BOOK REVIEW: VISHV PRIYA KOHLI, *COUNTERFEIT AND FALSIFIED MEDICINES IN THE EU A LEGAL PERSPECTIVE*

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The global Covid-19 crisis has created an unprecedented demand for personal protection equipment (PPE), vaccines and medicines. This has provided a significant commercial opportunity for criminals who have flooded the market with substandard and counterfeit products.[1] However, the counterfeiting of medical products is not a new phenomenon. In the classical world, Dioscorides of Anazarbus, Galen, Pliny the Elder and Theophstratus all expressed concern with the falsification of medicines, with Dioscorides advising on the detection of counterfeits in his Materia Medica, written between 50-70 AD.[2] Reflecting more recent times, a 2015 article in the American Journal of Tropical Medicine and Hygiene had the title: 'Responding to the pandemic of falsified medicines'.[3] It surveyed the number of articles on 'fake drugs' cited in PubMed and reported 27 papers from 1966 to 1999, 56 papers from 2000 to 2004, 122 papers from 2005 to 2009, and 294 papers from 2010 to 2015.

Professor Vishv Priya Kohli looks at the legal aspects of the trade in counterfeit and falsified medicines in the EU.[4] As she indicates in the first chapter there are three bodies of law which can address this problem: medicines law, intellectual property law and criminal law, although there is not agreement between them as to the conduct to be proscribed. Medicines law is concerned with both substandard and counterfeit medicines, reflecting the World Health Organization's (WHO) approach to allow the supply, particularly to developing countries of unauthorised medicines which contain at least some active ingredient. Under intellectual property law a counterfeit medicine is one which carries an unauthorised trade mark. There is as yet no EU criminal law which

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[1] See Europol, *Viral Marketing - Counterfeits, Substandard Goods and Intellectual Property Crime in the Covid-19 Pandemic*, Europol, 2020.

[2] Referred to in S. Foster, 'A Brief History of Adulteration of Herbs, Spices and Botanical Drugs', (2011) no.92 *HerbalGram*, 42 at 44.

[3] G.M.L. Nayyar, et al, 'Responding to the pandemic of falsified medicines', (2015) 92 *Am. J. Trop. Med. Hyg.*, 113.

[4] Vishv Priya Kohli, *Counterfeit and falsified Medicines in the EU. A Legal Perspective* (Edward Elgar, 2021).

deals with counterfeiting, following the rejection on constitutional grounds of a proposed 'Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights'.[5] However, the Council of Europe's Convention on Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health came into force in January 2016 requiring each Party to take the necessary legislative and other measures to establish as offences under its domestic law, 'the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.'

In the second chapter the author explores three case studies which illustrates the various forms of medicine counterfeiting. The first, 'Operation Volcano', concerned the theft in 2014 of a number of batches of Herceptin, used for the treatment of breast and stomach cancers, together with other medicines, which were reintroduced into the supply chain after having been tampered with. This case study seeks to illustrate the use of the batch numbers of legitimate products as a disguise for counterfeits. This technique is more explicit in the second case study, 'Operation Singapore' which involved the sale of counterfeit Plaviz, Zyprexa and Casodex, used for the treatment of psychosis, heart disease and prostate cancer, respectively by three international collaborators. The Chinese collaborator obtained the counterfeits, the French collaborator packaged them as goods of French origin and a UK national facilitated the distribution of two million doses to British wholesalers. Illustrating the complexity of legal proceedings concerning medicine counterfeiting, investigations involved 12 countries and the accused were charged with: trade mark offences, fraudulent trading, conspiracy to money launder, marketing authorization offences and disqualified doctor offences. The Chinese national was sentenced to six and a half years imprisonment, whereas the other accused were cleared of any fraud. The third case study, 'Operation Robin', illustrated a number of the other features of medicine counterfeiting. First, the use of online sales;[6] secondly, the dispatch of products in small packages through the mail services;[7] thirdly, the dispatch of packages through numerous international

[5] 2005/0127/COD./

[6] See EUIPO, *Study on Legislative Measures Related to Online IPR Infringements*, Alicante, EUIPO, 2018.

