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Pharma Biotech 2018: Expensive drug costs, compulsory patent licensing and the limits to compounding by pharmacists

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Abstract

Of late, the cost of medicines is a recurring subject of debate in Europe and it is anticipated that this topic will be discussed more intensely in the years to come. In this regard, the application of compulsory patent licensing and the (wider) application of the compounding exemption (formula magistralis) are seriously investigated by the Dutch Minister of Medical Care as an instrument to curb the cost of medicines. In respect to the latter, a legislative proposal is underway which would exonerate pharmacists from patent infringement when compounding medicinal products for direct use for individual cases on medical prescription in pharmacies. This presentation explores in view of the applicable legislation and case law whether these solutions have been correctly identified as the solution to the problem of expensive medicinal products. Pursuant to e.g. the TRIPS Agreement, compulsory patent licensing in view of the general interest is (at least) to be used in combination with an adequate remuneration. Nevertheless, it is worthwhile mentioning that a compulsory license in the public interest was recently granted (and upheld in appeal) in Germany for the HIV drug Isentress. The available case law with respect to compounding and the rationale thereof has demonstrated that it is solely to be utilized as an exception to the rule, which makes it unsuitable as a general solution. Patients are not guaranteed for the same quality control as authorized medicinal products and therefore a proper substantiated justification for this deviation is required. Such justification may when comparing European case law probably not be sought in financial gain leaving aside the fact that this affects the level playing field. This presentation is very relevant for parties manufacturing or marketing high-cost medicinal products. Recent Publications 1. Later-Nijland (2018) Annotation to e.g. ECLI:NL:RBDHA:2017:12046 ???The Alimta cases??? (Patent infringement cases concerning Alimta) Jurisprudentie Geneesmiddelenrecht (???Case law Pharmaceutical law???), (Apr 6) 2018, Sdu [in Dutch] 2. Later-Nijland (2018) Annotation to ECLI:NL:RVS:2017:1175 ???The Biodent case??? (The Dutch Council of State rules that this caries protection product should be classified as both a medicinal product by presentation as well as a medicinal product by function) Jurisprudentie Geneesmiddelenrecht (???Case law Pharmaceutical law???), Apr, 2018, Sdu [in Dutch] 3. Later-Nijland H. (2016) Statutory prohibition inducements concerning medical devices upcoming, Life Sciences & recht, Jan 26, DeLex [in Dutch] 4. Nijland H M J, Ruslami R, Stalenhoef J E, Nelwan E J, Alisjahbana B, Nelwan R H, Ven A J A M van der, Danusantoso H, Aarnoutse R E and Crevel R van (2006) Exposure to rifampicin is strongly reduced in patients with tuberculosis and type 2 diabetes. Clinical Infectious Disease 43(7):848-854. 5. Nijland H M J, L'homme R F A, Rongen G A P J M, Uden P van, Crevel R van, Boeree M J, Aarnoutse R E, Koopmans P P and Burger D M (2008) High incidence of adverse events in healthy volunteers receiving rifampicin and adjusted doses of lopinavir/ritonavir. AIDS. 22(8):931-5.

Biography

Hanneke Later-Nijland is an Attorney-at-law at Axon Lawyers, Amsterdam, Netherlands. Moreover, she has been trained as a Pharmacist. Furthermore, she has completed her PhD in Clinical Pharmacokinetics and is a former Inspector for Clinical Trials and Pharmacovigilance at the Netherlands Inspectorate for Healthcare, IGZ. She specializes in European and national legal and regulatory issues relating to medicinal products. In her practice, she advises life sciences and healthcare clients and litigates on a wide range of issues, often with a regulatory focus. Her areas of expertise in the medicinal products field covers marketing authorizations, reimbursement, compliance, pharmacovigilance and advertising issues. In addition, she also assists clients with product liability issues and IP and regulatory issues in transactions in the life sciences sector. Furthermore, she is a Lecturer at Leiden University Medical Centre. She regularly publishes on new European legislation and the impact of recent judgments in the sector.

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