptions are incorrect and unsustainable:

1 **'it is possible to develop a strategy without involving all stakeholders and without investigating current best practice.'**
The proposed information strategy is only applicable to Marketing Authorisation Holders. Other sources of information, such as doctors, pharmacists, and the media are excluded from this strategy. Ignoring other involved stakeholders makes it very unlikely that this strategy will be effective.

2 **'it is possible to combine 'the interests of patients' and European wide 'harmonization of practices of information provisions'.'**
Harmonization of information provision practices is unlikely to take differences between patients, differences between medicines and differences between contexts into account. It will lead to sub-standard information if it is not based on best practice in specific situations.

3 **'it is possible to define criteria to evaluate the quality of information without involving all stakeholders in the development process.'**
Criteria to judge the quality of information must be related to the activities of the users of information. The criteria in the proposal cannot be gauged, nor can they be controlled. These criteria are not suitable for legislation.

4. **'it is possible to clearly differentiate between advertising and non-promotional information.'**
There is no clear line between 'promotion' and 'information'. This distinction depends on the position of the reviewer. People are very capable of distinguishing between these two intentions.

5. **'Patients are at the moment unable to find information and are unable to judge the quality of information about medicines.'**
People are very capable of finding information about medicines and judging its quality. This information is frequently outside the realm of MAHs, but it is therefore not less valuable. Any change in the practical patterns will have substantial consequences that must be considered beforehand.

The fundamental problem with this proposal is that it is based on 'information about single medicines'. This information does not tell patients how to integrate medicine taking into their daily life, nor does not help patients who use more than one medicine.

If we want to help patients to take their medicines correctly and support appropriate health decisions, the proposed approach is detrimental. The proposed legislation is in direct conflict with its intended perspective of putting the interests of patients first.

If the DG Enterprise and Industry is worried that the pharmaceutical industry currently provides different information about the same medicines in different EU-countries (unequal access), or that this industry provides sub-standard information to patients (poor-quality, unreliable and promotional) than this should be addressed. The current legal proposal does not do this.

Conclusions:
The 'legal proposal on information to patients' is based on a number of incorrect assumptions. Implementation of this proposal will severely hamper the provision of information about medicines to people. **Please reconsider this proposal.**

1. Information strategy.

Assumption: 'it is possible to develop a strategy without involving all stakeholders and without investigating current best practice'.

Proposal: Section 2.1 states: *'Article 88a also provides that 'the Commission shall, if appropriate, put forward proposals setting out an information strategy …'.*

Comment: This aim is absolute correct and laudable. However, the proposed strategy looks at information about medicines from Marketing Authorisation Holders only. Information about medicines from other sources, such as pharmacists, doctors, the media, and other parties is not considered.

Consequence: Ignoring stakeholders and ignoring current best practice are serious shortcomings. Focusing on one specific type of information only has as a consequence that there is no relation with the information that is supplied by other providers such as doctors or pharmacists. If this proposal is implemented, it is likely that patients will receive too much, unrelated and conflicting information. This strategy therefore does not 'put the interest of patients first' because it is unlikely to make actions easier for patients.

Example: Patients receive information about a specific prescription medicine in many different forms. The outer box, a pharmacist's label, warning labels, and a package leaflet. Many doctors and pharmacists provide additional personalised information about medicines in a printed format. If several medicines are dispensed at the same time, the number of information sources that a patient receives becomes substantial. It is not clear where patients should start reading, and which information can be disregarded. Comparing the information that accompanies two products is already fairly difficult and confusing; interpreting the information of three products is very hard.

Alternative: It is necessary to develop a strategy about information for patients. If the patient is really central, than their position must be used as a starting point. This needs to be done in two steps:

1. The starting point for this proposal is that 'people do not have equal access to information' and 'information must be good-quality, objective, reliable and non promotional' across Europe. These statements must be investigated first because patients currently receive and appreciate information from a large number or sources. This investigation will reveal both the major practical problems as well as current best practice.
2. A second essential element of an information strategy is that it must involve all stakeholders. Ignoring, or at least not involving, all other providers of information is likely to lead to failure. Although the last paragraph of section 2.1 states that '*healthcare professionals should remain as they are today the primary source of health information.'* The information strategy must involve all healthcare professionals, because they can immediately support the information about medicines that is provided by the marketing authorisation holders.

