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Pharmaceutical Advertising 2012

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A practical cross-border insight into pharmaceutical advertising

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Preface:

■ **Preface** by Tom Spencer, Counsel, GlaxoSmithKline Plc.

General Chapters:

1 **The European Commission's Proposal on Providing Information to the General Public on Prescription-Only Medicinal Products** - Jackie Mulryne & Silvia Valverde, Arnold & Porter (UK) LLP 1

2 **Pharmaceutical Promotion and the UK Bribery Act** - Alison Dennis & Tony Lewis, Field Fisher Waterhouse LLP 8

Country Question and Answer Chapters:

3	**Australia**	Clayton Utz: Colin Loveday & Greg Williams	13
4	**Austria**	Herbst Kinsky Rechtsanwälte GmbH: Dr Sonja Hebenstreit & Dr Isabel Funk-Leisch	23
5	**Belgium**	Allen & Overy LLP: Geert Glas & Dieter Delarue	34
6	**Brazil**	Licks Advogados: Otto Licks	44
7	**Bulgaria**	CMS Cameron McKenna: David Butts & Angelika Dimitrova	51
8	**Canada**	Davis LLP: Bill Hearn & Samuel Schwartz	61
9	**Czech Republic**	CMS Cameron McKenna: Denisa Assefová & Vladěna Kuřecová	74
10	**Denmark**	Jusmedico Advokatanpartsselskab: Jan Bjerrum Bach & Lone Hertz	82
11	**England & Wales**	Arnold & Porter (UK) LLP: Silvia Valverde & Ewan Townsend	95
12	**Finland**	Roschier, Attorneys Ltd.: Mikael Segercrantz & Johanna Lilja	108
13	**France**	PDG Avocats: Paule Drouault-Gardrat & Juliette Peterka	118
14	**Germany**	Clifford Chance: Dr Peter Dieners & Marc Oeben	125
15	**Hungary**	CMS Cameron McKenna: Dóra Petrányi & Veronika Bednár	137
16	**Ireland**	Arthur Cox: Declan Hayes & Colin Kavanagh	146
17	**Italy**	Biolato Longo Ridola & Mori: Linda Longo & Andrea Moretti	155
18	**Japan**	Nishimura & Asahi: Somuku Iimura & Yoko Kasai	166
19	**Korea**	Hwang Mok Park P.C.: Kun Su Mok & Hye Yeon Lim	175
20	**Malta**	Ganado & Associates, Advocates: Dr. Anthony Cremona & Thomas Cutts-Watson	183
21	**Mexico**	Olivares & Cia., S.C.: Alejandro Luna & Juan Luis Serrano	195
22	**Netherlands**	Life Sciences Legal Advocaten: Anke E. Heezius	204
23	**Norway**	Advokatfirmaet Grette DA: Felix Reimers & Erik Helstad	212
24	**Poland**	Sołtysiński Kawecki & Szlęzak: Dr. Ewa Skrzydło-Tefelska & Agnieszka Jurcewicz	222
25	**Portugal**	Vieira de Almeida & Associados: Paulo Pinheiro & Francisca Paulouro	229
26	**Romania**	CMS Cameron McKenna: Valentina Parvu & Ioana Oprea-Barac	238
27	**Russia**	CMS, Russia: Vsevolod Tyupa	247
28	**Slovenia**	Avbreht, Zajc & Partners Ltd.: Andrej Kirm	254
29	**South Africa**	Adams & Adams: Alexis Apostolidis & Pieter Visagie	263
30	**Spain**	Faus & Moliner: Jordi Faus & Rodrigo Osorio	271
31	**Sweden**	Mannheimer Swartling Advokatbyrå: Helén Waxberg & Fredrik Lundegårdh	281
32	**Switzerland**	Schellenberg Wittmer: Andrea Mondini & Christine Beusch-Liggenstorfer	290
33	**Turkey**	YükselKarkınKüçük Attorney Partnership: Gökhan Gökçe & İrem Cansu Atikcan	301
34	**Ukraine**	Arzinger: Timur Bondaryev & Svitlana Postrygan	310
35	**USA**	Sidley Austin LLP: Coleen Klasmeier & Maura Norden	320
36	**Vietnam**	Tilleke & Gibbins: Tu Ngoc Trinh & Dzung Thi Thuy Nguyen	339

Chapter 1

The European Commission's Proposal on Providing Information to the General Public on Prescription-Only Medicinal Products

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Jackie Mulryne

Silvia Valverde

Introduction

Patients are increasingly interested in learning more about the medicines they take, and want more of a say in how they are treated. At the same time, they are confronted with a growing volume of information from various sources, and often find it difficult to identify reliable and accurate information.

