Another Anti-Counterfeiting Convention Emerges In Europe

By Monika Ermert for *Intellectual Property Watch* @ 12:57 pm

While the Anti-Counterfeiting Trade Agreement (ACTA) is getting a lot of attention with its draft consolidated version just published, there is another convention dealing with one major aspect it was always said ACTA would tackle. The Medicrime Convention of the Council of Europe sets the first international standard for criminalising the manufacturing and distribution of counterfeited medicine risking public health. And Medicrime will overtake ACTA, as the draft convention text is ready to be signed by the Committee of Ministers in May and be opened for signature in November.

"Medicrime is not overlapping with ACTA," said Kristian Bartholin, expert at the Council of Europe in Strasbourg, France, talking to Intellectual Property Watch after a meeting in Basel last week that started talks on the implementation of Medicrime.

"ACTA is regulating the market by protecting the regular supply chains against counterfeiting. Medicrime on the other hand does not try to regulate the market. It is about criminalisation of certain acts and related crimes," explained Bartholin with regard to the scope. "You can apply ACTA and Medicrime together; together you will get protection the whole way around."

Jan Kleijssen, director of the COE-Directorate for Standard Setting, in his keynote address to the Basel conference presented a case of an Argentinean victim of counterfeit medicine to illustrate what Medicrime is addressing. According to Kleijssen, 22-year-old Veronica Diaz from the Patagonian province of Rio Negro died from a falsified iron supplement she was given for treating her mild anemia. The false injection she got contained an iron derivative three times as high as the proper and legitimate ingredient (iron sorbitol) would have contained.

Though the Argentinean authorities succeeded in arresting and prosecuting some of the criminals responsible for the distribution of that counterfeit medicine, "the counterfeiters themselves were never found and brought to justice," said Kleijssen. It is high time to take action against "those cowardly criminals who are so willing to risk the lives of others for profit," he said. Counterfeiting is a "big business for shady entrepreneurs of organised crime." It is a multi-billion euro industry yet sanctions are still light internationally.

This is what Medicrime is expected to change, according to the authors at the Council of Europe (which is separate from and predates the European Union). Governments that sign the convention later this year commit to establish as offences "the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories (Article 5), "the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories" (Article 6) and also the "falsification of documents" (Article 7). Medicrime also covers falsified medical devices and aims to see "aiding, abetting and attempt" of the described acts criminalised.

There are also provisions describing corporate liability, jurisdictional issues, measures like seizures and destruction and sanctions. A special graph lays out how victims have to be protected. Victims, according to Medicrime, are natural persons suffering physical or psychological harm from the counterfeit medicine.

Medicrime's target is public health, it is not protecting intellectual property rights, explained Bartholin. While both agreements are talking about counterfeiting, "counterfeiting here means falsification," he said. There was consensus that IP rights were already protected and adequately covered and the convention therefore was "not going to offer additional protection here." What, on the other hand, was lacking was international regulation that addresses dangers to public health.

According to Medicrime, falsification of generic drugs also would be covered and so would the distribution of legal drugs on the black market like hormones sold without prescription to people who want to build up their muscles or enhance their performance. Also drugs brought to the market without undergoing existing controls would be covered, Bartholin said.

There is a similar initiative against falsified medicines at the World Health Organization (WHO), driven by the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), Holger Hestermeyer, a researcher at the Max Planck Institute for Comparative Public Law and International Law in Heidelberg, Germany, told *Intellectual Property Watch*. Yet at the WHO, concerns are that health issues are addressed via IP enforcement because of the use of the concept of "counterfeit." The researcher said it was surprising that Medicrime has not been much debated publicly or by nongovernmental organisations that had followed the IMPACT work closely.

Possible Overlap with Trademark Issues

On the substantive issues of the convention, Hestermeyer said that an overlap with the protection of trademark issues was still a possibility. "There is no problem with 'false representation with regard to identity'," he said. The trademark issue came in with the second definition for counterfeit which was 'false representation as regards source' where source should, according to the explanatory report to the convention, be understood in a "wide sense", as well as the term "counterfeit" itself which is used by the WTO with respect to trademark infringement.

Hestermeyer pointed out that both trademark infringement and selling a different substance as a medicine clearly should be illegal, but that they were of a different gravity and that the Medicrime convention seemed to mix the two using in its explanatory report the dramatic language that "counterfeiting of medical products and similar crimes violate the right to life." Why, asked Hestermeyer, would a package with the label 'aspirin' or even Bayer on it be dangerous if it contained acetylsalicylic acid? "It is a trademark violation, but can you label it as perilous?" he asked.

The one reason for including the trademark aspect could be that it would be made a "proxy". "It is much more difficult to investigate what is in it than to read what is printed on the package," he said. Implementing Medicrime also with respect to a closer look at trademark violations might thus indirectly lead to less falsified medicine.

On the overlap between ACTA and Medicrime one might draw one preliminary conclusion at least, ACTA is no longer necessary to address dangerous counterfeit medicine. Medicrime, driven by the ministries of health of the COE member and observer states, while prepared by a regional body will be open for everybody to join. And for a start, it has more partners than has the ACTA.

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