

“Hepatitis C: The beginning of the end - key elements for successful European and national strategies to eliminate HCV in Europe”.

The first EU Policy Summit dedicated to the elimination of hepatitis C in Europe.



Note by the Co-Chair of the Hepatitis B & C Public Policy Association
Professor Angelos Hatzakis MD, PhD

The Hepatitis B and C Public Policy Association brings together thought leaders and stakeholders from across the board to reflect on recent advances and challenges in understanding, measuring, preventing, diagnosing and treating hepatitis B and C and to develop policy responses that can effectively and

measurably address these challenges.

Over the past 6 years, it has organized three high-level meetings in cooperation with the EU Presidency of Belgium, the EU Presidency of Cyprus and the EU Presidency of Greece and has instigated and agreed with its partner associations on three Calls To Action addressed to the European Commission, the EU Member States and the Mediterranean and Balkan Countries. The Association also participates in related international and European scientific and policy meetings and lobbies to increase visibility of challenges and the urgency for responses.

The economic crisis has impacted on public health spending more than on any other public life sector shrinking budgets and necessitate austerity, in turn, austerity calls for cuts. Governments are faced with a dilemma: spend now to save later? On what? With what return on investment?

The first EU HCV Policy Summit held in Brussels on 17th February 2016 was an historic event and represents an important milestone, as it was the first ever high-level conference organised on the topic of elimination of hepatitis C on a European level. On 17th February, we gathered together the main stakeholders in the field of hepatitis C: clinicians, patient advocacy groups, representatives of key institutions and regional bodies from across Europe to present the case for a

European elimination strategy for hepatitis C in the presence of the EU Health and Food Safety Commissioner, Dr Vytenis Andriukaitis, and EU and national policy-makers.

During the HCV Summit, the case was made for the elimination of hepatitis C in Europe by demonstrating that elimination is a real possibility through a combination of availability of the new drugs and the implementation of prevention practices. The launch of the Elimination Manifesto with its 7 points provides a road map for action.

The European institutions and stakeholders represented were the European Commission, Dr Vytenis Andriukaitis, Commissioner of Health and Food Safety, DG Sante, Mr John F. Ryan, the European Parliament, Dr Cristian-Silviu Busoi, MEP and European Parliament Friends of the Liver Group, ECDC, European Centre for Disease Prevention and Control, EMCDDA, European Monitoring Centre for Drugs and Drug Addiction, WHO, World Health Organization, WHA, World Hepatitis Alliance, ELPA, the European Liver Patients' Association, EASL, the European Association for the Study of the Liver, ICMHD, International Centre for Migration Health and Development, Correlation Network, VHPB, Viral Hepatitis Prevention Board.

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One hundred and thirty-seven delegates attended the event. Thirty-three nationalities were present including Austria, Belgium, Bulgaria, Canada, Croatia, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Switzerland, Turkey, Ukraine, United Kingdom and the USA.

The Elimination Manifesto was launched and signed on the day of the Summit and was endorsed and supported by nine organisations. The Manifesto can still be signed at our website. The Manifesto was translated into ten EU languages for its launch at the Summit.

This issue of Hepatitis B and C Public Policy Association's Newsletter is dedicated the EU HCV Policy Summit. We invite you to read the meeting summary, share your thoughts with us and join in the effort to raise the bar for management of viral hepatitis in Europe.

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Hepatitis C: The beginning of the end-

Key elements for successful European and national strategies to eliminate Hepatitis C in Europe.

Report of the 2016 EU HCV Policy Summit



1. Introduction

The Hepatitis B and C Public Policy Association is a non-profit organization that aims to inform national and international policy on issues related to awareness, epidemiology, prevention and management of viral hepatitis B and C. The Association carries out its work through partnerships with relevant stakeholders including government representatives, health providers, patients, public health and civil society advocates and the private sector. Since its inception in 2009, the Association has held four high-level Summit meetings to move forward policy on Hepatitis B and C with national and international stakeholders, the most recent of which is detailed in this report.