This article describes the current regulatory framework in the EU governing information to patients on prescription-only products (POMs), and focuses on the recent amended Proposal published by the European Commission in February 2012 on this subject.

Directive 2001/83/EC (the Community Code on medicines for human use) [see Endnote 1] prohibits advertising of POMs to the general public, but provides little detail about what and when information about this category of products can be provided. The increased use of the Internet over recent years makes the need for clarity even more important, as online information on medicines can be imprecise, emotional rather than factual, or even false.

There have been calls to control the information that patients receive and to try to regulate what information can be provided. A focus of these suggestions has been on the activities of pharmaceutical companies. However, there is an inherent conflict: on the one hand, patients have the right to receive accurate and useful information about treatment options, and pharmaceutical companies are arguably best placed to provide such information about their products. On the other, there is a need to ensure patients are not exposed to undue influence or misleading information, and that the importance of the doctor-patient relationship is not undermined disproportionately. The possible distinction between promotion and information therefore requires consideration.

As part of the "Pharmaceutical Package" of EU medicines legislation, in December 2008, the European Commission published a proposal to amend Directive 2001/83/EC to include provisions about what information can be provided to patients. In February this year, the Commission amended this proposal to attempt to address some of the concerns expressed about the original draft. However, while the other two strands of the Pharmaceutical Package - relating to falsified medicinal products and pharmacovigilance - have been finalised, after more than three years, the amendments relating to information to patients seem no closer to being agreed upon, let alone implemented.

Current European Framework

Under Directive 2001/83/EC, "advertising" includes a wide range of activities that are designed to promote the prescription, supply, sale or consumption of medicinal products. [See Endnote 2.] There is a general prohibition on advertising POMs to the general public, [see Endnote 3] although it is permissible to advertise non-POM products, such as over-the-counter pain relief medication.

There are exemptions to this general prohibition, which leave open the possibility of supplying some information on POMs to patients without it being seen as promotional. The definition of advertising under the Directive does not include, among other things: (i) factual, informative announcements and reference material, provided no product claims are made; or (ii) information relating to human health or diseases, provided there is no reference, even indirect, to medicinal products. [See Endnote 4.] Companies can therefore provide "information" to the public and healthcare professionals. This is most obviously seen in relation to healthcare professionals, in the summary of product characteristics (SmPC), and in relation to patients, in the patient information leaflet (PIL).

Problems with the definition

The legislation at both a European and national level contains extensive provisions relating to the advertising and promotion of medicinal products. However, there is little detail as to how the exception for factual information operates. This has led to some divergence between Member States, who are free to establish their own approach to establishing the boundary between advertising and information. This is particularly so because the definition of advertising focuses on a subjective assessment of the purpose of dissemination, rather than the nature of the information supplied. It is therefore a judgmental matter to identify what falls outside the definition. In addition, the exemptions to the definition are broadly worded and expressed in the negative: what will not be considered as advertising, rather than what will be considered as information.

In many countries, industry relies on Codes of Practice from the industry's self-regulatory bodies to provide guidance. However, again, these are not consistent across the EU. For example, in the UK, the Association of the British Pharmaceutical Industry (ABPI) Code of Practice [see Endnote 5] generally allows the provision of non-promotional information to the public through press releases in non-scientific journals, for example, on the launch of a product or key milestones in research. However, other Member States, such as Italy, are more restrictive and such publications are prohibited.

The Commission's Proposal (2008/0255(COD) and 2008/0256(COD))

This inconsistent interpretation led the European Commission to develop a proposal to regulate how pharmaceutical companies can provide information to patients. Under Directive 2001/83/EC, the Commission had an obligation to consult and present a report on current practices with regards to the provision of information; [see

Endnote 6] it appears that even in 2004 when this amendment was inserted, the European bodies were unable to reach agreement on suitable provisions relating to information. The Commission presented its findings in December 2007, [see Endnote 7] and confirmed that Directive 2001/83/EC does not provide sufficiently harmonised rules for the provision of information about POMs to patients. It stated that there are a variety of approaches and understandings between Member States, and the information provided by authorities varies considerably, which "*results in unequal access of patients, and the public at large, to information on medicinal products*".

