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PRESS RELEASE

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NATIONAL VIRAL HEPATITIS AWARENESS DAY: CREATING THE CONDITIONS FOR UNIVERSAL ACCESS TO NEW HEPATITIS C TREATMENTS

Since 2014, the introduction of new Direct-Acting Antiviral (DAA) drugs has considerably changed the way hepatitis C infections are treated. These new highly-effective and well-tolerated treatments have enabled a sustained virologic response to be obtained in over 90% of patients in just a few weeks.

In terms of personal health, the treatment's benefit has been demonstrated in preventing the development of hepatitis and its various complications – particularly the most severe ones (cirrhosis, hepatocellular carcinoma). From a public health point of view, effective treatment of hepatitis C infections can help to significantly reduce, and even eradicate the epidemic, by optimising early treatment, screening and risk reduction strategies.

However, due to new DAA drugs' high costs, up until now the French public authorities have limited access to such treatments, by reserving their use for patients in the most advanced stages of hepatitis.

In a letter dated December 2015 sent to the French Ministry of Health and Ministry of Finance and Public Accounts, the CNS indicated that the current criteria for authorising financial reimbursement of DAA drugs were more restrictive than the therapeutic recommendations drawn up by experts. The CNS shared its concern over the possibility of treatment reimbursement being refused for a proportion of patients who are nonetheless eligible on therapeutic grounds, and their access being postponed until further deterioration of their condition.

This situation has been going on for too many months now to be considered merely temporary. Regarding a common infection, this is a case, unprecedented in France, of certain patients' access to new, more effective treatments being denied, solely on the basis of their high cost. Considering the absence of therapeutic justification, it is the CNS' belief that this differential access constitutes a form of discrimination between patients that is unacceptable in ethical terms.

This gap between therapeutic eligibility and actual conditions of access is only getting wider, since the experts' latest recommendations, advocate that antiviral treatment should now be offered to all hepatitis C virus (HCV) infected patients.

Over and above the lost opportunities they represent for the patients concerned, the current access restrictions are at odds with the public policies aimed at increasing the HCV screening. The attractiveness of screening is compromised by the lack of any subsequent offer of treatment, at a time when the availability of a range of rapid HCV tests should encourage earlier screening among more patients.

For these ethical and public health reasons alike, the French National AIDS & Viral Hepatitis Council (CNS) therefore considers it of the utmost importance that **HCV prevention policy in France should be reviewed as soon as possible to meet the objectives concerning screening and antiviral treatments availability for all HCV-infected patients**. Some European countries have already made this choice, and committed to implementing appropriate strategies to this end.

The public authorities must get fully behind this ambition in terms of drug pricing: the French President has highlighted that "France is determined to fight against the prohibitive price of certain

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new drugs, all while promoting innovation." and drawn attention once again to the need for G7 nations to rally to this cause.[1] The public authorities must therefore bring about a significant reduction in the prices of new direct-acting antiviral drugs through their contractual pricing policy with the pharmaceutical industry and, at international level, help to draw up a new regulation framework.

More generally, as far as organisation of the health service goes, all of the stakeholders involved must play their part: in a context where finances and human resources are tight, improving the uptake of screening and the availability of antiviral treatments to all patients with diagnosed HCV infection must result in the optimization of health services' current resources, and in a new division of tasks between healthcare professionals.

Over the coming months, the CNS will remain vigilant to ensure that the new DAA drugs reimbursement conditions are appropriately adjusted in line with therapeutic indications. Where necessary, it will contribute to discussions on the various issues relating to ethics, public health and operational implementation raised by these changes.

[1] François Hollande, "Towards a global agenda on health security", The Lancet, 2 May 2016

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