On February 17, 2016, the Hepatitis B & C Public Policy Association held the HCV Policy Summit Hepatitis C: The Beginning of the End - Key elements for successful European and national strategies to eliminate HCV in Europe. The aim of the meeting was to bring together high-level policy makers and academics, patient advocates, health organizations, and other stakeholders. The event served as a platform for one of the most significant disease elimination campaigns in Europe and culminated in the presentation of the HCV Elimination Manifesto, calling for the complete elimination of HCV in Europe by 2030. The Summit was held in collaboration with the European Association for the Study of the Liver (EASL), European Liver Patients Association (ELPA), European Parliament Friends of the Liver Group, the Viral Hepatitis Prevention Board, VHPB, the Correlation Network, International Center for Migration Health and Development, ICMHD, the World Hepatitis Alliance (WHA), and other international stakeholders and advocacy organizations. The following Organizations including World Health Organization (WHO), the European Commission, European Center for Disease Control, (ECDC), and European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) were represented.

2. Overview and Background: Tackling the challenges of the global burden HCV ⁽¹⁻⁶⁾

Hepatitis C virus (HCV) is a high prevalence chronic disease affecting an estimated 185 million people worldwide⁽¹⁾, and with an estimated 15 to 19 million chronically affected in Europe. The prevalence of HCV varies widely among European countries, and certain groups are at higher risk of infection. Up to one third of those chronically infected will develop liver problems such as cirrhosis or hepatocellular carcinoma. HCV is the leading cause of liver transplantation, and treatment of liver related diseases represents a significant cost to health systems. Without treatment, most patients die from liver related illness. This supposes a significant burden for productivity and, most importantly, individual quality of life.

Due to recent advances in treatment strategies and medications, the majority of those treated recover, and HCV cure rates are presently at over 90%, presenting for the first time the possibility of elimination of the disease at population level. However, HCV presents specific challenges that require holistic, patient-centered and health system wide approaches that address awareness, prevention, care and treatment through the joint collaboration of health providers, patients and stakeholders. In the current context faced by many European countries- with threats to the fiscal security of health systems and neglect of marginalized populations- putting HCV on the health policy agenda is even more crucial ⁽⁷⁾.

The question that arises for many is, why does HCV continue to be a major public health problem in Europe, with seven times greater prevalence than HIV and 27,000 – 29,000 newly diagnosed cases each year? ⁽⁷⁾. The answer lies in the fact that HCV patients often have no symptoms for the first 20 to 30 years of infection. Surveillance of HCV is weak across many EU countries. Also, the burden of HCV is disproportionately borne by marginalized populations including people who inject drugs (PWID) prisoners, migrants and homeless, who generally have poor access to health care and are vulnerable to poverty, other health problems, and social stigmatization ⁽⁸⁾. Systematic screening policies are lacking, and it is not clear what are the most effective methods for recruiting these hard to reach populations into screening, care and treatment programs ⁽⁹⁾.

New medicines and technologies are currently expensive enough to seriously compromise the ability of health systems to provide treatment to all patients.

Key issues for addressing HCV in Europe

A “silent” epidemic

The undetected spread of HCV is one of the most important challenges to address, as the disease is often only detected in the late stages, if at all. Fewer than 40% of all cases are detected, even in developed countries ⁽³⁾. As a silent epidemic, HCV rates are increasing in Europe, mainly among PWID, who are disproportionately affected by HIV, tuberculosis and who face stigmatization and social exclusion.

Improving surveillance

Collectively, European countries must improve surveillance. Currently, EU countries with good surveillance systems present high HCV prevalence rates, but true prevalence rates are unknown. Meeting this challenge requires action on prevention, treatment (e.g. medical products, agreements on joint procurement and pricing of drugs), and health technology assessment. Also necessary is the involvement of EU agencies including the ECDC. The European Commission (EC) has invested over €30 million to date in scientific cooperation on HCV at the EU level and should guide the process ⁽¹⁰⁾.