In December 2008, the Commission published a proposal on the provision of information to patients (the Proposal). [See Endnote 8.] This proposed a draft Directive amending Directive 2001/83/EC to exclude "*information by the marketing authorisation holder to the general public on medicinal products subject to medicinal prescription....*" from the definition of advertising, while maintaining the prohibition on direct-to-consumer advertising. The Proposal applied to POMs only, and parallel amendments would be made to Regulation 726/2004/EC [see Endnote 9] to refer to the new provisions in Directive 2001/83/EC.

Action since the Proposal

The Proposal has been controversial due to the general suspicion, held by many in the European Parliament of the intentions of the pharmaceutical industry. There is an assumption that industry will use any provisions allowing information to be provided to the public as a method of direct-to-consumer advertising. The fear of a move towards direct-to-consumer advertising of the type allowed in the USA is acute, and is in part based on a concern that this will put added pressure on healthcare budgets in countries which predominantly operate state funded healthcare arrangements. Questions are also raised over whether the pharmaceutical industry is best placed to provide information to patients, as many think there is an inherent conflict of interests. The table below sets out a timetable of the legislative proposal, and indicates the long delays between the various stages:

Date	Event	Reference
10 December 2008	Legislative proposal published by the Commission	COM(2008)0663 (Dir.) COM(2008)0662 (Reg.)
10 June 2009	Economic and Social Committee opinion	CES1022/2009
30 November 2009	Debate in Council	
28 September 2010	Vote in committee, 1st reading	
19 October 2010	Committee report tabled, 1st reading	A7-0290/2010 (Dir.) A7-0289/2010 (Reg.)
22 November 2010	Debate in Parliament	
24 November 2010	Decision by Parliament, 1st reading	T7-0429/2010 (Dir.) T7-0430/2010 (Reg.)
6 December 2010 and 30 May 2011	Debate in Council	
11 October 2011	Modified legislative proposal published by the Commission	COM(2011)0633 (Dir.) COM(2011)0632 (Reg.)
10 February 2012	Amended legislative proposal published by the Commission	COM(2012)0048 (Dir.) COM(2012)0049 (Reg.)
22 February 2012	Economic and Social Committee opinion	CES0809/2012

The Economic and Social Committee provided its comments in June 2009, although it did not propose amendments on the Proposal. Instead, it highlighted key concerns that should be addressed before the Proposal proceeded. [See Endnote 10.] The most recent Committee opinion simply refers back to that original opinion. The European Parliament provided its comments in November 2010. [See Endnote 11.] Like many other respondents, they were concerned to maintain the ban on direct-to-consumer advertising. However, they ultimately agreed that there needed to be a clear distinction between information and advertising. In addition, the European Parliament suggested that pharmaceutical companies should have an *obligation* to provide certain information, and that there should be pre-vetting of materials by the competent authorities.

The Amended Proposal, February 2012

In October 2011, the Commission published a second draft of the Proposal taking into account the Parliament's comments. [See Endnote 12.] The amended Proposal also contained proposed amendments in relation to pharmacovigilance and drug safety, but the Commission has since removed the pharmacovigilance proposals so that those amendments could be pursued more quickly. [See Endnote 13.] In February 2012, [see Endnote 14] an updated amended Proposal was published, which removed the pharmacovigilance provisions, but otherwise kept the proposals as in the October 2011 draft. Again, similar amendments were suggested in relation to Regulation 726/2004/EC.

The Amended Proposal

The amended Proposal aims to clarify the line between information and advertising, and to provide a clear definition of what constitutes information. The Commission, in part, seeks to define advertising by reference to information proactively "pushed" to patients, and contrasts information provided in response to a "pull" from the patient, for instance, through active inquiry. The current "negative" exemption to the definition of advertising relating to factual, informative announcements has been deleted, and instead, there are positive provisions based on what information can be provided in a new Title VIIIa: "*Information to the general public on medicinal products subject to medical prescription*". The exemptions to the definition of advertising now include only clearly defined items, such as information for investors (provided the restrictions concerning information to the general public are complied with if individual products are mentioned) and information relating to human health and diseases (provided there is no references, even indirect, to individual medicinal products).

In particular, the amended Proposal provides that:

1. Only certain information on POMs is allowed to be made available to the general public, some of which must be made available, and some of which is voluntary.
2. Information is only allowed to be made available through limited channels of communication.
3. The information must fulfil recognised quality criteria.
4. Information which has not been previously approved must be verified by competent authorities prior to being made available.

