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Yann Bisiou

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Medical Cannabis : What Europe should do

*Disruptive activities are use to challenge Law.
If they can do it, they will do it ; and they can do it.*

Dr. Yann Bisiou
Assistant-Professor
CORHIS Lab, Université Paul Valéry Montpellier 3
yann.bisiou@univ-montp3.fr

A few weeks ago, the EMCDDA and Europol published a report on the drug markets in Europe. The 260 pages described the exhausting and fruitless War on Drugs, yet only lightly mentioned the legal trading of cannabis and its derivatives. A box and two sentences to explain the future necessity to “closely follow and evaluate the potential consequences and risks of the evolution of both trade and medical regulations happening on an international level, and in the Member States.” Although a large majority of European countries already allows the use of medical cannabis, and though “wellness” CBD trade is growing despite the obstacles, Europe miss the boat.

The EMCDDA isn't to blame for the silence. Given the lack of consensus, the Union's competences are limited and Europe failed to grasp the new stakes of therapeutic cannabis use. Today, a new competence is necessary for the European citizens's best interest (I), and to prevent Europe from getting overwhelmed by the international transformations of cannabis use, which has become the stowaway of Free Trade (II).

1. A new necessary competence

When it comes to the question of narcotic drugs and cannabis, the European Union only has one competence, far from complete. One example can easily illustrate this situation: out of the three Conventions of the United Nations concerning narcotics and psychotropics substances, the Union is a signatory for the most repressive one,

the 1988 convention, but not of the two previous ones that defined the notions of narcotics and psychotropics substances. All the European policies are therefore off balance, focused on the repression of trafficking, only lightly concerned with fighting the addictions and ignoring the new stakes of the progressive legalization of cannabis and its derivatives.

Yes, many European institutions intervene in the field of therapeutic cannabis or wellness CBD. Within the Commission, the Directorate-General Agriculture and Rural Development is in charge of the cultivation of cannabis light in THC, the Directorate-General Health and Food Safety handles the European catalogue of cultivated plants, the Directorate-General Internal Market, Industry, Entrepreneurship and PME deals with cosmetics and maintains the COSING database with the Scientific Committee on Consumer Safety, which recently allowed the use of the cannabis leaves for cosmetics. The European Environment Agency focuses on the botanical aspect of cannabis, The European Medicines Agency grants the Marketing Authorisation Applications and participates to the European Pharmacopoeia Commission of the European Council, the European Union Aviation Safety Agency is concerned with the consumption of cannabinoids by glider pilots, the European Food Safety Authority, controls the Novel Foods and is also concerned with the hypothetical presence of THC in milk and animal foods. Finally, the European External Action Service, like "Monsieur Jourdain" in Molière's *Le Bourgeois Gentilhomme*, takes care involuntarily of cannabis when it negotiates the commercial treaties of the Union.

For lack of political impulse, those multiple administrative competences create confused, disorganized results. The creation of the Horizontal Working Party on Drugs (HDG) supposed to "answer efficiently to the intersectoral nature of drug issues" within the Council remains insufficiently efficient, and the Member States' initiatives stay contradictory. The five tenders launched by the 5 countries that have already allowed the prescription of cannabis flowers only confirm those contradictions. None of the countries use the same status. In the Netherlands, medical cannabis was qualified as a "pharmaceutical product", Italy classified it in the category of "Various Medicinal products", Germany in "Medical equipments, pharmaceuticals and personal care products", and Luxembourg as "plants used in pharmacy" ! As for the Danish government, facetious, it considers that medical cannabis is... medical cannabis, *sui generis* category, invented for the occasion, avoiding the European tenders. The regulatory status of the cannabis flower is all but imprecise. For being considered in turn as a raw material, an active substance, a medical drug, and soon probably a medicinal plant, the flower is subjected to very different regulations from one Member State to another.

Same goes with pharmacopoeia, necessary step for every pharmaceutical product. While the European monograph of cannabis will not be published by the European Council before 2020, or even 2021, three Member States – Germany, Denmark and the Netherlands – published their own monographs, each with their own particularities. Patients, as well as health professionals, cannot see clear in this labyrinth which allows cannabis consumption for different cases depending on the country, and thus, concrete access to care becomes a real issue. Out of the 21 European countries authorizing the use of medical cannabis, only 7 make the products truly accessible.

2. Cannabis : the stowaway of Free Trade

For Europe to be able to guarantee the high level of health protection required by the founding treaties, cannabis has to be a part of the therapeutic panoply available to patients. It comes down to convincing the Member States of the necessity of a political frame for the administrative action of the European Union. The Member States believe they still master the status of therapeutic cannabis on their territories, yet it is no longer the case. Cannabis and its derivatives have become stowaways of European policies. They slithered their way in the big treaties of Free Trade, CETA, Economic Partnership Agreement with Japan (EPA), Free Trade Agreement with the Socialist Republic of Vietnam, without any thought being granted to the political consequences.

Let's take the example of the very publicized CETA. Narcotic drugs are technically part of the political and non-constraining agreement, adopted at the same time as the economic treaty. However, by becoming a medical product, sometimes a consumer product, cannabis and its derivatives become "Goods" subject to the treaty. From then on, all the dispositions of the CETA are applicable with consequences disregarded by the signatories. Thereby, the provision on national treatment requires the Canadian authorities to open the market of cannabis and its derivatives to European companies, when it is currently restricted to companies implanted in Canada. In Europe, government and EU tenders (especially the health ministries) above 162.500€ have to be open to Canadian companies for all "medical equipment and supplies" a category that includes medicinal cannabis. And, contrary to previously held beliefs, the rule of mutual recognition of the Good Manufacturing Practices (GMP) attached to the CETA, much more wider than the previous one, applies on the EU market, no matter the status given to the plant by the Member States. The Canadian companies thus can use their own GMP when exporting plants or cannabis flowers for medical treatments or therapeutic experimentations. Those are not rhetorical reflections. Yet CETA is only running provisionally into force. Some of key provisions like the arbitration court for investors are not yet implemented. Furthermore, the treaty, composed of tens of thousands of pages and

annexes, is particularly complex and devious, and many companies, and lawyers, are yet to understand its reach. But history shows that they are also prompt to use the rights they get from Free Trade agreements. The American DEA learned this lesson to its cost when the Canadian society KENEX challenged, within the frame of NAFTA, the American laws preventing the trade of products containing traces of THC. KENEX won before the national jurisdictions before the international arbitration court has rendered its decision. In Canada, Health Canada has to defend itself after being filed by Cen Biotech, an American cannabis producer, which asked for \$4,8 billions of allowances.

Many more judicial questions should arise shortly. The Free Trade Agreements allow for commercial restrictions justified by health requirements if they are founded on Scientific statements. What will be the States's answer when they'll deny the importance of therapeutic cannabis, while the scientific documentation confirms it? How will the European Union maintain its commercial constraints on CBD based products when the WHO affirms that nothing justifies that the substance falls under the international treaties on narcotics and psychotropics drugs?

The member States and European instances should keep in mind that disruptive economic players are used to defy the Law. If they can do it, they will do it. As for cannabis, they certainly can. Europe can bow in front of those changes, but it would be wiser, with the help of the Member States, to become an active contributor to the new economic sector that is medicinal cannabis and its derivatives without psychoactive effects, in the best interest of patients and citizens of the European Union.