Focus on high risk populations

In Europe HCV is now transmitted primarily among PWID. Globally, 67% of PWID are infected with HCV, and PWID also account for the majority of HCV/HIV co-infection worldwide ⁽¹¹⁾. In high-income countries, PWID account for 50-80% of HCV infection ⁽¹¹⁾. In Europe, recent increases in HCV prevalence reflect poor treatment access and uptake among this group. Historically HCV treatment guidelines have excluded PWID, due to concerns about effectiveness, adherence and re-infection. However, a growing body of literature shows that treatment is highly effective and there is no difference in treatment adherence between PWID and others ^(12,13). Therefore, different international guidelines all recommend treatment among PWID

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^(14,15). However, PWID face barriers and are often denied treatment. Advocacy efforts are fragmented and there is a lack of knowledge among staff working in prevention and harm reduction efforts, and HCV can not be eliminated without a concerted focus on raising awareness and coordinating prevention, care and treatment of the PWID population.

Burden on health systems

The cost of HCV to European health systems is significant. The WHO estimates that around 150 million people infected have developed or will develop chronic diseases, with around 3 to 4 million cured annually ⁽⁹⁾. Costs to health systems include ongoing treatment of cirrhosis, HCC and end stage renal disease, among others, which amount to an enormous expenditure by European countries. HCV was responsible for an estimated 86,000 deaths and 1.2 million DALYs in the EU region in 2002 ⁽¹⁶⁾. HCV is also related to a loss of productivity among those infected, when patients are unable to participate fully at their workplaces and in society.

Unnecessary burden on quality of life

Eliminating HCV is not just an urgent financial matter - it is a question of human rights, as living with HCV greatly impacts the quality of life of families and communities. Aside from being a practical possibility, a cure is revolutionary for the patient ⁽⁴⁾. Though the majority of cases are not yet identified, risk groups are well known, and the tools and means for eliminating the disease are available with appropriate commitment from government, the pharmaceutical industry, patients, health providers and others stakeholders.

Improving coordination among member states

Although there has been a call to action among member states, including ongoing discussions and initiatives among stakeholders in conjunction with patient associations like the European Liver Patients Association (ELPA), there is still a general lack of coordination among member states. Coordination must happen at the EU and national levels with the wider involvement of stakeholders including policy makers, non-governmental organizations, patients, the health sector and others. EU level discussions have begun to address the high price of treatment, but a new approach is needed that engages at-risk groups to improve patient access.

Engaging stakeholders

At the EU level, it is widely believed that the current opportunity to eliminate HCV will require the engagement of partners around Europe to link research, services,

health providers and policy makers. Key focus areas for stakeholder engagement include: 1) access to affordable/free treatment and care 2) scale-up of harm reduction by connecting marginalized groups to needed services and addressing barriers like stigma and discrimination as well as laws that criminalize drug use and 3) the full involvement of the affected communities in these processes.

Indeed, advocacy groups and associations such as the European Association for the Study of the Liver (EASL) and the Correlation Network are working with stakeholders to advance elimination by creating and disseminating HCV management guidelines, raising awareness, collaborating with ECDC, WHO, EMCDDA and other groups to estimate HCV disease burden, and treatment access

3. Eliminating HCV in Europe, Current Challenges and Criteria for Success ⁽¹⁷⁻²²⁾

HCV burden in Europe

As mentioned, a key challenge to HCV elimination in Europe is the lack of reliable estimates of the burden of disease. Knowing the true burden of disease and the profile of those infected is necessary in order to design programs and policies to scale-up prevention and treatment. It is also necessary for estimating the cost that these efforts entail for European health systems.

In an effort to produce more reliable prevalence estimates, the Center for Disease Analysis (CDA) has been to nearly every country in the EU to assess HCV disease burden through expert consultation and modeling. CDA estimates show 3.6 million viremic infections in Europe, with 1.7 million diagnosed, 1 million treated and 500,000 cured. Overall, there is a viremic prevalence of around 0.7%, which was less than expected. In 2015, there were an estimated 133,000 patients treated (3.7% of those infected).

HCV treatment rates vary dramatically across the EU, and in order to reduce the number of individuals needing treatment by 2030, new infections must decrease by 90%, through increased screening and treatment eligibility. However, treatment cannot be limited to those under age 70, it must be expanded in order to see a reduction in new infections; 230,000 will need to be treated annually to meet reduction targets.