The following paragraphs explain the main provisions in more detail:

i. Who can make information available?

The focus of the amended Proposal is on information provided by marketing authorisation holders; the recitals state that national competent authorities and healthcare professionals should remain

the main sources of information for the public. It is important to note that, for the purposes of the amended Proposal, marketing authorisation holders include third parties acting on their behalf or following their instructions. [See Endnote 15.] When information is made available by such third parties, any financial or other benefits received from the marketing authorisation holder must be declared.

ii. What information can and must be made available?

The amended Proposal sets out certain information that *must be* made available by the marketing authorisation holder [see Endnote 16] (such as the most recent versions of the SmPC, labelling and PIL and assessment report, as approved by the competent authorities), and certain information that *may be* made available to the general public [see Endnote 17] (such as information on the environmental impact of the medicine (i.e. disposal and collection systems), prices, pack changes, instructions for use, pharmaceutical and preclinical tests and clinical trials). Patients, therefore, have the right to have access to a minimum amount of information. Voluntary information can also include summaries of frequently submitted requests for information and answers to those requests, and other types of information relevant to support the proper use of the medicine.

Any information made available by marketing authorisation holders must meet certain quality criteria, including that the information is objective and unbiased (i.e. including risks, as well as benefits), is patient-oriented so as to meet adequately the needs and expectations of patients, is based on evidence, is legible, up-to-date, factually correct and not misleading. Further, information must clearly identify the source, including the author and references, and, perhaps most importantly, must not contradict the SmPC, labelling and PIL. [See Endnote 18.]

The amended Proposal also outlines certain statements that must be included with the information, such as that the product is a POM, that the information is intended to support, and not replace, the patient's relationship with his doctor, and that a healthcare professional should be contacted for more information. [See Endnote 19.] Further, certain information is prohibited, including comparisons and the information currently included in Article 90 of Directive 2001/83/EC (for example, the information should not suggest that the effects of taking the medicine are guaranteed, unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product). [See Endnote 20.] Implementing acts will be adopted explaining how these quality provisions will operate, and also to provide additional guidance on the information that may be made available in accordance with these provisions. [See Endnote 21.]

iii. Where can information be made available?

The amended Proposal prescribes the media that can be used to make information available: (i) through printed materials made available on request or through healthcare professionals; (ii) through Internet websites on medicinal products; and (iii) in written answers to specific requests for information about a medicinal product. [See Endnote 22.] The focus is on patients "pulling" information from defined sources, rather than companies "pushing" it, and the provisions explicitly exclude unsolicited material actively distributed. In addition, information cannot be made available via the television, radio or printed media.

Competent authorities must also ensure that marketing authorisation holders include the mandatory information to be provided (such as the SmPC etc.) on their websites. [See Endnote 23.] Arguably, package information should therefore provide the website address where this information is available, although this is not specifically dealt with in the amended Proposal. Such websites should be registered with a national competent authority (or the European Medicines Agency (EMA) for centralised products), usually in the country of the top level domain for the website (i.e. the UK for .co.uk websites). Marketing authorisation holders should include a statement that the website has been registered and is subject to monitoring by the relevant authority, and should not contain links to other marketing authorisation holders' websites, unless they are also registered (which should be clear from that website).

iv. How is information monitored?

As a general rule, information should be approved by the competent authorities (or the EMA under the procedures to be inserted into Regulation 726/2004/EC) before it is made available. [See Endnote 24.] There is also a general oversight role for the EMA, whereby Member States can inform the EMA if they believe that information provided in another Member State does not comply with the requirements. [See Endnote 25.] It is interesting to note that the European Parliament deleted the original proposal that Member States could adopt a self-regulatory scheme or co-regulatory bodies, which was favoured in some Member States both to reduce costs and the administrative burden on the competent authorities, and to fit into already established self-regulatory schemes.

The competent authorities will not need to specifically approve all documents that are published. The information that must be made available (such as the SmPC etc.) has already been approved at the time of authorisation (or variation), and no re-approval is required before it is made available to the general public.