2. Aims: Harmonization and interests of patients.

Assumption: 'it is possible to combine 'the interests of patients' and European wide 'harmonization of practices of information provisions'.'

Proposal: Section 2.2 starts with *'the forthcoming proposal will put the interest of patients first'*.
Section 3 states that *'a fundamental objective of the legal proposal should be to provide rules that harmonise practices of information provisions to patients in member states'*. This is presented as a 'key idea'.

Comment: There is a conflict between '*will put the interest of patients first'* and *'to harmonise practices of information provisions'*.

Harmonization of provision of information in Europe implies that there is a 'best practice' of providing information. There is simply no point in harmonizing 'poor practice'. 'Best practice of information provision' indicates that it is essential to start from the actual use of information about medicines by people.

The observation of actual use reveals that there are differences between patients, differences between medicines, differences in practical contexts, and differences in historical developments. It is unlikely that a single harmonization can be helpful to develop information that is suitable in specific circumstances.

Consequence: The harmonization of information provision practices will cause that all patients will receive similar information about all medicines across Europe. In practice, patients across Europe might need similar information about identical medicines, but they don't need similar information about different medicines. A harmonization programme fails if it does not acknowledge the differences between patients and the differences between medicines.

Example: Harmonization of package leaflets has led to a standardized format across Europe. This harmonization has been applied to all medicines. All medicines must supply their information in package leaflets in a standardized structure. The same structure is used for medicines that are given in hospitals and at home, and for short term and chronic diseases. For patients, this structure is frequently inappropriate. From a patient's point of view, there is a major difference between a painkiller, an oral contraceptive, an injectable antibiotic and an HIV-tablet. Patients would like to receive information that is based on these differences.

Alternative: Harmonization is possible, but only if the harmonization is based on categories that are determined according to the perception of patients. It would be worth considering if it is possible to start the harmonization process with a limited number of groups of medicines or for specific groups of patients.

3. Criteria to evaluate the quality of information.

Assumption: 'it is possible to define criteria to evaluate the quality of information without involving all stakeholders in the development process.'

Proposal: Section 1.1 mentions *'good-quality, objective, reliable and non promotional'*.
Section 2.2 states slightly different criteria: *'understandable, objective, high-quality and non-promotional information about the benefits and risks of their medicines'*.
Section 3 adds: *'The proposal should enable EU citizens to get objective information from reliable sources.'*
Section 3.2 states: '*Clear criteria should distinguish the information that is allowed from the information that is not allowed. A bit further in the same section 'In addition, specific quality criteria should be defined and respected.'*
Section 4 provides some other criteria: *'All information provided to citizens should fulfill specific criteria concerning the quality of the information. The information provided should be objective and unbiased, patientoriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information.'*
The table in part 6 adds the following criteria:
1. Objective and unbiased
2. Patient oriented
3. Evidence-based
4. Up-to-date
5. Understandable
6. Accessible
7. Transparent
8. Relevant
9. Consistent with approved product information
10. Non-promotional
11. Information should not include any comparative sections between medicinal products

Comment: The list of criteria to evaluate the quality of information in this proposal is substantial. Only very few of these criteria can actually be determined through any form of test. Most of the criteria cannot be measured or monitored at all. The majority of these criteria is useless in practice. Nobody can stick to these criteria because they cannot be gauged with any accuracy.

Some criteria are even theoretically impossible. Information can never be 'objective', nor can it be 'relevant' or 'understandable' in a general sense.

Furthermore, the main criterion is not mentioned: 'Does the information enable patients to act appropriately?'

Consequence: Criteria that cannot be monitored or measured must not be incorporated in legislation because they make it impossible to enforce this legislation. It is impossible to determine if information is 'objective' or 'relevant'. These criteria depend on the position of the reviewer.

Furthermore, these criteria are in direct conflict with the third aim of the proposal: *'Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation'*. Unclear criteria will cause unnecessary bureaucracy because it will require a substantial number of guidelines to explain what is exactly meant by unclear criteria. The development of legislation and guidelines relating to package leaflets in the last 16 years should be taken as a warning.

