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Country Question and Answer Chapters:

Providing Information to Patients in the EU: Where Are We Now?

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Patients like to be part of their healthcare decision-making, wanting information on the medication they are taking, and the choices available to them. However, they often find it difficult to identify reliable sources. Further, pharmaceutical companies, who know most about the medicines on the market, are severely restricted in what information they can provide to patients. This has led to many, including the European Commission, believing it is necessary to improve the quality of information available to patients, and to allow companies to be a part of that process. But there is an inherent conflict: on the one hand, patients have the right to receive accurate and useful information, but on the other, they should not be exposed to undue influence or misleading information, and the importance of the doctor-patient relationship should be maintained. The perceived benefits and risks of companies providing information directly to patients underlines the need for clear rules and limits, ensuring objectivity of the information and avoiding any promotional character.

After the failure of various legislative proposals in 2008, the Commission is now focused on non-legislative options, via updated guidance and initiatives to increase and improve the quality of information available to patients. However, the focus of these initiatives is on *how* information is provided, rather than *what* information is available. As such, on their own, they arguably do little to address the concerns identified, or the needs of patients.

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. There is a general prohibition on advertising prescription-only medicines ("POM") to the general public,[i] although it is permissible to advertise non-POM products, such as over-the-counter pain relief medication.

There are exceptions to this prohibition, which allow pharmaceutical companies to supply information on POMs directly to patients without it being seen as promotional. In particular, the definition of advertising 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 to medicinal products. Companies can therefore provide "information" to the public and healthcare professionals ("HCP"). This is most obviously seen in the summary of product characteristics ("SmPC") directed at HCPs, and the patient information leaflet ("PIL") directed at patients; these documents can be, and in some countries are encouraged to be, posted on company websites. Companies can also respond to questions from HCPs and patients, provided the information is factual and non-promotional, and is limited to that necessary to respond to the request.

Although there are guidelines on how an applicant should prepare the SmPC and PIL,[ii] there is little guidance to what information may be proactively provided outside of these documents. The line between what is advertising, and what is information, is often hard to draw and will be fact-specific depending on the nature of the product, how it is used, and the details of how, why and what particular information is provided. This has led to divergent interpretation and application across the EU. Furthermore, the self-regulatory guidance produced by industry bodies at national level is not consistent between Member States. This does little to provide equal access to information, and leads to the risk of unreliable, and even illegal, sources of information being publicly available.

Commission's Proposal to Amend Directive 2001/83/EC

To address these concerns, in December 2008 the European Commission published a proposal to amend the Directive[iii] as part of the "Pharmaceutical Package" of proposals to update the EU medicines legislation. This suggested removing "*information by the marketing authorisation holder to the general public on medicinal products subject to medical prescription...*" from the definition of advertising, while maintaining the prohibition on direct-to-consumer ("DTC") advertising. This would mean companies could provide information about medicines to patients, rather than simply general information about diseases. However, the proposal was controversial from the outset, largely due to an inherent mistrust of the motivations of the pharmaceutical industry in providing this information, and a lack of clear demarcation between information and advertising. Denmark, Sweden and the UK supported the Commission's proposal, whereas other Member States opposed any move to loosen the limits on the provision of information on POMs by companies. As a result, the proposal was opposed by the Council, and dropped by the Commission, ultimately being withdrawn in May 2014.[iv]

A second part of the "Pharmaceutical Package" related to pharmacovigilance.[v] This proposed the introduction of new sections to the SmPC and PIL setting out "key information". This was aimed at allowing patients and HCPs to rapidly identify key safety messages, balanced with information on the benefits of medicines. This proposal, however, was not included in the legislation adopted in 2010;[vi] the Commission wanted to assess the added value of such a section before codifying it into legislation.

Commission Report: Recommendations

With seemingly little appetite for legislative intervention to improve the information available to patients, the Commission has taken a new approach to solving the perceived problems within the constraints of the existing law and guidance.