[7] See OECD/EUIPO, *Misuse of Small Parcels for Trade in Counterfeit Goods: Facts and Trends*, Illicit Trade, Paris, OECD Publishing, 2018.

addresses;[8] and the mingling of medicine counterfeiting with narcotics offences.[9] This case resulted in two perpetrators receiving life sentences in Thailand, with 23 other accused receiving prison sentences of up to 16 years and the seizure of assets worth 70 million euros as well as falsified medicines and machines for making tablets.

These three case studies noted the importance of international collaboration in dealing with medicine counterfeiting, particularly because of the involvement of organized crime groups.[10]

The focus of the second half of the book is on how the EU has attempted to deal with this trade. Under the heading of Medicines Law, the author looks at the Falsified Medicines Directive of 2011.[11] This directive has a couple of limitations. First it deals only with falsified medicines entering the legal supply chain. It has nothing to say about the illegal supply chain. The term 'falsified medicine' includes any medicinal product with a false representation of identity, source or history of a product. This does not deal with medicines carrying branding which is deceptively similar to legitimate brands, but the Directive acknowledges the concurrent operation of intellectual property laws. The Directive also deals with safety features such as alphanumerical codes enabling the identification and authentication of individual packages and prohibitions on tampering with those codes. It would have been useful if the author could have given examples of the implementation of the Directive by EU Member States.

In the chapter dealing with the application by the EU of intellectual property law, the book discusses the Enforcement Directive[12] and the Customs Regulation.[13] Both of these are concerned with the civil enforcement of intellectual property rights, which are largely in the hands of rights holders such as trade mark proprietors. This is suitable in some instances of counterfeiting, but is often inappropriate where organized criminal groups are involved. This issue is picked up in the fifth chapter which looks at the application of the criminal law. In the absence of EU criminal legislation, the author is obliged to call in aid the Council of Europe's Medicrime Convention. This has been ratified by 12 European countries (Austria, Cyprus, Denmark, Finland, Germany,

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[8] See OECD/EUIPO, *Trade in Counterfeit Pharmaceutical Products*, Paris, OECD Publishing, 2020.
[9] Europol/EUIPO, IP Crime and its Link to Other Serious Crimes. Focus on Poly-Criminality, Alicante, EUIPO, 2020.
[10] See UNICRI, *Counterfeit medicines and organised crime*, Turin, UNICRI, 2012..
[11] Directive 2011/62/EU.
[12] Directive 2004/48/EC
[13] Regulation (EU) No. 608/2013

Iceland, Italy, Liechtenstein, Luxemburg, North Macedonia, Serbia and Slovenia) and by six non- members of the Council of Europe (Ecuador, Israel, Mali, Ivory Coast, Morocco and Niger) and has been signed by another 18 countries.[14] At an informal meeting on 29 January 2021 of the EU Ministers for Justice, a majority agreed that more efforts were needed to ensure that Member States ratified and implemented the Medicrime Convention 'as an important substantive and procedural law instrument for judicial cooperation in criminal matters.'[15]

In other words, despite the substantial adverse impacts of medicine counterfeiting, the EU has been unable to legislate in a comprehensive way to introduce criminal sanctions. Although a negotiating partner of the group of countries, including Australia and the USA which promulgated the Anti-Counterfeiting Trade Agreement (ACTA), which was designed to strengthen the criminal provisions of the World Trade Organization on Trade Related Aspects of Intellectual Property Rights (TRIPS), the EU refused to ratify ACTA, reflecting its reluctance on constitutional grounds to enact criminal laws.[16]

[14] https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=211,
[15] https://data.consilium.europa.eu/doc/document/ST-9287-2021-INIT/en/pdf.
[16] See M. Blakeney, *Intellectual Property Enforcement. A Commentary on the Anti-Counterfeiting Trade Agreement (ACTA)*, Cheltenham UK, Edward Elgar, 2012.