In addition, the amended Proposal recognises that in certain Member States (such as Sweden and Denmark), there are strict rules prohibiting the pre-approval of published materials, which is considered to be a limitation on free expression and freedom of the press (an issue arises as to whether similar considerations apply, in any event, under the Convention on Human Rights with which all Member States are expected to comply. This allows freedom of commercial expression to be restricted on grounds of protection of public health, but only to the extent that the restriction is proportionate). Member States can therefore rely on other mechanisms of monitoring information, such as raising concerns after the information has been made available, provided that such mechanisms ensure a level of adequate and effective control equivalent to the approval mentioned above. The Commission has stated in its explanatory memorandum to the amended Proposal that it will enter into dialogue with Member States concerned about pre-approval in order to find suitable solutions that comply with the Directive.

In relation to websites, the competent authority where the website is registered is under an obligation to monitor the website and ensure that the information contained on it meets the requirements set out above. [See Endnote 26.] After registration of a website, the information contained on it can be published on other websites within the EU that provide information on medicinal products and that are operated by the marketing authorisation holder. In addition, Member States cannot generally prohibit the reproduction of information contained on a website registered in another Member State, although some comments can be made, such as about translation. Marketing authorisation holders will not, therefore, be required to obtain approval in every Member State for information provided on its website.

In order to assist this monitoring, marketing authorisation holders should also keep copies of all information and other relevant information (such as to whom the information was addressed, the method of communication, and date etc.) for the competent authorities, and assist competent authorities, as and when requested to do so. [See Endnote 27.]

v. What sanctions can be imposed?

The Proposal states that Member States should put in place "*adequate and effective measures*" to sanction non-compliance with the Directive. [See Endnote 28.] These should include financial penalties, cessation and prohibition orders, and the possibility of publishing the name of offending marketing authorisation holders. However, there is also a provision whereby marketing authorisation holders are entitled to be represented and heard when they are accused of non-compliance, and there is an express right of appeal against any decisions as to non-compliance.

Next Steps

The amended Proposal is subject to the ordinary legislative procedure (previously the co-decision procedure) by the European Parliament and Council. An examination of the amended text is scheduled for June 2012, although this may be delayed. However, there have been suggestions that the Proposal may not progress any further due to the continued controversy and concerns surrounding the provision of information by pharmaceutical companies directly to the public. There certainly does not seem to be any particular urgency in trying to reach agreement on the Proposal.

Implications of the Proposal

Given the caution expressed by many over the Proposal, there are concerns that the current draft does not actually address all the problems experienced with the current regime. Most importantly, it is unclear whether patients will in fact benefit from the amended Proposal. While there are clear categories of documents that may now be provided as information, in practice, it is likely that many of the same problems will arise in relation to specific publications. In particular, as materials have to be pre-approved by the competent authorities, the potential remains for inconsistency between Member States in relation to the interpretation of these provisions. In addition, the introduction of a regulatory role at European level could lead to conflicts between the European institutions and the national agencies and courts, as control over medicines advertising is currently a matter of national competence.

Further, a pre-approval system will create a real challenge in terms of workload for the current European and national institutions, in particular for the EMA. A blanket approach to vetting non-promotional materials would be disproportionate to the risk of dissemination of non-compliant information, and will create delays in the process. In any event, the provisions in the amended Proposal will lead to increased costs, particularly in relation to competent authorities monitoring websites and information to be made available to the public. In reality, any increase in costs will, at least in part, be passed on to industry through increased fees.

As the amended Proposal only addresses information provided by marketing authorisation holders, there is still a question surrounding how information from other sources should be dealt with. The amended Proposal does not address the numerous websites that contain information on medicinal products, both positive and negative, or information from other jurisdictions where direct-to-consumer advertising is possible (such as the USA). Arguably, it is this information that causes the most harm to patients as they research possible treatment options. The amended Proposal does nothing to address or limit such publications, and it is clearly very difficult, if not impossible, to control.

Due to the controversy surrounding the Proposal, the amendments also do not go far enough to address the type of information patients actually want to receive. For example, as part of the quality criteria set out in the amended Proposal, information must not contradict the SmPC and product information. In reality, many patients require information that goes beyond the SmPC, but that is consistent with it, such as the optimum area of injection, general information about compliance or emergencies, and how to identify related problems. There has been a recent case before the European Courts - *Novo Nordisk AS v Ravimiamet* [see Endnote 29] - about information provided to healthcare professionals that concerned information that went further than the information in the SmPC. The Court said that marketing authorisation holders could provide information to healthcare professionals that supplemented the information in the SmPC, provided it was compatible with it. However, one of the factors in this decision was the greater scientific knowledge of healthcare professionals compared to the general public. It therefore remains to be seen whether marketing authorisation holders will be able to provide information that goes beyond the SmPC to patients.