On 22 March 2017, the Commission adopted a report in accordance with Article 59(4) of the Directive, assessing the current shortcomings in the SmPC and PIL, and how they could be improved to better meet the needs of patients and HCPs (the "Report").[vii] To support the Report, two studies were carried out to provide input from a range of stakeholders, including patients, HCPs, the pharmaceutical industry, and regulatory officers: (i) the *PIL-S Study*,[viii] which analysed the shortcomings of PILs and SmPCs as a source of information for HCPs and the public, the potential consequences of these shortcomings on the health of patients, and made recommendations to improve both documents; and (ii) the *PILS-BOX Study*,[ix] which assessed the feasibility and value of a possible "key information" section in PILs and SmPCs, the feasibility of introducing such a tool in the context of the EU legislation, and the potential cost/efficacy of adding such a section.

The Report produced a set of six outcomes and recommendations. It is anticipated that these will be implemented through the improvement of existing regulatory guidelines, templates, and other non-legislative means.

- *Room for improvement of the PIL*: In general, few issues were identified with the SmPC, with HCPs finding them to be of reasonable quality and containing valuable information. As such, the Report recommended focusing on improving the PIL, but noted that companies should also consider whether it is appropriate to make any related changes to the SmPC, as the two documents are inherently linked.
- *Amendments to guidelines*: The Report noted that patient comprehension of PILs could be improved, and made recommendations in relation to font size, line spacing and the overall length of the leaflet. The Report also identified language-related issues, particularly where lay language, introduced during user-testing, had been literally translated. The Report recommended that, in order for information to comply with the legislative requirements on legibility,[x] and to ensure that it is "clear and understandable",[xi] the Readability Guideline[xii] and Packaging Information Guideline[xiii] could be improved to include principles of good information design, whereby content and layout are considered jointly. The Report noted that the Quality Review of Documents ("QRD")[xiv] templates are too restrictive and should be amended so there is more flexibility to adapt the PIL to specificities of each product, while respecting the limits of the legislation. Further, any amendments should take into account the needs of specific groups of patients, including the young and the elderly, and those with mental illnesses.
- *Improving patient input in developing and testing PILs*: The Report recognised the benefit of user-testing, recommending that this is further improved by making the process more iterative, and ensuring that a well-advanced version of the PIL is used. The Commission envisages that user-testing will occur in parallel with the marketing authorisation process in order to avoid delay of the procedure, and will focus on the content of the leaflet to ensure it is well understood by patients.
- *Promotion and exchanges of best practice*: To assist pharmaceutical companies in developing PILs, the Report recommended that regulators make available and promote good, user-tested examples of PILs. These examples should include not only the finished product, but also information on the development process.
- *Electronic SmPCs and PILs*: In view of the increased access HCPs and patients have to electronic media, the Report considered the benefits of using this to provide information to the public. However, further exploratory work should be undertaken to develop key principles on how to use this technology within the scope of the legislation. The Commission does not envisage that electronic versions of the PIL would replace paper versions, but instead be complementary to the paper format to ensure full availability of information.
- *"Key information" section in SmPCs and PILs*: The Report considered whether there would be any benefit in including a "key information" section within the PIL. However, it concluded that more evidence needs to be gathered on the potential usefulness of this feature, for example, through user-testing. In particular, further information needs to be sought on the format and positioning of the section, the amount of information that should be included, and whether the use of this sort of tool truly leads to a more informed (and therefore safe and effective) use of medicines.

The PIL-S and PILS BOX studies, and the resulting Report, are a first attempt at developing a full picture of the issues around the communication of patient information. However, this research seems to focus on good information design, rather than the information patients should be receiving. Other initiatives, which are not covered by the Report, are more focused on practical patient-centric education. For example, the European Patients' Academy ("EUPATI") is a pan-EU Innovative Medicines Initiative made up of patient organisations, pharmaceutical companies and universities, focusing on the education and training of patients in the research and development of medicines. This project included improving the availability of objective, reliable, patient-friendly information.[xv] In particular, EUPATI established a robust content production, review, and approval process for materials provided to patients, which involved a wide variety of stakeholders. The Report also fails to mention the work done by DG Connect through its eHealth initiatives,[xvi] which aim to enhance the flow of information to patients by taking advantage of new technologies. Through the development of technical standards, this initiative aims to help maximise compatibility, interoperability, safety, repeatability and quality of data.

As such, even if the recommendations from the Report are implemented in full, this fragmented approach to the development of information to patients, and the absence of legislative proposals, may continue to hamper a cohesive and effective attempt to improve the information a patient receives.

Response to the Report

While the Report makes a number of recommendations, it does not provide any concrete action that companies or authorities should take. That said, a number of initiatives have recently come about, both from regulators and industry bodies.

