Competition and Regulation in Dinamically Growing Sector of Life Sciences (From Volume Editors)

Articles

Marek Świerczyński, **Patent infringements on second medical use in the light of the reimbursement system**

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Summary: This paper relates to patent infringements on second medical use in the light of competition law and the reimbursement system. It is inspired by two recent rulings delivered by English and Dutch courts. They have considered whether the sale of generic drugs may be regarded as an infringement of a patent relating to a second medical use (not indicated on the labels) in situations where the facts of the case showed that these drugs have actually been used in a way covered by this patent (i.e. off-label use). In the light of these rulings, the main purpose of this paper is to answer the question whether it is appropriate, in the light of competition law, to limit the scope of the patent on second medical use in situations where drugs based on the substance are subject to reimbursement, in order to provide wider access to these drugs to patients.

Key words: invention, patent, medicinal products, reimbursement

JEL: K32

Joanna Wiszniewska, **Prohibition of pharmacy advertising – the origins and the evaluation of the regulation**

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III. Conclusions

Summary: The main purpose of this paper is to present the origin of the introduction of the prohibition of pharmacy advertising into the Polish legal system. The first part discusses the reasons why the partial prohibition of pharmacy advertising, related to reimbursed drugs, was implemented in 2007. The paper then focuses on the absolute prohibition of the advertising of pharmacies and their operations introduced in 2012, which constitutes the strictest regulation of such kind in Europe. This will give the opportunity to critically examine both the law and its implementation. In conclusion, the current initiatives to abolish the regulation will be presented.

Key words: pharmacy advertising, drug advertising
JEL: K23

Mikołaj Rajca, **Legal framework governing medicinal advertisement in the Internet – a critical analysis**

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Summary: Advertising medicinal products *en bloc* generates a great deal of heated debate among professionals of various scientific orientations. In spite of this fact, on 2 July 2016, the Polish Minister of Health issued an ordinance summoning a special committee with the objective of preparing certain recommendations and references concerning, among others, advertising of medicinal products, dietary supplements and medical devices. The following article is structured so as to critically asses and analyze the legal framework governing the advertisement of medicinal products, with emphasis on their on-line advertisement. Particular significance is placed on: 1) the issue of pharmaceutical spam, including a discussion of the dangers it poses and the possible responses it can face, including

those initiated by EU agencies (ENISA and EMA), and 2) the advertisement of medicinal products on social media (Web 2.0). The discussion provides an in-depth coverage of decisions issued by the Polish Chief Pharmacy Inspectorate (regulatory board; GIF) in relation to medicinal advertising (on-line) and features a brief summary of chosen foreign practices. The analysis also covers the issue of supervision over advertising medicinal products. In the course of the article, the author uses a formal-dogmatic assessment method, operated and supported by the legal theory of law in action, in order to close the article with conclusions and *de lege ferenda* postulates.
Key words: pharmaceutical advertising, medicinal advertisement, social media advertising, prevention of false advertising, the advertising ordinance, supervision over advertising of medicinal products, patients' rights, IT law
JEL: K23, K24, K32, I18

Zbigniew Więckowski, **Distance selling of medicinal products – national legislation**
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I. Introduction
II. Pharmaceutical Law Act
III. Ordinance of the Minister of Health of 26 March 2015 on mail-order sales of medicinal products
IV. Conclusions

Summary: The subject matter of this article concerns the question of distance selling of medicinal products considered from the perspective of national legislation. The author analyzes in detail the provisions of the Polish Pharmaceutical Law and the Ordinance of the Minister of Health of 26 March 2015 on mail-order sales of medicinal products in order to find the answer to the question why pharmacists show little interest in further developing this distribution channel for medicine. The author focuses also on the analysis of the provisions governing mail-order sales of medicines in terms of ensuring patient safety.
Key words: sale at a distance of medicinal products; mail-order sales of medicines; medicinal product; pharmaceutical law
JEL: K23, K32

Monika Chojecka, Adam Nowak, **Telemedicine against the background of Polish legal rules – opportunity or threat?**
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IV. Scope of the amendment
V. Assessment of the amendment
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Summary: Modern technology found in the diagnostic and treatment process of patients can be the future of medicine. This so-called "telemedicine" is also an important legislative issue. The article analyzes legal rules which are the cornerstone of this field in the Polish legal system. Special attention is placed on recent works devoted to the creation by the legislator of a new approach to

the legal framework for telemedicine. The paper also contains an assessment of the effectiveness of the functioning of these legal solutions.

