Hepatitis B and C
Public Policy Association

NEWSLETTER

Prof. Angelos Hatzakis MD PhD, Editor-in-Chief

MARCH 2018 ISSUE

Hepatitis C Elimination in Europe European Policy Guidelines

An interview with Charles Gore, Chief Executive, The Hepatitis C Trust UK
HepBCPPA Co-ordinator for the development of the European Policy Guidelines.

Newsletter Contents

Q. What is the background behind the Hepatitis B and C Public Policy Association's hepatitis C policy guidelines which were launched at the EU Parliament in Brussels in November 2017?

As you know, in February 2016 the Association organised the first EU Policy Summit on the elimination of hepatitis C. This summit launched the EU Hepatitis C Elimination Manifesto, which set out 7 high-level policy asks in a vision for a hepatitis C-free Europe. This Manifesto is what underlies the guidelines.

Q. What is the purpose of the guidelines?

The Manifesto is a very important document but at the end of the day it is just a piece of paper. It needs to be turned into action so in 2017 the Association launched a series of national mini-Summits at the European Parliament to bring together policy-makers at a country level, in particular parliamentarians from both the national parliament and the EU parliament, to drive the change we all need to rid Europe of hepatitis C. The guidelines were developed to support these mini-Summits and indeed any policy advocacy by setting out very concrete examples of the actions policy-makers can take to advance the Manifesto.

Q. So how exactly do the guidelines work?

The guidelines take the 7 policy asks of the Manifesto one by one. The environmental context for each is then set out, followed by 3 or 4 recommendations for policy-makers to achieve what is set out in the policy ask. Each recommendation then has suggestions for relatively simple actions that a policy-maker could undertake. You can think of the guidelines like a step-by-step instruction book.

Q. You mean it's like an Ikea manual

Exactly. Except you're not building a wardrobe; you're building a hep C-free Europe!

Q. Can you give an example?

Indeed. So Manifesto Ask 2 says: "Ensure that patients, civil society groups, healthcare professionals and other relevant stakeholders are directly involved in developing and implementing hepatitis C elimination strategies, with existing best practice examples and guidelines serving as the basis for people-centred health system-based strategies that emphasise tailored implementation at the local level". One of the recommendations for policy-makers under this ask in the guidelines is to "ensure strategies to improve health systems are people-centred". One of the suggested actions a parliamentarian could undertake to achieve this is "holding a parliamentary evidence session to understand what the HCV community needs from a national elimination strategy (e.g., where testing would be most convenient, where treatment should take place) and communicating the outcomes to the Minister of Health". So you can see the guidelines are full of practical suggestions.

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Q. Who are they intended for? The policy-makers?

Not exactly. They are of course about what policy-makers can do but they are really aimed at people involved in advocacy. Too often advocates go to see policy-makers and are either too vague in what they ask for or they ask for too many things or for things that are beyond what a policy-maker can do. The guidelines contain examples of exactly the concrete things a policy-maker could deliver, recognising that members of parliament for example have a thousand other topics they are being lobbied about and simply don't have a lot of time to devote to any one of them. Asks to them need to be clear, relatively easy to do and not too time-consuming.

Q. You say these are examples. So this is not a definitive list of things policy-makers should be asked to do?

Absolutely not. That would be impossible. There are all sorts of different policy-makers the guidelines will be applicable for, even if it is primarily aimed at national MPs and MEPs. On top of which, the guidelines are designed for all of Europe and the situation in each country varies. Nonetheless, most of the examples chosen will be applicable as they stand.

Q. How were the guidelines produced?

They were produced by a team of internationally-respected public health experts with extensive experience of policy and of advocacy with great support from a very experienced public affairs agency.

Q. So, what are your hopes for these guidelines?

I hope, above all, that they are useful and that they get used. We have this opportunity in Europe to eliminate hepatitis C not just by 2030 but in the next 5 to 7 years but it will require some real impetus from policy-makers to get it done. I really hope these guidelines will help fuel that impetus.