European Medicines Agency

The European Medicines Agency ("EMA") has published an Action Plan[xvii] that seeks to improve the information patients receive about their medication, and that will follow the Commission's recommendations. To improve the readability of PILs, the EMA plans to review the Readability Guideline, the SmPC Guideline and the QRD templates. It also plans to develop new guidance on translations. Iterative user-testing will be designed, and the EMA intends to put in place a process for reimbursing patients who enrol in the user-testing process. It also supports the use of electronic

SmPCs and PILs, and plans to map current initiatives and develop key principles for using electronic versions. Finally, the EMA intends to implement pilot testing of a "key information" section in the European Public Assessment Report ("EPAR") summaries.

The EMA has taken a number of steps to further this Action Plan. In March this year, it was reported that the EMA and the Commission plan to organise a multi-stakeholder workshop in the fourth quarter of 2018, to develop key principles on the use of electronic formats.[xviii] The EMA has started a multi-stakeholder mapping exercise to ensure a comprehensive overview of all ongoing initiatives is available at the workshop.[xix] The EMA is also drafting "key principles on the use of electronic product information" for public consultation. The EMA does, however, acknowledge that its proposed actions are likely to require relevant expertise, time and resources. Taking into account the impending administrative burden of Brexit and the relocation of the EMA, the timelines set out in the Action Plan are likely to be delayed.

In addition, the EMA has conducted a number of other work streams aimed at improving transparency and information available, although not specifically aimed at patients. For example, the Benefit-Risk Methodology Project that ran from 2009–2012 sought to make the assessment of the benefits and risks of medicines more consistent, more transparent and easier to audit. In the context of PILs, it was thought that the information focuses too heavily on the risks of medicines without also setting out their benefits, and it is hoped that the outcome of the benefit-risk project could redress the balance. The EMA has stated that it hopes these approaches could be incorporated into the updated guidelines so that patients can also benefit from such advances.

National competent authorities

In the absence of a coordinated approach at EU-level, some Member States are taking their own steps to improve the information available to patients.

In the UK, the Medicines and Healthcare products Regulatory Agency ("MHRA") has, in general, taken a significant role in pressing for improvements at EU level, particularly to the PIL. For example, it was one of the first countries to introduce legislation relating to PILs (on a voluntary basis) in the Medicines Act 1968, before this was included in EU-wide legislation. More recently, the MHRA announced this year that, building on the success of simplified requirements on information to prescribers for over-the-counter products in 2014, it intends to develop proposals to extend this to POMs. Specifically, it has suggested (and in some cases required) using a "headline section" in PILs for certain products, intended to set out key safety and efficacy messages. The legal justification for this is article 62 of the Directive, which allows the inclusion of information that is useful for patients, consistent with the SmPC, and non-promotional in nature. According to the PILS-BOX study, this will be useful when considering whether, and if so how, a "key information" section should be introduced at EU level. Further, the MHRA has stated it is considering amending the UK legislation to make product information more complete and useful. Given Brexit, and the possibility to diverge from EU-wide legislation in the future, this may be an area that the MHRA seeks to further develop.

France has also taken a pro-active approach to improving information to patients. For example, the French National Agency of Medicine and Health Products Safety has, since October 2017, permitted companies to affix a QR (Quick Response) code to the primary or secondary packaging, or included in the PIL, which can be scanned through a specific mobile application that provides access to information about the medicinal product. Further, last December, the French Minister of Health set up a dedicated task force to issue recommendations on the best way to improve information to patients and, in particular, make such information more interactive. The task force intends to issue recommendation by the end of May 2018.

In other Member States, less definitive action has taken place to implement the Report. In Italy, no steps have been taken in relation to the improvement and simplification of the PIL specifically, but the Italian Medicines Agency has been working on the provision of electronic versions of the PIL. For instance, a recent change to the legislation[xx] provides that where there are changes to the package leaflet, the patient has the right to choose how to receive the updated leaflet, either in paper form or through alternative digital means, meaning both systems should be available. Similarly in Denmark, the Danish Medicines Agency and Ministry of Health are aware of the Report and are participating in the EU-wide discussions about whether the PIL can be provided electronically. However, no steps have been taken to implement the Commission's other recommendations. In Germany, there are no ongoing legislative initiatives regarding the improvement or simplification of the PIL, and the Federal Institute for Drugs and Medical Devices has not suggested that it intends to change the requirements regarding the design of the leaflet.