The first Global Hepatitis Strategy

With the advent of new treatments, eliminating HCV in Europe is now a possibility, but making it a reality requires EU and regional leadership, according to the WHO. Efforts are currently underway globally, evidenced by the explicit inclusion of hepatitis in Goal 3 of the Sustainable Development Goals and the forthcoming

WHO Global Health Sector Strategy on Hepatitis (GHSS) – the Global Hepatitis Strategy 2016-2021. The overall goal of the GHSS is to eliminate hepatitis as a health threat within the framework of universal coverage rather than as a specific disease intervention. To this end the Strategy focuses on stronger prevention and health system efforts with five strategic directions including: 1) information for focus and accountability 2) interventions 3) quality and equitable delivery 4) financing and 5) innovation. While reducing hepatitis as a health threat does not necessarily imply eradication, elimination is achievable with a scale-up of treatment and prevention services.

In order to eliminate hepatitis as a health threat, the Strategy sets impact targets of a 90% reduction in new cases of chronic HBV and HCV in addition to a 65% reduction in deaths. Some strategy interventions have already made significant progress, but others represent challenges, for example to reach the targets, 90% of those living with hepatitis B and C will need to be diagnosed and 90% of those put on treatment, which represents an enormous scale-up in testing and treatment.

Given current European political and social contexts, this scale-up is only possible through adopting a public health approach, through a focus on innovation and committed partnerships with government, civil society and the private sector, in addition to concrete and tailored actions by European national governments. All of this needs to be translated into national action plans, which will be discussed at the next World Health Assembly.

The cost of HCV elimination

The cost of treating the disease is a serious threat to the opportunity to eliminate HCV. However, modeling techniques show- taking into account estimates of the true cost of the disease- that HCV can become a rare disease in the next 20 to 25 years, with a significant budget commitment, but one that pales in comparison to the amount spent on treatment of HIV and many NCDs, for example and the cost of doing nothing.

For Europe, where public health systems assume the majority of the cost burden, the case for accepting the cost of eliminating HCV is made by considering the cost savings as well as the value of the health benefits gained. Modeling studies show that the cumulative disease burden over the next 35 years will decrease dramatically with the implementation of new therapies, and a sharp decline can be expected in the number of deaths. Thus, resources spent on HCV provide good value for money, given that high initial annual spending will give way to decreased costs in the medium term.

One potential option suggested for

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obtaining funds needed to expand HCV treatment is the creation of a European Hepatitis Fund⁽¹⁷⁾. Such a fund would receive money from donors and serve as a platform for negotiating prices with drug companies and managing cash flow. A Hepatitis Fund would serve to help countries manage the initial increase in health spending needed to combat the disease, with the benefit that later costs are recouped through health savings.

Current action on HCV at EU level

At the EU level, action on HCV is underway by the EC, which coordinates the response of member states to public health threats. Action includes engaging the EU Health Program, where some viral hepatitis activities are financed, particularly with regard to improving access to testing and access to care.

Other European action includes the EU HIV/AIDS Action Plan 2014-2016, which treats viral hepatitis as a co-infection, and the work of EU agencies that provide independent scientific advice. The EC has organized country visits to member states, and agencies such as ECDC and EMCDDA play a role in surveillance. Viral hepatitis is covered by surveillance, which is a requirement of EU member states; there are systems for early warning and outbreaks, which are followed up by the health security committee.

In terms of support for treatment⁽²²⁾, in 2014-2015 the European Medicines Agency authorized five new medicinal products that were subjected to accelerated procedure. The agency is also initiating a new mechanism whereby member states can purchase together to obtain better prices and conditions. Health and technology assessment can also benefit from being carried out in a common way among member states.

EU health systems sustainability

A major barrier to addressing HCV is sustainability of health systems and cost of treatment. As the 7th leading cause of mortality worldwide, encouraging policy efforts at national level and calls for political attention to hepatitis are important. With European health systems under financial stress, efforts aimed at key ministers and decision makers that come from NGOs, patient organizations, health professionals and civil society are key to raising awareness of the disease and ensuring it has a place on the policy agenda.