Hepatitis B and C HCV Policy Guidelines

http://www.hcvbrusselssummit.eu/images/documents/reports/HCV-Elimination-PolicyGuidelines.pdf

Article by ACHIEVE members on the European Parliament resolution of 5 July 2017 on the EU's response to HIV/AIDS, Tuberculosis and Hepatitis C

Introduction

The ACHIEVE (Associations Collaborating on Hepatitis to Immunise and Eliminate the Viruses in Europe) coalition aims to politically advance the fight against viral Hepatitis B and C in Europe, in line with the WHO Global Health Sector Strategy, the WHO Europe Action Plan and the UN Sustainable Development Goals. ACHIEVE represents patients and community, clinicians and researchers, including the following organisations: The European Liver Patients' Association (ELPA), the Viral Hepatitis Prevention Board, Hepatitis B and C Public Policy Association, EASL International Liver Foundation, European Aids Treatment Group (EATG), Correlation Network, the World Hepatitis Alliance and the Barcelona Institute for Global Health (ISGlobal). It is enabled by the support of Abbott, CEPHEID, Gilead Sciences and MSD.

After the European Parliament decided to work on a European Parliament Resolution on the EU's response to HIV/ AIDS, Tuberculosis and Hepatitis C in spring 2017, ACHIEVE was in close contact with Members of the European Parliament to highlight relevant policy issues with regard to viral hepatitis.

Q. What are the most important points on viral hepatitis B and C made by the 5th July 2017 European Parliament Resolution on the EU's response to HIV/ AIDS, Tuberculosis and Hepatitis C?

The European Parliament Resolution highlights the opportunity of eliminating viral hepatitis as a public health threat by 2030, referring to the WHO Global Health Sector Strategy and the UN Sustainable Development Goals. At the same time, the Resolution clearly states the obstacles on the way to elimination. The obstacles identified by the Parliament include deficient national plans which are frequently inconsistent, underfunded or lacking altogether.

Importantly, Parliamentarians refer to the difference in surveillance and monitoring approaches, testing practices and programmes, which make it difficult to track progress and fulfil the EU commitment to monitoring the implementation of the UN SDGs for viral hepatitis. The Resolution compares the situation of viral hepatitis to that of HIV, where the Dublin Declaration on Partnership on fighting HIV/ AIDS in Europe and Central Asia from 2004, was essential in generating political will and establishing an effective monitoring system.

The Resolution therefore calls on the Commission and the Member States to develop a comprehensive EU Policy Framework addressing HIV/ AIDS,

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tuberculosis and viral hepatitis, as well as to strengthen work with communities and vulnerable populations through multi-sectoral cooperation. Furthermore, the Resolution calls on the Commission to discuss with Member States and future Council Presidencies the possibility of updating the Dublin Declaration to put HIV/ viral Hepatitis and TB on an equal footing.

Parliamentarians also call on the Commission and on Member States to ensure sustainable funding of national viral hepatitis elimination plans, and to make use of EU Structural Funds and other available funding.

Finally, the Resolution calls for EU-wide harmonised surveillance programmes to be put in place that can detect outbreaks of viral hepatitis, TB and HIV in a timely manner, assess trends in incidence, provide disease burden estimates and effectively track in real time the diagnosis, treatment and care cascade, including for specific vulnerable groups.

Q. How many Members of the European Parliament (MEPs) supported the Resolution?

The draft Resolution was put forward to the European Parliament's full assembly, the Plenary, by its Committee for the Environment, Public Health and Food Safety (ENVI). Although there is no track record of votes available, it can be said that the Resolution was supported by all major political groups by an overwhelming majority on 5th July 2017 in Strasbourg.

Q. What did the European Commissioner for Public Health, Dr. Vytenis Andriukaitis, say in the exchange of views preceding the adoption of the Resolution?

The Commissioner confirmed the European Commission's commitment to helping Member States achieve the UN SDGs with regard to HIV/ AIDS, Tuberculosis and viral Hepatitis. In his view, the integration of prevention, treatment and care for HIV/ AIDS, Tuberculosis and hepatitis should become standard practice across Europe. With the support of the EU Civil Society Forum, which now includes viral hepatitis and tuberculosis along HIV/ AIDS, the Commission will seek to identify concrete steps on how to scale up prevention and testing programmes, and discuss how to reach out to the most vulnerable, combining health with social instruments.

Q. What is the impact of the European Parliament Resolution?

The Resolution is being shared by the European Parliament's President with the Council of Health Ministers, the European Commission, the Member States and the World Health Organization. Although there is no legal obligation to act on the Parliament's calls, the Resolution sends a strong political signal to EU decision-makers and stakeholders on the need to act to achieve the WHO elimination target by 2030 and the UN SDG of combatting hepatitis.

