



VHPB Newsletter

Towards a hepatitis-free Europe: how to make it feasible and affordable



The arrival on the market of new direct-acting antiviral agents for treatment of hepatitis C has transformed the potential for elimination of the disease. They are safe, with few side effects; they cure most infections within 12 weeks or less and are highly cost-effective. With them, the arsenal of agents to counter all forms of viral hepatitis is now well-stocked: vaccines against hepatitis A, B and E, treatments for managing chronic hepatitis B and curative treatments for chronic hepatitis C.

For that reason, the Viral Hepatitis Prevention Board (VHPB) held a meeting in London in June 2015 to try to find answers to the questions of how to achieve a hepatitis-free future and how that goal could be reached affordably in Europe.

An ignored global health burden

Globally viral hepatitis is among the top 10 leading causes of death. In Europe an estimated 19 million people are infected with hepatitis C virus, but, as in the rest of the world, most of them are unaware of their infection. Existing data are inadequate and complicated by the fact that consequences of hepatitis virus infections such as liver cancer are not always included in the mortality statistics for viral hepatitis. The numbers are estimates because awareness of viral hepatitis is still generally low among both the general public and health professionals, and surveillance is poor. Most cases are diagnosed only in the late stages of illness when severe and hard-to-treat complications arise.

Viral hepatitis is belatedly gaining recognition as a public health problem.

It features as a target in the health-related sustainable development goals adopted by the United Nations General Assembly in September 2015. A world summit on the disease was held in Glasgow, also in September. The World Health Organization is drafting a global strategy for progress towards elimination of hepatitis B and C, and is supporting regional and national plans; in Europe, it has set regional goals for elimination. Bodies such as the United States Centers for Disease Control and Prevention, the European Centre for Disease Prevention and Control, the European Liver Patients Association and the European Association for the Study of the Liver are heavily involved.

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Slides of the presentations at
the meetings are available on
www.vhpb.org



Viral hepatitis is gaining recognition as a Public Health Problem

Many, but not all, governments have already drafted national plans for controlling and preventing viral hepatitis, with leadership at the highest political levels in some cases. The varied responses of Belgium, Bulgaria, Georgia, Greece, Romania, Scotland and Slovenia presented at the meeting exemplified the range and nature of issues being faced and sometimes overcome. Scotland, for instance, was one of the first countries to initiate a national plan (in 2006) and Slovenia has a progressive programme with good levels of treatment adherence. On the other hand, Greece has a heavy disease burden (an estimated 134,000 needing treatment) but no national plan and is facing cuts in spending on treatment and prevention.

Globally, most countries have introduced hepatitis B vaccine as part of their routine immunization programmes, but a few notable exceptions remain in north-western Europe. There is a growing recognition that treatment constitutes secondary prevention.

The medical and scientific optimism about the new treatments for hepatitis C was tempered by their list prices (around US\$ 84,000 for a course of treatment with sofosbuvir and US\$ 94,500 for the sofosbuvir/ledipasvir combination), although substantial discounts are being negotiated. The potential number of patients who need treatment is beyond the financial reach of most health systems, especially in times of austerity. Even though modelling studies for France and Romania show that treatment will decrease illness and death rates and the general view that it is cost-effective, insurers and governments will have difficulty in

paying for these treatments for years to come. But cost is not the only impediment: for instance, there are gaps in our knowledge of the evolution and natural history of hepatitis C; questions surround when to start treatment; even the new medicines are not fully effective against all genotypes of the virus; and many symptomatic infected subjects do not have access to care, for reasons ranging from poor health systems and weak insurance cover to stigmatization and discrimination.

The achievement of bringing to market safe and effective alternatives to interferon-based treatments is being overshadowed by the dismay caused by the high list prices, especially as the basic manufacturing costs are estimated to amount to much less than 1% of those figures. A spokesman for one company, Gilead, described how it had introduced tiered pricing for its hepatitis C treatment, offering one of its combination treatments at a lowest price of US\$ 300 per bottle, but critics argue that the threshold prices for some middle-income countries will still be unaffordable. The company is supporting Georgia's ambitious multi-partner hepatitis C treatment programme, under which 5000 people would receive sofosbuvir free in 2015, followed by a further 20,000 courses of sofosbuvir/ledipasvir a year. The company has also signed non-exclusive licence agreements with manufacturers of generic versions of sofosbuvir for sale in 91 countries, although this figure excludes many low- and middle-income countries, including China. Hopes rest on the possible prequalification of the new treatments by WHO.





Innovation, learning from other crises and opportunities

Lessons from the AIDS epidemic show that generic competition is the most effective way to lower the prices of medicines. Compulsory licensing, one of the flexibilities allowed in the Agreement on Trade-Related Aspects of Intellectual Property Rights, has also been used to counter high prices (not only for HIV medicines). Other strategies for governments include public pricing and payback taxes (as applied in France), parallel import and pooled procurement or joint negotiations.

At the same time as efforts focus on lowering prices, attention is turning to innovative financing mechanisms. Potential solutions include adapting or extending existing mechanisms such as the Pan American Health Organization's

Revolving Fund for the purchase of vaccines and related products, the GAVI Alliance, UNITAID and the Global Fund to Fight AIDS, Tuberculosis and Malaria. Other approaches include outcomes-based pricing, municipal bonds, social impact investment bonds and public-private partnerships such as bonds to finance health and prevention. One group at the meeting described the development of a proposal for a finance bond for preventing and controlling hepatitis C, engaging stakeholders with a view to launching a pilot scheme in a European country. Other proposed approaches range from crowd-funding to micro-credit and health insurance schemes.

Meeting conclusion: first have a plan, then discuss the cost!

The conclusion of the meeting was that elimination of viral hepatitis and the creation of a hepatitis-free Europe are achievable objectives. Agreement on strategies and the development, enrolment of a national hepatitis plan is a higher priority than discussing the lowering of prices alone. The tools are available, but access and affordability need

to be ensured. All parties, from international organizations and governments to the pharmaceutical industry, civil society organizations and new stakeholders such as banks and philanthropic entities, need to act in concert.

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