From the perspective of patients and advocacy groups, there is the sense that there has been more focus in Europe on producing abundant recommendations than on using or implementing them, as evidenced by the European Liver Patients' Association action plan on key recommendations at EU and national levels. The plan highlights the well-documented recommended focus areas

for HCV and HBV, which can be classified in terms of; 1) monitoring and data collection 2) awareness 3) prevention 4) testing and diagnosis 5) assessment and 6) treatment. In addition, any HCV strategy should include prevention, diagnosis and treatment, and should place patients at its core.

4. Good Practices in HCV Elimination at the National and Local Levels⁽²³⁻²⁹⁾

Despite the well-documented need for action to address the spread of HCV, the existence of detailed guidelines and strategies, and well identified barriers to care for high-risk groups, HCV is still a major public health challenge to be addressed in Europe. As a communicable disease with cross-border implications, best practices should be shared to support an overall coordinated continental response.

There are many cases of good practices in HCV strategies for policies, prevention, screening and treatment across Europe, including France, Germany, Scotland, Portugal, and The Netherlands. Countries have developed successful practices through political engagement, a commitment to research and the use of evidence to inform policies and programs, and a concerted focus on the most marginalized groups at increased risk for HCV, including drug users and prison populations.

France

A key challenge to HCV elimination is that, despite the fact that new treatments offer higher efficacy, most patients are entirely unaware of their infection. Putting emphasis on treatment obscures the fact that most of those infected are not screened. The wide range of differences by country in terms of HCV prevalence, diagnosis and treatment reflects low screening in many countries.

Screening guidelines should be revisited in the era of more effective treatments, moving from a strategy based on risk factors towards a birth cohort strategy or general population screening. In France in 2014, of an estimated 74,000 undiagnosed HCV and HBV patients age 18-80, 37% are age 70-80 (ages 60-80 are mostly women), and the majority of those 18-59 are men^(23,29). Thus the undiagnosed HCV population in France is mostly men under age 70. New French guidelines from 2014 emphasize a risk-factor based, targeted screening strategy in addition to population-based testing for HIV, HBV and HCV, focused on all men ages 18-59 and pregnant women at their first prenatal visit.

Germany

The German Action Plan on Hepatitis (2013) includes providing; 1) better information to drug users 2) sterile or

hygienic drug use paraphernalia 3) recruiting more addicts into therapy and 4) employing specially trained HCV nurses for patient monitoring. The plan is informed by research- for example the DRUCK study, a multi-site serobehavioral study of 2077 drug users in 8 cities, the conclusions of which reveal the reasons behind high HCV prevalence. The study showed frequent unsafe drug use, unknown infection status, gaps in knowledge about the means of transmission, and imprisonment as an element of the risk profile, among others. In providing information on the hidden population of drug users, this study and others have helped generate better knowledge of the population affected in order to inform hepatitis prevention efforts among drug users in Germany.

Scotland

Scotland has had considerable success in linking HCV patients to care. Scotland's Hepatitis C Action Plan (2006-2015) has prioritized patients with advanced fibrosis, under the assumption that curing those with moderate to severe fibrosis brings about greater impact. The action plan led to concrete gains in its six focus areas of prevention, diagnosis, treatment, prevalence, coordination and evaluation/ research monitoring.

The strategy has led to a 50% reduction in infection, an increase in the proportion of people diagnosed, greater numbers initiating treatment and a reduction in overall prevalence. The effort has been documented in scientific journals.

Scotland's approach prioritizes those with the most advanced or severe cases. However, this approach relies heavily on monitoring. Scotland has implemented a system to document individuals by disease stage, location, and treatment type. The system aggregates data to look at how many people are treated and their disease stage in order to support elimination of hepatitis C as a public health problem.