The amended Proposal also focuses on information about products that have been granted a marketing authorisation. In practice, many patients are interested in accessing information on unlicensed medicines and about clinical trials. The Directive does not directly cover products under trial, but the amended Proposal allows for information on pre-clinical tests and clinical trials to be provided as voluntary information, which must be pre-approved. However, the fact that the amended Proposal has deleted the previous exceptions for "*factual, informative announcements and reference materials*", could be interpreted as meaning that information about unlicensed products is no longer permitted. It is likely that the Codes of Practice in individual Member States will address such information, but it is also likely that the confusion - and inconsistency - currently surrounding such information will remain. In practice, this change in emphasis will have a larger impact on Member States that currently takes a pragmatic view on what information can be provided, such as the UK that allows information on products in development to be made available provided it is strictly non-promotional, compared to other countries that take a more restrictive approach.

In the Meantime...

There has been some case law in recent years about the role pharmaceutical companies can play in providing information to patients and healthcare professionals. These cases, in addition to the case of *Novo Nordisk AS v Ravimiamet* discussed above, provide useful guidance to companies while the European institutions are debating the amended Proposal:

i. Criminal proceedings against Frede Damgaard [see Endnote 30]

This case involved a journalist who was promoting an unlicensed product contrary to the advertising rules. The European Court ruled that the concept of advertising includes activities for both commercial and non-commercial purposes, because the reasoning behind the provision is the protection of public health. Therefore, third parties who are independent of the marketing authorisation holder, are also subject to the rules on advertising.

The key fact (as stated by the Advocate General, although his analysis was not explicitly endorsed by the Court) is the party's "*deliberate and direct intention*". It is then up to Member States to determine if a particular publication is advertising given the circumstances of the particular case. The amended Proposal states that: "*Third parties, such as patients and patients' organisations or the press, should be able to express their views on POMs, and should therefore not be covered by the provisions of this Directive, providing that they are acting independently form the marketing*

authorisation holder, when making available information, third parties should declare any financial or other benefits received from marketing authorisation companies". [See Endnote 31.]

This arguably means that this case now has less relevance. However, third parties would be wise to consider this judgment before publishing information on medicinal products, particularly if they have received any previous support from the pharmaceutical company.

ii. R (on the application of ABPI) v MHRA [see Endnote 32]

This case involved a prescribing incentive scheme operated by Primary Care Trusts in the UK, in which doctors were being paid to prescribe cheaper generic rather than branded medicines. The UK competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA), questioned the legality of this scheme and the legality of paying "inducements" to prescribe that are banned by the provisions on promotion in the Directive, but ultimately decided it was legal.

The Court agreed with the MHRA and disagreed with its own Advocate-General, saying that the *Damgaard* decision does not apply to information disseminated by public authorities. Public authority prescribing schemes are part of public health policy, and reflect the general economic pressures to produce costs savings. Such schemes cannot therefore be regarded as objectionable promotion of particular prescribing. The Court also stated that the risks to public health underlying *Damgaard* are not relevant to inducements by authorities because it is the task of authorities to supervise public health; doctors' objectivity is not compromised because of professional conduct rules; and in supervising the activities of doctors, the authorities can provide "recommendations" relating to prescription without prejudicing objectivity. Therefore, incentive schemes by the competent authorities are permissible and are not promotion under Directive 2001/83/EC.

iii. MSD Sharp & Dohme GmbH v Merckle GmbH [see Endnote 33]

This case clarified that pharmaceutical companies can make information on POMs available to the general public without it being considered as advertising, provided it has been approved in advance by the appropriate regulatory authority. Therefore, SmPCs, PILs and product packaging can be made available. This is in line with the currently accepted situation in many Member States, such as the UK, and is consistent with the amended Proposal. However, some Member States, such as Germany where this case originated, did not previously allow such information to be made available.

The Court stated that selected extracts or redrafting of such documents would not be acceptable if "*such manipulation of information can be explained only by an advertising purpose*". Arguably, if there was another justifiable reason for the redrafting, it may be acceptable, but this is a question for individual Member States on the facts. In particular, it may be hard to have such a justification if a particular text has been approved by the authorities. The purpose for which the information is made available is key, and the recipient and method of dissemination should also be considered. Interestingly, the Court stated that "pop-ups" may carry a presumption of advertising, compared to information which a patient has actively to identify and access; this is similar to the "push"/"pull" distinction in the amended Proposal.