Q. What is the view of ACHIEVE on the European Parliament's Resolution?

The ACHIEVE coalition is delighted about the adoption of the European Parliament Resolution on the EU's response to HIV/ AIDS, TB and Hepatitis C. We are also glad to have been able to contribute by briefing key MEPs on the challenges and opportunities for viral hepatitis elimination in Europe, in particular the problem of insufficient monitoring along the cascade of care.

ACHIEVE hopes that future Council Presidencies, such as the upcoming Council Presidency Trio of Romania, Finland and Croatia, will respond to the call of the European Parliament by adopting Council Conclusions on the topic.

These Conclusions should mandate the European Commission to develop the pending EU Policy Framework on HIV/ Aids, Tuberculosis and viral Hepatitis, and give guidance on how to expand the Dublin Declaration on HIV/ Aids in EU and neighbouring countries to include hepatitis and TB. This way, effective monitoring of viral hepatitis will be ensured throughout Europe, allowing decision-makers in public health to track progress on achieving the WHO elimination target by 2030.

European Parliament resolution of 5 July 2017 on the EU's response to HIV/AIDS, Tuberculosis and Hepatitis C

http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2017-0301

Australia on-track to achieve HCV elimination before 2030

Professor Gregory Dore

Head, Viral Hepatitis Clinical Research Program, Kirby Institute, UNSW Sydney

Q. What have been the key features of Australia's response to HCV over the last two decades?

Australia has a history of national HCV strategic development, with the 1st National Hepatitis C Strategy launched in 2000, is in a 4th Strategy (2013-2017), and is developing a 5th Strategy. This strategic development has been underpinned by partnerships between Government, clinical, academic, and civil society stakeholders. Government funding for national and State-based hepatitis and drug-user community organizations has been pivotal to these partnerships, and has driven community-based education and advocacy. HCV education and training for primary care and addiction medicine physicians from the early 2000s has facilitated high levels of screening (an estimated 81% of people with chronic HCV are diagnosed), and laid the foundation

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for the current major involvement of these groups in DAA prescribing. Broad implementation of harm reduction strategies for people who inject drugs (PWID), from the early 1990s, maintained low HIV prevalence (around 1% among PWID), prevented many HCV infections (although chronic HCV prevalence was 45% prior to DAA scale-up), and provided the public health interface to enable a highly marginalized population to have high levels of HCV screening. Finally, as with the HIV response in Australia, bipartisan (from both major political parties) support and political leadership has been crucial to the development of HCV public health strategies that are pragmatic, highly cost-effective, and generally well accepted by the broader community.

Q. What were some of the major milestones in the development of the unrestricted DAA access program in Australia?

A pivotal meeting was convened in 2014 by Dr. Sue Hill, Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent body that evaluates applications for Government subsidization of therapeutic agents. Representatives from the Government, clinical, academic, civil society groups, and the pharmaceutical industry were present. The hepatitis and drug user community-based organization representatives were particularly vocal in advocating "access to all", rather than a liver disease stage-restricted access strategy that most high-income countries were pursuing.

In March 2015, the PBAC evaluated the initial DAA regimens and recommended access for all patients with chronic HCV infection aged 18 years or older. Importantly, the PBAC stated that the cost-effectiveness of these therapies should be at the $AUD 15,000 ($US 12,000)/ICER level, rather than the generally accepted benchmark for therapeutic interventions of $AUD 40,000-50,000 ($US 32,000-40,000)/ICER, thus sending a clear message to the pharmaceutical companies (Gilead, Bristol-Myers Squibb) that lower prices would be required to enable an unrestricted DAA access program.

Several months of price negotiations between the Australian Government and the pharmaceutical companies ensued (PBAC is not directly involved in these negotiations), with the announcement by the Australian Government Health Minister, Sussan Ley, in December 2015 of an investment of $AUD one billion ($US 800 million) over the 2016-2020 period for DAA treatment. I believe that the development of a longer-term contract (5 years) was a pivotal component of the successful negotiation.