Portugal

The success of Portugal in effectively advancing its national agenda on HCV treatment illustrates many of the fiscal, political and social challenges faced by European countries in developing HCV policies. In 2011 Portugal faced many difficulties in addressing HCV, including low investment in public health, low number of identified chronic HCV patients as compared to estimated prevalence, outdated guidelines on diagnosis and treatment, no clear hospital referral network for HCV, and the high cost of new, innovative treatments. The context of economic crisis and cuts in services amidst the pressures of interest groups and activists created a highly charged political environment in which patients suffered without access to treatment.

Thanks to the efforts of the Ministry of

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Health and the coordinated work of a group of stakeholders that included doctors, patients, managers and health system representatives, a literature review and consensus paper was produced on the need for an overall focus on HCV elimination and new prevention policies, new financing and access models, lower prices from drug companies, a national action plan and a central patient registry. As a part of the resulting National Action Plan for Hepatitis C the Ministry of Health announced a new risk-sharing model for patient treatment, full funding for patients and creation of the registry. As a result, all of the identified HCV patients (13,015) were included in the new program, resulting in a decrease in the time from treatment request to authorization, over 8,000 HCV patients have been authorized for treatment, and two thirds have initiated treatment. To date 1,230 patients have been cured.

The Netherlands

The Netherlands demonstrates the effectiveness of strategies targeted at high-risk populations for addressing HCV with its “pragmatic tolerance approach” towards key vulnerable groups including drug users and prison populations.

Amsterdam’s harm reduction approach builds on what was begun in 1982 by the National Health Service programs that aimed to reduce drug users’ risk of harming themselves while building a trusting relationship with the most problematic people who use drugs (PWID). According to the Amsterdam Cohort Studies, since 1986, the incidence of HCV among PWUD has decreased dramatically⁽³⁰⁾. However, the study results show an increase in HCV incidence among HIV positive men who have sex with men (MSM)⁽³¹⁻³²⁾. Amsterdam’s current policy initiatives provide prevention, screening, linkage to care, treatment, social welfare and participation for all groups affected by HCV and HBV.

5. Conclusions: European Union and National Support for the Elimination of Viral Hepatitis in Europe⁽³³⁻⁴⁰⁾

Despite the well-documented need, HCV has struggled to become recognized as a public health priority in Europe. HIV, in contrast, has been significantly reduced in terms of incidence in Europe and serves as a model for promoting access, cooperation and partnership when faced with an outbreak of infectious disease. Questions arise about what the EU role should be in responding to those living with HCV and how to equally prioritize prevention.

Increasingly, EU member states are developing national plans on viral hepatitis. In addition, surveillance is being scaled

up with successes in prevention of all infections related to the healthcare setting and- in some member states- successes in access to treatment. However, there is still an urgent need to raise awareness and promote a better understanding of the epidemic to facilitate tailored policies, collaboration, and sharing of best practices. Improving EU national policies related to HCV is a priority for treating and eventually eliminating the disease.

In facing this challenge, member states count on the support of the ECDC. The ECDC works with member states to provide information, share good practices, help build capacity, and provide scientific advice. The organization coordinates an HCV surveillance program across EU/EEA countries, maintains a network of European scientific experts, supports countries in prevalence estimates, and provides risk estimates taking into account the characteristics of the European populations. As noted, any elimination strategy can only be successful with a focus on PWID as a key risk group⁽³⁶⁾. The ECDC directly provides evidence based guidance and technical support with a focus on key populations. As with any other policy area, the active participation of affected individuals and communities in the development of responses- in design, implementation and evaluation- is the most effective way to ensure that responses fit the needs of patients.

In addition to the difficulty in prevention and screening, the cost of treatment of HCV continues to be a major obstacle to European efforts to eliminate the disease. Countries will spend a considerable portion of their health budgets on costs related to HCV, whether treating the disease or treating liver-related associated diseases, which are costs that already accrue to the health system. Thus, HCV treatment is an investment that can be recovered in the future through health savings, however, the issue of political viability of making such an investment is still present in EU countries.

Currently scientific breakthroughs have made eliminating hepatitis C a possibility, with the potential to save lives and lead to a significant savings in societal and economic costs. The specific challenges of hepatitis C require holistic, people-centered, health system-wide approaches to disease awareness, prevention and integrated care and treatment with all stakeholders combining their diverse skills and resources in a unified response.