Industry associations

The EU industry body, the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), has responded positively to the Report and its recommendations. In particular, it welcomes the use of electronic formats for both PILs and SmPCs. However, it "strongly" opposes the Comission's and EMA's plan to introduce a "key information" section in PILs. Its main concern is that, taking into account the differing needs of patients, a "key information" section may lead to liability issues if patients only read the summary section. On the other hand, it does not oppose the EMA's plan to introduce a "key information" section in the EPAR,[xxi] presumably because this is a more comprehensive document, setting out greater detail for HCPs, compared to the summary information in PILs.

A joint industry task force also commented on the Report,[xxii] supporting the recommendations. However, the task force's analysis suggests that the recommendations could be "more ambitious and innovative". It believes the development of electronic PILs should be "given highest priority", recognising the flexibility this could give patients, but notes the need to distinguish between different patient settings, such as hospital-only products where electronic information is already routinely used.

The task force's analysis also highlights the issues that will not be so easy to address. For example, the Report suggests that font size and line spacing should be increased. However, this will inevitably increase the overall length of the PIL, and so a wider interpretation of the legislation would need to be permitted. A knock-on effect will also be the increased pack size necessary to contain the longer PIL, which will have cost implications. In addition, industry groups are concerned that, despite the Commission's assurances to the contrary, additional user-testing could cause delays to the marketing authorisation and variation timelines, potentially delaying the provision of up-to-date safety information to patients. Similarly, the task force agrees that the introduction of a "key information" section is premature, and agrees with EFPIA's concerns about patients focusing on this section only and the corresponding liability issues.

Overall, the view from the industry has been that the Report does not go far enough, as it focuses on the format of the information, while disregarding some of the more patient-focused initiatives that are also being worked on.

Guidance from the USA?

The position in the USA is obviously very different from the EU, as DTC advertising of POMs is permitted. How such information is provided in the US, and how it is received by patients, could prove a useful resource for the EU, notwithstanding the very different environments in which such information is provided.

In the US, regulators – most notably the federal Food and Drug Administration ("FDA") – have long focused on the comprehension of the risk and benefit information by patients and other individuals who lack technical scientific or clinical training. In particular, the FDA has the authority to bring enforcement action against a pharmaceutical company for failing to provide adequate directions for use, for failing to adequately disclose risk information or overstating efficacy information, or for engaging in communications that are otherwise untruthful or misleading. So-called "reminder ads" (that mention a product by name to increase recognition by patients and doctors, but do not make product claims and therefore are not required to be accompanied by complete risk and indication information) are prohibited for certain categories of higher risk products that carry FDA-directed "Boxed Warnings". DTC communications are generally held to a higher standard when the FDA evaluates whether content could be "false or misleading". Further, for certain medicines, the FDA requires the manufacturer to develop a more patient-friendly version of the Package Insert (known as a "Medication Guide") that must be approved by the FDA and conveys indication, dosing, and safety and efficacy information that the FDA feels is essential for safe and effective use of the product. The Medication Guide becomes part of the required "adequate directions for use" that must accompany most labelling and advertising materials, and be provided with the physical product in interstate commerce. Guidance relating to such Guides, and the effect of their implementation, may assist the EU with the development of the "key information" sections of the PIL.

The US plaintiff's bar also monitors DTC advertising and other communications closely – often to raise arguments during pharmaceutical tort litigation that the "learned intermediary" doctrine should not shield a manufacturer from liability for drug-related patient injuries stemming from alleged failures by the doctor to fully inform the patient of the potential for those injuries. How such an argument, or the provision of such information, would operate in the EU in the context of the Product Liability Directive[xxiii] is unclear.

The FDA has been actively engaged for several years in evaluating how industry communications affect patients. For example, the FDA's Office of Prescription Drug Promotion ("OPDP") has numerous ongoing and completed research projects on assessing "applied and theoretical issues" related to DTC advertising and other promotional communications for POMs.[xxiv] Last year, OPDP evaluated issues such as disclosure of additional risks in DTC television ads, and price information in DTC and HCP-directed advertisements. OPDP is currently examining, among other issues, the ability of consumers and HCPs to identify deceptive promotion, and how the promotional communications affects "attitudes and intentions toward the promoted drug". Such social science research reflects the FDA's interest in balancing its public health priorities with the interests of the regulated industry in disseminating information about their products, and the results may inform policy going forward. While the Trump Administration has expressed a willingness to review certain FDA regulations and enforcement policies to favour a less restrictive exchange of information between industry and HCPs, it remains to be seen whether there is interest in re-examining any of the current regulations governing DTC communications. Nevertheless, such research will likely be a useful resource for legislators and regulators in the EU seeking to improve the information available to patients.

