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NOTE EQUIVALENT TO AN OPINION

DRUG ADDICTION

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2006 APRIL 27TH

NOTE EQUIVALENT TO AN OPINION ON THE CLASSIFICATION OF BUPRENORPHINE AS A NARCOTIC

Following the positive opinion issued by the National Commission on Narcotics and Psychotropics, the Interministerial Task Force Against Drugs and Drug Addiction (MILDT) requested that buprenorphine (Subutex®), currently listed as a venomous plant, be listed as a narcotic, in a process independent from any public health undertaking. The request for reclassification came in response to the Minister of the Interior's desire that measures be taken to combat misuse and drug trafficking.

The WHO's Expert Committee on the classification of psychoactive products met in Geneva in late March 2006. Following that session, the experts decided not to classify buprenorphine as a narcotic for the time being, in light of the negative effects this might have on the product's market availability. The Expert Committee recognised that buprenorphine plays a central part in treating opiate dependency and that it contributes to the effectiveness of prevention and treatment efforts relating to HIV/AIDS, as well as those targeting other blood-transmitted diseases, in particular viral hepatitis[1].

The characteristics of buprenorphine themselves are the reason for the real progress achieved in risk-reduction policy. Were the drug to be classified as a narcotic, that progress might become jeopardised. For this reason, Conseil national du SIDA (CNS) would like to reassert, as it has in the past[2], that risk reduction is a priority and that healthcare must continue to be provided to drug users.

SIGNIFICANT RESULTS ACHIEVED THANKS TO BUPRENORPHINE IN THE FIGHT AGAINST HIV

ACCESSIBILITY AND EFFICACY ARE VITAL TO RISK-REDUCTION POLICY

Where drug use is concerned, the risk reduction policy is operated through a wide range of tools, including sterilised needles, needle dispensers and substitution product. The characteristics of buprenorphine have helped attain the objectives set out under the policy, in particular those designed to reduce HIV-transmission. The drug offers three unanimously-recognised benefits, which have made it possible to achieve significant results: accessibility, efficacy and ease of use. These features are the direct result of the product's simple distribution methods. As soon as it came on the market, in 1996, it was decided that the product would be easily prescribed by general practitioners, via a secured prescription process. In addition, as the product is provided in an individualised package, it is easier to use and therefore more effective. Consequently, the number of opiate-addicts currently receiving buprenorphine is currently estimated at 90 000.

STUNNING PROGRESS IN THE PREVALENCE OF HIV-INFECTION IN INTRAVENOUS DRUG USERS

Over the past few years, stunning progress has been achieved thanks to buprenorphine, in particular with regard to HIV/AIDS transmission, with the AIDS epidemic halted in drug addicts and HCV transmission reined in. In 2004, drug addicts accounted for only 3% of new HIV-infections detected, as compared to 40% of AIDS cases twenty years earlier, before buprenorphine emerged. Recognised for those very good results, the French system is seen as an example for many countries, particularly in Europe. Therefore, it is important not to discourage the policies of other countries and not slow down access to care for thousands of newly-detected heroine-dependent patients in those countries.

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[1] http://www.euro.who.int/aids/prevention/20060405_1?language=French

[2] Conseil national du sida, *Press release: Policy on the use of drugs: CNS reasserts that risk reduction is a priority*, 6 April 2004.

THE DRAWBACKS OF NARCOTIC CLASSIFICATION FOR BUPRENORPHINE

WEAKENING RISK-REDUCTION POLICY

Classifying buprenorphine as a narcotic would have dire consequences for accessibility. The recent benefits of our health policy on drugs and, more broadly, our risk-reduction policy would be called into question. As indicated above, buprenorphine is part of a set of tools and measures designed to be used together, achieving effects that range from reduction in damages to full cessation. Classifying the product as a narcotic would lay on the line the consistency of the existing range of tools and would challenge the current level of priority given to developing addiction medicine. Moreover, it would increase pharmacists' workloads by subjecting delivery procedures to special constraints. Lastly, the safety concerns in play would go against all of the progress achieved in the field of risk reduction over the past ten years. A few years ago, the CNS condemned "the overly frequent confusion and contradiction between efforts to protect public health and those aimed at public safety"[3]. Consequently, the priority should not be given to repression, but rather to healthcare, risk reduction and prevention. Lastly, as recommended by the Lyon Consensus Conference in June 2005, it is necessary to set up a National Commission on Risk Reduction, to follow the National Substitution Commission.

MAKING THE FIGHT AGAINST TRAFFICKING AND MISUSE INEFFECTIVE

It has in no way been established that the suggested classification would be effective in fighting against illegal drug dealing, and it can even be expected that new trafficking zones would emerge, with the increase in prices charged on the alternative market or the professionalisation of trafficking. The lack of safety would only be greater, just when it had begun to decrease, with a sharp reduction in overdoses, a drop in criminal activity due to heroine trafficking and the reintegration of thousands of HIV sufferers into society. Risk-reduction policy on drug use has had a positive impact on public safety. Moreover, the misuse is the result of a minority group, often not including drug addicts: studies have shown that only 2% of "patients" are involved in such activity. The misuse itself would not decline either, as the classification could sustain the false impression for users that the product offers narcotic effects, when this is not the case, leading them to increasingly test combinations with other substances, as long as they do not achieve the desired effects. One form of misuse is administering buprenorphine by injection. This raises the question of treating addiction intravenously, something still unknown in our country. Yet, for many years, other European countries have supported medically-assisted heroine use programmes. Any consideration for implementing such programmes in France needs to take into account the support systems without which they cannot be successful.

The existence of trafficking and misuse cannot be denied. However, it is necessary to find and use appropriate tools for fighting such abuse. In 2004, the public health insurance system set up an inspections plan that helped lower the number of fraud incidents, by suspending healthcare for guilty parties and allowing the public health insurance system to file legal suits. Today, the public health insurance system needs to be given the means to fight against such abuse, as was recommended by AFSSAPS[4]. The recent reform of the health insurance system makes it possible to easily establish the connection between the selected practitioner, the patient and the pharmacist. This is why it appears possible to regulate traffic by tracing buprenorphine back through the various players in the healthcare system. The health insurance system's "Web médecin" system already offers access a one-year history of prescriptions.

Consequently, CNS wishes that buprenorphine be maintained in its current category, in order to sustain the good results achieved in terms of public health and risk reduction policy. In recognition for the value of ensuring that the product remains limited to medical use, CNS invites the relevant authorities to make full use of existing means to fight against misuse and trafficking.

In addition, it now appears that the current range of risk reduction tools needs to be expanded. Several new avenues need to be support and tested. Methadone could benefit from an easy access procedure, with the first prescription coming from the general practitioner and a galenic gel cap form developed. Applying the same care model as that used with long-haul illnesses (Article 324-1 of the Social Security Code), patients on buprenorphine could benefit from specially-tailored protocols, provided that adequate training is given to the physicians and a better connection be established between pharmacists and physicians.

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[3] Conseil national du sida, Report, *Opinions and Recommendations on Risks due to Drug Use as a Public Health Issue. Proposals for Redesigning the Legislative Framework*, 21 June 2001.

[4] AFSSAPS, *"Coordination Committee on Health Product Vigilance, 2004 Review"*, version corrected on 10 November 2005.