Key words: telemedicine, health benefits, amendment
JEL: K10

Ewa Rutkowska, Barbara Trabszys, **Seller's liability for a hazardous product brought by him into Poland from another EU Member State – doubts arising from cases relating to medical devices**

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IV. Conclusion

Summary: The article presents the problem of the incompatibility of the manner of the implementation of the term 'importer' into Polish law with respect to the issue of liability for a hazardous product with the provisions of Directive 374/85, and the problems which arise as a result with regard to liability of sellers bringing a product into Poland from another EU Member State. The article provides a proposal for the interpretation of the term 'importer' under Article 449^5 § 2 of the Civil Code, until the necessary legislative change is made that would ensure the compliance of the Polish law with Directive 374/85.

Key words: hazardous product liability; liability for damage caused by a product; hazardous product; defective product; distributor; importer; seller; medical devices; Directive 374/85
JEL: K13, K20

Józef Haczyński, Zofia Skrzypczak, **Consequences of the new Reimbursement Act for patients and the public payer**

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I. Introduction
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III. NFZ (National Health Fund) spendings on the reimbursement of medicines
IV. Consequences of the law from the perspective of the purchasers of the medicine – macro- and microeconomic look

Summary: The Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices came into force on 1 January 2012. Its purpose was to transform the Polish medicine reimbursement so that the available public funds corresponded as closely as possible to the current social needs in the supply of refunded products. The consequence of the new reimbursement act – experienced painfully by patients - was a decrease in the share of reimbursement (and thus increase in patients' contribution) in the value of the purchased medicine on prescription (Rx).

Key words: Drug expenses, reimbursement, patients contribution
JEL: I11, I15

Legislation and Case Law Reviews

Magdalena Bąkowska, **Limitations of Internet sales of OTC veterinary medicinal products**

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    2. Regulations on mail-order sales
III. Interpretation of mail-order sales of veterinary medicinal products by the veterinary inspection and the courts
IV. Analysis of the correctness of currently binding law and its interpretation
V. Expected changes

Summary:

The article presents binding legal provisions on the retail distribution and mail-order sales of veterinary medicinal products, which are the basis of the interpretations used by the Polish veterinary inspection and administrative courts whereby Internet sales of OTC veterinary medicinal products are not allowed under Polish law. The paper presents the legal background of this issue in order to assess the correctness of existing jurisprudence in this case. Additionally, the article comments on the expected changes to existing law in this field drafted at the EU level.

Key words: medicinal products; veterinary medicinal products; retail sales; mail order sales of medicinal products; Internet sale of veterinary medicinal products

JEL: K23, K32

Jarosław Sroczyński, **Dispute about homeopathy (or who rules the market?)**

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I. Introduction
II. Background of the dispute
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IV. Meaning of the court rulings on homeopathy for competition law
V. Powers of the Supreme Doctors' Council
VI. Summary

Summary: The article discusses the effects of rulings issued by the Court of Competition and Consumer Protection (SOKiK) and the Court of Appeal concerning homeopathy upon the scope of the powers of medical self-government to regulate markets. The author provides an analysis of these powers on the basis of competition law, since the latter intersects with pharmaceutical law and laws regulating the professional activities of doctors. The author draws attention to the fact that depriving the competition authority – the UOKiK President – of the power to scrutinize the activities of professional self-government bodies may lead to adverse effects for competition and consumers protection. These would consist of the limitation of the freedom of market access of undertakings as well as limit consumers' free choice to access legally sold products and services.

Key words: prohibited agreements, competition, medical self-government, homeopathy, Supreme Doctors Council, OCCP, iKAR
JEL: K23, K24, K32

System of fixed prices for the sale of prescription-only medicinal products for human use by pharmacies as a measure having equivalent effect to a quantitative restriction on imports.
Case comment to the Judgment of the Court of Justice of the European Union of 19 October 2016 in case C-148/15: *Deutsche Parkinson Vereinigung eV* v. *Zentrale zur Bekämpfung unlauteren Wettbewerbs eV* (Tomasz Kaźmierczak)

Pay-for-delay agreements as "by object" violations of competition law.
Case comment to the Judgment of the General Court of 8 September 2016 in case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd* v. *European Commission* (Paulina Wosik)

Anti-competitive agreement between undertakings on the domestic market of *in-vitro* fertilization services.
Case comment to the decision of the President of the Office of Competition and Consumer Protection (UOKiK) No. RLO 4/2016 of 1 September 2016 (Emilia Kasjanowicz)

Books Reviews

R. Stankiewicza (ed.), *Instytucje rynku farmaceutycznego*, [*Institutions of the pharmaceutical market*], Wolters Kluwer, Warszawa 2016 (*Tadeusz Skoczny*)

Rafał Stankiewicz, *Krajowe systemy ochrony zdrowia a Unia Europejska. Przykład Polski* [*National healthcare systems vs. the European Union. The Polish example*] Wolters Kluwer, Warszawa 2016 (Mirosław Pawełczyk)

Event and Activity Reports

Report on the National Conference "Biological medicinal products. Legal aspects". Warszawa, 2 December 2016 (Natalia Łojko)