6. Presentation of the HCV Elimination Manifesto

On February 17, 2016, government representatives, policy makers, patients, medical associations and committed individuals gathered in Brussels at the EU HCV Policy Summit to express commitment to the elimination of HCV in Europe by 2030. The commitment to

elimination is based on a public health and a human rights approach, given that HCV is a life-threatening disease that affects millions in Europe.

The HCV Elimination Manifesto is the result of work and collaboration from a variety of stakeholder groups. It builds upon what has been done and sets the direction for a focus on needed future action to eliminate hepatitis C in Europe by 2030. Attendees were asked to assist or support the manifesto with concrete action in the key areas needed to move forward, including making hepatitis C a public health priority, ensuring involvement and participation of all stakeholders, developing integrated care and treatment pathways, prioritizing the link between hepatitis C and socially marginalized groups, harmonizing and improving surveillance, holding a European Hepatitis week, and promoting the Manifesto and monitoring the achievement of its objectives.

With much emotion the Manifesto was publicly presented on February 17, 2016; its seven key action areas were read by seven of the manifesto’s signatories in their native languages, reflecting the global nature of both the impact of HCV and commitment to its elimination.

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Manifesto Hepatitis C Elimination in Europe

“Our vision for a Hepatitis C-free Europe”



We, the signatories of this declaration, gathered in Brussels on the occasion of the first European Union HCV Policy Summit, on 17 February 2016, are committed to the elimination of hepatitis C in Europe.

- Hepatitis C is a life-threatening disease; it affects millions of people across Europe and has a significant morbidity and premature death burden¹;
- Today, scientific breakthroughs give us the unique opportunity to eliminate hepatitis C in Europe, averting a significant toll in terms of deaths and societal and economic costs;
- The specific challenges of hepatitis C require holistic, people-centred, health system-wide approaches to disease awareness, prevention and integrated care, with all stakeholders combining their diverse skills and resources in a unified response.

We share the vision that eliminating hepatitis C in Europe by 2030² will require us to:

1. Make hepatitis C and its elimination in Europe an explicit and adequately resourced public health priority, to be pursued using appropriate means at all levels – through collaboration between individual citizens, civil society organisations, researchers, the private sector, local and national governments, European Union institutions – including the Commission, ECDC, EMCDDA, the WHO Regional Office for Europe and other relevant regional bodies;
2. Ensure that patients, civil society groups 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;
3. Make the development of integrated care pathways a core component of hepatitis C elimination strategies, taking into account the specific health system barriers and other challenges related to the management of hepatitis C infection;
4. Pay particular attention to the links between hepatitis C and social marginalisation, and for all hepatitis C elimination-related activities to be consistent with fundamental human rights principles including non-discrimination, equality, participation and the right to health;
5. Strengthen efforts to harmonise and improve the surveillance of hepatitis C across the European Union, to inform and evaluate hepatitis C elimination strategies;
6. Introduce a European Hepatitis Awareness Week (the week of World Hepatitis Day) to hold intensive, coordinated awareness-raising and educational activities across Europe;
7. Review progress on achieving the objectives and goals set out in this manifesto on a regular basis and promote the manifesto at all relevant opportunities.

Endorsed by:



Continued on page 9...

(continued from page 8)

TO NOTE

In developing this Manifesto, the following documents were taken into consideration:

- World Hepatitis Summit, 2-4 September 2015, Glasgow
- Glasgow Declaration on Viral Hepatitis, September 2015
- World Health Assembly, Resolution 67.6 on Hepatitis, 24 May 2014
- WHO, Prevention and Control of Viral Hepatitis Infection: Framework for Global Action, 2012
- World Health Assembly, Resolution 63.18 on Viral Hepatitis, 21 May 2010
- Hepatitis B and C Public Policy Association, High Level Meeting “Economic crisis and healthcare – ensuring access to public health services: the case of hepatitis B and C”, 3-4 June 2014
- Hepatitis B and C Public Policy Association, Summit Conference on Hepatitis B and C in Mediterranean and Balkan Countries, 5-7 September 2012
- Hepatitis B and C Public Policy Association, Summit Conference on Viral Hepatitis, 14-15 October 2010, Brussels