Q. What are the key features of unrestricted DAA program, that was launched in March 2016?

Some details of DAA drug pricing and the Australian Government risk-sharing arrangement with the pharmaceutical companies remain confidential. There are, however, several features that together make the program relatively unique and clearly highly cost-effective. The initial DAA regimens (sofosbuvir/ledipasvir; sofosbuvir plus daclatasvir) were subsidized from March 2016, with additional regimens added in May 2015 (paritaprevir/ritonavir/ombitasvir plus dasabuvir with or without ribavirin), January 2016 (grazoprevir/elbasvir,), and August 2017 (sofosbuvir/velpatasvir). Australian recommendations for the management of hepatitis C infection: a consensus statement 2016 were developed by the key stakeholder groups in Australia, released for the DAA program launch in March 2016, and updated in January 2017 and August 2017.

From the start of the DAA program, there were no restrictions based on liver disease stage or drug/alcohol use. There is no cap on number of patients able to be treated per year, but through the risk-sharing arrangement between the Australian Government and the pharmaceutical companies capped annual expenditure (probably $AUS 250-300 million). Thus, the higher number of patients treated (assuming the cap is reached each year), the lower the overall price per patient course. There is minimal out-of-pocket cost for the patients (co-payment of $AUS 7–36 per month).

The Australian Government made the crucial decision to allow prescribing by any registered medical practitioner. In the initial period (March to November 2016) a "consultation" between non-specialists and a gastroenterology or infectious diseases specialist was required. This generally involved completing a short pro-forma with demographic, HCV clinical, and planned regimen details which was sent (usually via email) to a specialist. This consultation requirement was removed in November 2016 for non-specialists who had gained experience in DAA-based treatment during the initial months of the program, but remains in place for less experienced prescribers. Successful primary care physician prescribing pilot programs had been undertaken in the interferon-based therapy era, however, these involved a small number of clinicians. A DAA prescribing accreditation course was not required to be completed, but there has been considerable investment in education and training by Government and pharmaceutical companies over the last two years.

Unlike many settings, there is limited paperwork/administration required to gain patient authorization for DAA therapy, with only a short phone call (1-2 minutes) to an Australian Government department (Pharmaceutical Benefits Scheme, PBS) to provide key information, including patient identifiers, HCV genotype, cirrhosis status, and planned regimen and duration. Importantly, DAA dispensing is allowed through both hospital-based community (retail) pharmacies.

Specific provisions to ensure treatment for prisoners were included within the DAA program, with the Australian Government bearing the DAA therapeutic costs, despite this generally being a State Government responsibility. The Australian Government Health Minister, Sussan Ley (member of the Liberal "conservative" Party), made prison-based access a particular priority for the DAA program.

Importantly, in the context of HCV elimination, retreatment of HCV reinfection is allowed in both community and prison settings.

Q. How is DAA treatment uptake progressing in Australia?

A large number of patients (n=43,360) have received DAA therapy through the Australian Government funded program from March 2016 to June 2017. An estimated 4,340 patients had received DAA therapy from late 2014 to February 2016, through Pharmaceutical company compassionate access programs (estimated n=1,930, the vast majority with cirrhosis), clinical trials (estimated n=910), and generic importation (estimated n=1,500). The combined figure of 47,700 patients who have received DAA therapy is equivalent to 21% of the estimated chronic HCV population in 2015 (n=227,000).

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The proportion of patients treated by specialists (predominantly gastroenterologists and infectious diseases physicians) has declined from 77% to 40%. An estimated 70% of the total population with HCV-related cirrhosis initiated DAA treatment from 2014 to 2016, important for reducing HCV-related mortality.

There is also evidence that the broadening of DAA treatment has included younger patients with earlier liver disease, but high risk of HCV transmission. Data from the Australian Annual Needle and Syringe Program Survey (ANSPS) showed that 22% of participants with HCV infection self-reported DAA initiation in 2016 (compared to 3% in 2015).

Additional data indicate DAA treatment uptake in 2016 of >60% among patients with HIV/HCV coinfection (predominantly men who have sex with men), a further high-risk population for ongoing HCV transmission.

Q. What is required to keep Australia "on track" for HCV elimination?

Australia is included in a list of nine countries considered to be "on-track" for HCV elimination. The initial period of the DAA program has been a great success, but renewed efforts are required to achieve HCV elimination goals.