Example: Information designers have a long experience in establishing if information is suitable and appropriate for people. The design of for example utility bills, tax forms, public transport signage, voting systems, and instruction manuals has lead to methods that result in verifiable improvements of information. In stead of formulating general criteria – as this proposal does – it is best practice to describe very specific actions that must be successfully accomplished with the support of the information. Those activities that pose the highest risks should be attended to first.

Alternative: It is very well possible to state clear criteria to evaluate the quality of information for patients. For example Directive 2004/27/EC article 63 paragraph 2 states that information *'must enable the users to act appropriately'*. That is a phrase that requires the developer of information to establish three elements:

1. Who is the user? (patient, doctor, pharmacist, regulator, …)
2. Which actions need to be undertaken by each of these users? (for patients: make a decision, follow an instruction, remember side effects, …)
3. What is an appropriate level of success for each action? (is it acceptable if 50% of patients can undertake an action successfully, or do 95% of these patients need to be successful?)

Establishing these three elements provides all the relevant criteria for a specific medicine. These criteria can be accurately gauged because it is fairly easy to observe if users act in an appropriate way. If people do not act in an appropriate way, or if the success levels are not achieved, the information must be modified. This approach also makes it possible to establish, implement and control criteria for specific groups of patients: the very elderly, visually impaired, children.

4. The difference between advertising and non-promotional information.

Assumption: 'it is possible to clearly differentiate between advertising and non-promotional information.'

Proposal: The second bullet in section 2.2 states: *'Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and nonpromotional information.'*
Section 3 adds: *'A major part is to present a clear distinction between advertising of and information provided on prescription medicines.'*
Section 3.3.1. suggests: *'Under the clear safeguard that all advertisement to the public is banned, it should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals.'*
The definition of advertising is provided in the table and refers to Article 86 of Directive 2001/83/EC.

Comment: In practice, it is impossible to make a clear distinction between 'information' and 'promotion'. Section 3.2 states that *'clear criteria should distinguish the information that is allowed from the information that is not allowed'*. It would be very useful, before this proposal is taken any further, to develop and publish a list of these 'clear criteria'. This is an impossible task because these criteria depend on the position of the reviewer of the information.

Consequence: It is very unlikely that anyone can come up with clear criteria to precisely and incontestably judge whether an artefact is 'information', or 'promotion'. This futile search will lead to a very long process of discussions, committees, conferences and so on, while the result is clear from the beginning: it depends on the position of the reviewer of the information.

Example: Because this is such a substantial issue in the proposal, I provide four examples.

Example 1. The Belgian website www.bcfi.be provides information about medicines. It contains the Belgian Repertorium and lists all registered medicines. The price of each medicine, per pack and per unit, is provided. The website is financially completely independent and it provides only evidence based information. One of the intentions of this website is to support the prescription of cheaper variations of medicines. According to Directive 2001/83/EC, this is 'advertising'. The website is 'a form of inducement designed to promote the prescription of medicinal products'.

Furthermore, the website contains medicines that are not available, or available at a higher price, in France or the Netherlands. It is likely that this attracts Dutch and French patients to Belgian pharmacies. This example shows that there is no 'objective information'. All information comes from a specific source and has specific intentions.

Example 2. It is currently not allowed to place the logo of a medicine on the package leaflet because this is seen as 'advertising'. Patients however need to relate package leaflets to packaging and blisterpacks and they would use a medicine-logo for this purpose. This would be especially useful when several leaflets and several boxes have been separated and need to be re-united. It is likely that a strong visual relation between packaging, package

leaflet and inner packaging would reduce the number of errors. The differentiation between ‘advertising’ and ‘information’ is in this case not helping patients.

Example 3. Product placements in films and sponsoring sport events are a common ways to promote products. It is likely that this option will be used by the pharmaceutical industry to promote medicines on a global scale. It would be impossible to prevent internet downloads of films and internet viewing of sportevents that contain advertising for medicines.

Example 4. A comparison of the supply of information about medicines with an invoice for the use of a mobile telephone provides a final example. A telephone invoice is highly individual: it states the name, address and phone number of an individual user. It provides information about telephone use in a month, subdivided into ‘calls received’, ‘calls made’, ‘sms messages received’, ‘sms messages send’, ‘internet connection time’, and a string of more detailed information including suggestions which subscription format would be more suitable. This last element is clearly ‘promotional’. These kinds of invoices are send to millions of mobile phone users every month.