Conclusion

The Commission's Proposal has prompted a debate and raised important questions since its first publication in December 2008. There is a certain amount of confusion under the current regime, and the Proposal goes some way to resolving this. However, the controversy underlying this Proposal is whether the pharmaceutical industry in general, and marketing authorisation holders in particular, are an appropriate source of information for the public on POMs. Stakeholders have conflicting views, and this Proposal would be a good opportunity to strike the correct balance between protecting patients from undue influence and empowering them with vital information.

However, the signs from the European institutions, including the splitting of the amended Proposal to remove the provisions on pharmacovigilance, suggest that there is no urgency in the mind of the Member States or the European institutions to pursue these amendments, certainly in the short term. The recent European Court judgments on advertising and the provision of information go some way to clarifying the dividing line between information and advertising. This will hopefully lead to less variation between Member States, particularly in relation to the ability to publish copies of key documents, such as the SmPC and PIL. However, the amended Proposal has created uncertainty for marketing authorisation holders over the last three years, and it is hoped that if the discussions do prove fruitless, the amended Proposal will be formally removed to avoid any further confusion.

Endnotes

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
2. See Reference 1, Article 86.
3. See Reference 1, Article 88.
4. See Reference 1, Article 86(2).
5. ABPI Code of Practice for the Pharmaceutical Industry, 2012.
6. See Reference 1, Article 88a.
7. Communication from the Commission to the European Parliament and the Council concerning the Report on Current Practice with regard to Provision of Information to Patients on Medicinal Products in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use, COM(2007) 862 final, 20 December 2007.
8. Proposal for a Directive amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM(2008) 663 final, 10 December 2008.
9. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
10. Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use, 2009/C 306/04, 10 June 2009.
11. European Parliament debate, P7-TA(2010)0429, 24 November 2010.
12. Amended proposal for a Directive of the European Parliament and of the Council Amending Directive 2001/83/EC, as regards information to the general public on medicinal products subject to medical prescription and as regards pharmacovigilance, COM(2011) 633 final, 11 October 2011.

13. Council of European Union press releases, 17943/11, 2 December 2011.
14. Amended proposal for a Directive of the European Parliament and of the Council Amending Directive 2001/83/EC, as regards information to the general public on medicinal products subject to medical prescription and as regards pharmacovigilance, COM(2012) 48 final, 10 February 2012.
15. See Reference 1, Article 86 (as amended by the Proposal), and new provisions to be added to Directive 2001/83/EC, Article 100a.
16. New provisions to be added to Directive 2001/83/EC, Article 100b(1).
17. New provisions to be added to Directive 2001/83/EC, Article 100b(2).
18. New provisions to be added to Directive 2001/83/EC, Article 100d(1).
19. New provisions to be added to Directive 2001/83/EC, Article 100d(2).
20. See Reference 1, Article 90 (as amended by the Proposal), and new provisions to be added to Directive 2001/83/EC, Article 100d(3).
21. New provisions to be added to Directive 2001/83/EC, Article 100d(4), 100g(3).
22. New provisions to be added to Directive 2001/83/EC, Article 100c.
23. New provisions to be added to Directive 2001/83/EC, Article 100e(1).
24. New provisions to be added to Directive 2001/83/EC, Article 100g.
25. New provision to be added to Regulation 726.2004/EC, Article 20c(3).
26. New provisions to be added to Directive 2001/83/EC, Article 100h.
27. New provisions to be added to Directive 2001/83/EC, Article 100j.
28. New provisions to be added to Directive 2001/83/EC, Article 100i.
29. Case C 249/09, *Novo Nordisk AS v Ravimiamet*, 5 May 2011.
30. Case C 421/07, *Criminal proceedings against Frede Damgaard*, 2 April 2009.
31. See Reference 14, Recital 9.
32. Case C 62/09, *R (on the application of ABPI) v MHRA*, 22 April 2010.
33. Case C 316/09, *MSD Sharp & Dohme GmbH v Merckle GmbH*, 5 May 2011.

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Ms. Valverde has extensive experience advising international pharmaceutical companies on EU and UK regulatory matters, handling issues which arise throughout the life cycle of the product, including research, manufacture, licensing, supply and promotion.

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