Mathematical modelling indicates that around 20,000 per year will be required to be treated to achieve HCV elimination goals by 2026-2030.

These models assume that there is equivalent DAA uptake across HCV transmission risk populations, thus ongoing monitoring of uptake in high-risk populations is crucial.

Further community awareness campaigns are needed, to raise awareness among the affected population who have been diagnosed but not linked to treatment, and the population who remain undiagnosed. Continued development of diverse models of care and broad prescriber involvement is also required. Simplification of assessment and DAA treatment should also support continued uptake.

A key example of this is within the Australian prison setting. An estimated 1500 inmates were treated during the first year of DAA therapy, but based on current trends, treatment uptake should rise significantly in 2017 and 2018. Part of the enhanced capacity in the prison setting is the move from predominantly directly observed therapy (daily dosing at prison clinic) to predominant monthly dispensing with inmates taking medications in their cells.

Additional models of care are also required to reach more marginalized PWID, including those injecting stimulants (In Australia, predominantly methamphetamines). NSP has provided a potential infrastructure for HCV assessment and delivery of therapy to PWID. NSP sites Pilot initiatives will soon evaluate DAA therapy delivery through NSP sites, with peer-based support.

An increasing number of non-specialist prescribers are becoming involved in DAA treatment, with an estimated 9,760 patients having been prescribed DAA by general practitioners (GPs) by June 2017. This is extremely encouraging, but further efforts are required to encourage and train additional prescribers. Maintenance of a harm-reduction framework is essential. High levels of DAA uptake could be undermined by a lack of HCV prevention services.

Fortunately, Australia is one of the few countries that has both high NSP (400 needle-syringes distributed per PWID per year) and OST (40 per 100 PWID) coverage. Finally, in order to inform further strategies for HCV elimination in Australia, a program of monitoring and evaluation is essential. The key elements should cover information on DAA uptake, treatment outcomes, and population-level impact on HCV prevalence, incidence, and disease burden.

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The crucial importance of targeting people who inject drugs in a country's national hepatitis C virus elimination strategy

An interview with Alexis Goosdeel, Director of the European Monitoring Centre for Drugs and Drug Addiction, Lisbon

Q. Why do people who inject drugs matter in the fight against HCV?

People who inject drugs (PWID) are a key population for Hepatitis C Virus (HCV) transmission in Europe. The majority of newly diagnosed infections in Europe, where the transmission route is known, are related to injecting drug use and this indicates active transmission among PWID.

In several EU countries, more than one in two people who inject drugs are HCV-antibody positive; among long-term drug users HCV prevalence can reach more than 80%. This high prevalence of infection among PWID is leading to high morbidity and mortality if left untreated. In order to eliminate HCV as a public health threat in Europe, we therefore have to focus on people who inject drugs (PWID).

Q. How can we reduce the burden of HCV among PWID?

The hepatitis C virus is still spreading among this population despite known effective prevention measures, reliable diagnostic tests and treatment.

First, prevention measures — such as the distribution of sterile injecting equipment and opioid substitution treatment that reduce the risk of blood-borne viruses infections (not only HCV but also HBV and HIV) — are cost effective and should be made available to all PWID, whether in the community or in prisons.

Second, all PWID should have access to HCV testing in order to be aware of their status and to be directed to appropriate care, including treatment. This holds for all blood-borne viruses. New data from drug treatment centres show that a large proportion of PWID entering drug treatment have never been tested and that only a minority is tested on a regular basis every year, as we recommend.

Third, providing treatment to all PWID testing positive for chronic HCV infection would not only cure the patients but also reduce further transmission in the community. And of course, as outlined in the WHO Regional Action Plan, a national HCV policy that is inclusive towards marginalised populations, and is funded, is an important milestone.

Data on prevention, testing and access to care among PWID in Europe are sparse, but suggest: sub-optimal harm-reduction provision; many undiagnosed infections; and poor treatment uptake among PWID. We will eliminate HCV only by increasing our efforts on these three fronts simultaneously, but scaling up effective harm-reduction measures to reduce re-infection and the number of new infections is a crucial step.

Q. What are the main reasons for poor access to treatment among people who inject drugs?

Many people with an injecting history are unaware of their infection, delaying entry into effective treatment and increasing risks of further transmission. Infectious diseases testing must become more accessible to this target group.