Information about medicines is exactly the opposite. All EU-citizens receive an identically structured leaflet that follows the QRD template. Regardless of the type of medicine, regardless of the patient, regardless of the context: all package leaflets use an identical structure and provide identical types of information.

The quality difference between a simple phone-bill and information about medicines is not easy to comprehend. Patients would like similar individual information about their medicines in relation to their treatment too.

The difference between ‘information’ and ‘promotion’ of telephone companies is clear to every EU-citizen. Before introducing legislation that is based on the idea that patients are not capable of distinguishing between ‘promotion’ and ‘information’ about medicines, it might be worth looking at how EU-citizens are very able to make this difference in other areas.

Alternative: People are remarkable aware of the difference between promotion and information. They know – through experience and through a network of reliable advisors – which information can be trusted and which information is suspect. This is valid for patients, but just as well for doctors and pharmacists.

This knowledge should be used as a basis for the development of legislation that tries to distinguish between ‘information’ and ‘advertising’.

Assumption 5. The ways in which patients use information.

Assumption: 'The proposal is based on the idea that patients are at the moment unable to find information and are unable to judge the quality of information about medicines.'

Proposal: Section 3.3: *'A distinction should be made between the cases where the patient is passively receiving the information ('push') or actively searching for the information ('pull') in terms of the monitoring mechanism.'*

Comment: The words 'passive', 'soft pull' and 'active pull' in the second column of the table indicate that 'the general public' can take these positions. That is not the case. All information processing is an activity which requires effort, time and concentration. There is no 'passive type of action by the general public'. That is an insult. Certainly if 'printed material' (first column in table) or 'written information in printed media' (first column in table) are concerned. 'Reading' is a highly active process and cannot be paternalistically belittled to a 'passive action by the general public'. [note: What is the difference between 'printed material' and 'written information in printed media'?]

The actions that people undertake to take medicines, and the integration of appropriate medicine taking behaviour in day-to-day life is fairly complex. Far more complex than a simple division in 'passive', 'soft pull' and 'active pull'. Information fulfills a crucial role in supporting these complex actions. There are many more information suppliers than Marketing Authorisation Holders only, and most people will refer to family, doctors, pharmacists and internet long before contacting an MAH.

Consequence: The proposal treats patients as if they are not capable of finding information for themselves, and are not capable of judging the quality of this information. There are two major consequences of this assumption about the ways in which people use information about medicines.

1. The division in 'passive', 'soft pull' and 'active pull' is far too simplistic to be used as a base for any information strategy or legislation. At the moment, most patients seem to be able to make suitable decisions about their health with the support of health care providers. People do not wait for Marketing Authorization Holders to inform them: they will have had contacts with other information suppliers, such as doctors and pharmacists before.
2. The problem with the suggested approach is that it starts from single medicines. Marketing Authorization Holders can only provide information about a single medicine. In practice, a single medicine is usually only a part of a treatment. If a patient has to take more than one medicine, or wonders if there are alternative therapies, the whole suggestion of 'passive', 'soft pull' and 'active pull' fails. The question that patients are asking cannot be classified into these three categories.

Both these consequences are in direct conflict with the aim of the proposal: 'to put the interests of patients first.'

Example: Antibiotics interfere with oral contraceptives. It is highly likely that most females who take oral contraceptives for a long period will be taking antibiotics for a brief period at some point too. The package leaflet of both types of medicines suggest that a patients needs to contact the MAH to ask if this combination is safe. In the proposal, this is described as 'an active pull'. Unfortunately, it is not possible for MAHs to give a direct and clear answer other than: 'you've got to discuss this with your doctor or pharmacist'. It would

be unwise to provide information to individual patients about medicines of other MAHs. Even though a patient actively pulls the information, the answer is not worth the effort.

Alternative: People find information about their medicines in different ways. This depend on their personal situation (age, preferred methods of information retrieval, experience, availability of assistance, …), the type of medicine (duration of treatment, method of administration, …) and context (hospital, home, emergency, …). Information needs to be suitable for individuals and available in all sorts of formats to 'enable people to act appropriately'.