Implications for the Future

Despite an apparent acceptance that patients in the EU could benefit from more information about the medicines they take, and that pharmaceutical companies may well be best placed to provide that information, the current Commission and EMA initiatives do little to increase the information available. They are instead focused on how the information is presented or accessed. Even the initiatives from some Member States do not go far enough to address the type of information patients actually want to receive. For example, the strict wording of the legislation, and the inconsistent national interpretation of it, remains, and any information provided must not contradict the SmPC. However, 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. The judgment of the Court of Justice in *Novo Nordisk AS v Ravimiamet*[xxv] – about information provided to HCPs that went further than the SmPC – acknowledged that marketing authorisation holders could provide information to HCPs that supplemented the information in the SmPC, provided it was compatible with it. However, there is still uncertainty and diversity about how exactly this should be interpreted. One of the factors in the Court's decision was the greater scientific knowledge of HCPs compared to the general public. It therefore remains to be seen whether marketing authorisation holders are able to provide information that goes beyond the SmPC to patients.

Procedures and research on the impact of such communications from the USA may assist EU regulators with decisions on how to loosen the restrictions in the EU. Given the resistance the Commission received to its original proposals in 2008, it seems unlikely that substantive changes will be introduced anytime soon.

Endnotes

i. Article 88, 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.

ii. *See*: Notice to Applicants Volume 2C: (i) Guideline on the Summary of Product Characteristics, September 2009 ("SmPC Guideline"); (ii) Notice to Applicants Volume 2C: Guideline on the Packaging Information of Medicinal Products for Human Uses Authorised the Union, December 2016 ("Packaging Information Guideline"); and Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use, 12 January 2009 ("Readability Guideline").

iii. 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.

iv. OJEU: Information and Notices C153; Volume 57, 21 May 2014.

v. Proposal for a Directive amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM (2008) 665 final, 10 December 2008.

vi. Directive 2010/84/EU and Regulation (EU) No 1235/2010.

vii. Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of 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. COM (2017) 135 final.

viii. *Study on the Package Leaflets and the Summaries of Product Characteristics of Medicinal Products for Human Use: PIL-S Study*. Nivel and the University of Leeds, July 2014.

ix. *Feasibility and value of a possible "key information section" in patient information leaflets and summaries of product characteristics of medicinal products for human use: The PILS-BOX study*. Nivel and the University of Leeds, July 2014.

x. Articles 59(3) and 63(2) of Directive 2001/83/EC.

xi. Article 63(2) of Directive 2001/83/EC.

xii. Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use, 12 January 2009.

xiii. Notice to Applicants Volume 2C: Guideline on the Packaging Information of Medicinal Products for Human Uses Authorised the Union, December 2016.

xiv. Notice to Applicants Volume 2C: Guideline on the Packaging Information of Medicinal Products for Human Uses Authorised the Union, December 2016.

xv. EUPATI Project Executive Summary: Closing Report of EUPATI 2012–2017, 8 June 2017.

xvi. EU Commission Leaflet: EU actions on eHealth, 7 September 2016.

xvii. EMA action plan related to the European Commission's recommendations on product information, 14 November 2017, EMA/680018/2017.

xviii. 80th meeting of the Pharmaceutical Committee, 8 March 2018.

xix. *See*: https://ec.europa.eu/eusurvey/runner/EPI.

xx. Law no. 124 of 4 August 2017.

xxi. Pink Sheet, *EFPIA welcomes EMA's electronic format plan for package leaflets but not 'key info' idea*, 17 November 2017.

xxii. AESGP, EFPIA and EGA Response to NIVEL Study Reports PIL-S and PIL-Box, January 2016.

xxiii. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

xxiv. Office of Prescription Drug Promotion Research, *available at* https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm.

xxv. Case C 249/09, *Novo Nordisk AS v Ravimiamet*, 5 May 2011.

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