One way to achieve this is to provide it in non-medical settings, such as community-based harm-reduction centres. In September 2015, European countries agreed upon Minimum Quality Standards in Drug Demand Reduction in which they stipulate that 'Treatment services [should] provide voluntary testing for blood-borne infectious diseases, counselling against risky behaviours and assistance to manage illness'.

But there has also been a lack of response in terms of treatment of HCV among PWID in the past decades: previous interferon-based treatments triggered serious side-effects and were contra-indicated among those who suffer from mental health problems, in particular depression, which is the case for a large proportion of drug users.

The situation changed in 2014, when highly effective HCV treatments that were not based on interferon became available.

With very few side effects, these medications could play an essential role in reducing the HCV burden among PWID in Europe — if they were made more accessible. The high price of the medications remains a barrier to widespread scale-up of HCV treatment, although in terms of public health, people who inject drugs are a priority group for HCV treatment.

Q. In which areas is the EMCDDA active?

In the framework of its mandate, the work of the EMCDDA is focused on four elements, namely to:

- consolidate the estimates of the size of PWID populations (to contribute to improve estimates of the population at risk);
- consolidate estimates of the prevalence of HCV among PWID (to contribute to improve estimates of the burden of disease);

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- monitor range and coverage of effective harm-reduction interventions (2018: focus on testing in drug treatment facilities); and
- exchange models of good practice in viral hepatitis policies, harm reduction, prevention and care responses for people who inject drugs.

The established monitoring system of the agency contains robust and meaningful datasets that will contribute to monitoring the implementation of the WHO Regional Action Plan for the Health Sector Response as part of a wider EU indicator framework.

We collaborate closely with the European Centre for Disease Prevention and Control (ECDC) to assist EU member states in building national monitoring capacity and implement evidence-based responses.

The EMCDDA plays a unique role, as it provides a comprehensive view of the drugs problem, not only from a health, but also from a drug markets' perspective. Furthermore, through the agency's network of national focal points, information exchange and collaboration with specialised drugs agencies takes place.

Staff at these agencies are key-partners in the response to the HCV epidemic, because they can reach out to current PWID with information on prevention and testing offers; they pave referral to further diagnostics and unblock treatment pathways for those in need.

The launch of a global strategy aimed at the elimination of viral hepatitis provides us with an opportunity to increase efforts and collaborations at all levels.

Q. Why is monitoring so important?

Monitoring is the basis for evidence-based decision making. It also allows assessment of the impact of public health interventions. The high prevalence of HCV among people who inject drugs in Europe, and the fact that many of them became infected a long time ago, has a severe impact on the burden of disease in Europe.

Chronic HCV infection — often worsened by heavy alcohol use — accounts for an increasing number of cases of liver disease, including cirrhosis and liver cancer and an increasing number of deaths among an ageing population of people who use or have used drugs by injection. Putting together the full epidemiological picture for each country and for Europe as a whole is crucial for policy makers to understand the situation and to be able to invest scarce health budgets wisely, selecting the most effective responses. There is room for improvement: not all countries have up-to-date estimates of the size of the key-population of people who inject drugs and only 20 European countries have recently conducted local or national studies to determine HCV prevalence among this group.

It is therefore crucial to invest in strengthening epidemiological surveillance and in new studies on risk behaviours among PWID to better focus prevention and harm-reduction interventions — in complement to hepatitis C treatment — and to reduce the burden of HCV and other blood-borne infections.

Q. Finally, in one sentence, what is the main message of the EMCDDA for those who develop national elimination strategies?

Elimination will be achieved only if we identify PWID as a major key population and if we define specific actions and targets for this group.

Alexis Goosdeel, EMCDDA

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SAVE THE DATE

Hepatitis B&C Public Policy Association

2nd EU HCV Policy Summit "Securing sustainable funding for hepatitis elimination plans"

Steigenberger Wiltcher's Hotel

Brussels

6th June 2018 11.30-18.30

Items on the Agenda:

1. The cost of HCV Elimination in the EU 28.

2. The cost of patient reported outcomes and productivity loss due to HCV in EU 28.

3. Innovative Financing of HCV Elimination.

4. HCV Elimination and European Financing Institutions.

5. Elimination Manifesto 2: Declaration for sustainable funding of HCV elimination in Europe