It is essential to use this current practice as a basis for the development of an information strategy.

Discussion

The 'Legal proposal on information for patients' seems to be based on five assumptions. Each of these assumptions is very problematic.

Monitoring
The proposal fo the DG Enterprise and Industry suggests to set up a 'structure for monitoring and sanctions'. Each of the five assumptions show that this would be close to impossible. The monitoring of information about by competent authorities would be based on:
- an information strategy that does not include all stakeholders,
- a harmonization process that is not based on 'best practice',
- unclear and unsuitable criteria for the evaluation of the quality of information,
- an unclear differentiation between 'promotion' and 'information',
- an underestimation of the abilities of European citizens.

These are not really good starting points for any monitoring system.

Pharmaceutical industry
The proposal tries to address two issues. Section 2.2 states that the proposal *'should aim at reducing differences in access to information and should ensure the availability of good-quality, objective, reliable and non-promotional information on medicinal products.'* Section 2.1 makes clear that a Directive would only be applicable to information provided by Marketing Authorisation Holders.

If the DG Enterprise and Industry is worried that the pharmaceutical industry provides different information about the same medicines in different EU-countries (unequal access), or that this industry provides sub-standard information to patients (poor-quality, unreliable and promotional) than this should be addressed. The current legal proposal does not do this.

Alternative
The following points need to be considered before this legislation is put into force:
1 - investigate and describe 'best practice'. There are many organizations and individuals working to improve information about medicines. These activities should be supported and enhanced.
2 - involve all stakeholders in an 'information strategy'. Focussing on Marketing Authorisation Holers only does not do any justice to current practice.
3 - harmonize only those information provisions that have proven to be beneficial for patients.
4 - use appropriate criteria. Criteria need to be performance based and related to the activities of people.
5 - there is no clear line between 'information' and 'promotion'. Any information has an intention and tries to persuade the reader to change knowledge, beliefs and actions. It would be worth investigating how people at the moment distinguish between different types of information about medicines.
6 - at the moment, patients are very capable of finding information and judging its quality. It would be worth investigating how people at the moment interpret information about medicines, and what the real effects of 'unequal accessibility' and 'variable quality' are.

None of these six points is new. Information designers have applied these principles for decades in the development of a wide variation of information artefacts.

Concluding

This text discusses five assumptions on which the 'Legal proposal on information for patients' seems to be based. None of these assumptions is supported, and all can be seriously questioned. Developing legislation based on these assumptions is very problematic.

The proposed approach is likely to lead to four results:

1. An increase in the supply of information about medicines that is not optimally usable by people. This reduces the confidence in the European commission, and it makes the activities of regulators, pharmaceutical industry and healthcare professionals more difficult. Some of it will be detrimental because the information does not optimally support the activities of patients.
2. Unclear criteria and unspecified aims are likely to lead to a plethora of guidelines, amendments and discussions. This leads to more bureaucracy, not less.
3. The proposal will not prevent the development of 'promotional information' by the pharmaceutical industry. The proposed legislation does not address this issue sufficiently.
4. The proposal will not lead to equal access nor to an improvement in quality, objectivity, and reliability of information about medicines.

I would therefore ask you to reconsider this approach and seriously investigate alternatives.

About the author:

Dr Karel van der Waarde studied graphic design in the Netherlands (Eindhoven) and in the UK (Leicester, Reading). He received his doctorate in 1994 for: *'An investigation into the suitability of the graphic presentation of patient package inserts'*. In 1995, he started a design - research consultancy in Belgium specializing in the testing of information design. The company develops, designs and tests package leaflets, instructions, forms, protocols, and the information architecture for websites.

One of the activities of the consultancy is to conduct 'Readability tests' of package leaflets. In the last 15 years, several thousand patients were interviewed about their needs for information related to medicines. Additional interviews with nurses, doctors and pharmacists provide professional feedback. Most of the comments in this reaction are based on these interviews.

Karel van der Waarde frequently publishes and lectures about medical visual information. He is professor Visual Rhetoric at Avans University in Breda, a board member of the International Institute for Information Design (IIID), and a fellow of the Communication Research Institute (CRI).