References

1. The WHO estimates that there are 14 million people affected by hepatitis C across WHO European Region and various accounts report some 6 million living in the European Union alone
2. In line with the goals of the draft WHO Global Health Sector Strategy 2016-2021, November 2015

Hepatitis C-free Europe is possible by 2030

Press release 17.02.2016



BRUSSELS, 17 February 2016 – Europe's leading experts, medical specialists and patient advocacy groups on hepatitis announced their intention to work towards the elimination of Hepatitis C Virus (HCV) in Europe by 2030.

The 'Hepatitis C Elimination Manifesto' was presented at the first EU HCV Policy Summit, organised by the Hepatitis B and C Public Policy Association, and supported by the main European patient and clinician groups.

Signatories of the 'Hepatitis C Elimination Manifesto' pledge to:

- Make hepatitis C and its elimination in Europe an explicit public health priority to be pursued at all levels
- Ensure that patients, civil society groups and other relevant stakeholders are directly involved in developing and implementing hepatitis C elimination strategies
- Pay particular attention to the links between hepatitis C and social marginalisation
- Introduce a European Hepatitis Awareness Week

Vytenis Andriukaitis, Commissioner for Health and Food Safety, delivered a keynote speech at the event, commenting: "Hepatitis C has in the past been referred to as a "silent" epidemic within the European Union. It is high time that we brought this "silent" epidemic out of the shadows and into the light, so I welcome initiatives such as this Summit and the Elimination Manifesto to create momentum for action, for raising awareness and for stimulating discussion".

After twenty-five years of research, scientists have delivered the means to effectively cure hepatitis C, paving the way for elimination in Europe within the next decade. "What would have taken a hundred years for us to achieve, is now at hand! This is a unique opportunity, but political action is needed to make this happen", stated Prof Angelos Hatzakis, Co-Chair of the Hepatitis B and C Public Policy Association. "Our 'Elimination Manifesto' is a rallying platform for policymakers and advocates. If we act now, Europe will be hepatitis C free by 2030", continued Prof Hatzakis.

The specific challenges of hepatitis C require holistic, people-centred, health system-wide approaches to disease awareness, prevention and integrated care, with all stakeholders combining their diverse skills and resources in a unified response.

"Succeeding against hepatitis C in Europe is even more important given the current international crises and refugee flows towards our countries", explained Cristian-Silviu Buşoi, MEP, who continued: "Elimination strategies need to take into consideration the links between hepatitis C and marginalised groups, such as migrants, people who inject drugs and others."

"The Manifesto sets out our vision and commitment to eliminate hepatitis C in Europe", declared Prof Michael P. Manns, Co-Chair of the Hepatitis B and C Public Policy Association, "concrete actions at all levels must follow to achieve our goal". The Manifesto will be presented to national and local governments as well as to the European institutions to encourage action.

Signatories

The Elimination Manifesto is supported by the following organisations:

- European Liver Patients Association (ELPA)
- European Association for the Study of the Liver (EASL)
- Viral Hepatitis Prevention Board (VHPB)
- The Correlation Network
- The International Center for Migration Health and Development (ICMHD)
- The World Hepatitis Alliance (WHA)
- Hepatitis B and C Public Policy Association

About Hepatitis C in Europe

- Hepatitis C (HCV) is a **major public health problem** in Europe. In the EU more people die each year from HCV than from HIV.
- HCV is 7 times **more prevalent than HIV** in Europe.
- An estimated 15 million Europeans are chronically infected, including **5.5 million living in EU**; each year there are **27,000-29,000 newly diagnosed** HCV cases in the EU/EEA.
- Existing evidence shows that, for some European countries, **annual deaths from HCV have quadrupled over the past 20 years**.
- Even with Europe's generally good tracking of epidemics, HCV continues to spread undetected as a "**silent pandemic**" as patients often have no symptoms during the first 20-30 years.
- HCV is the **leading cause of liver transplantation** in adults;

healthcare costs increase exponentially with the progression of liver disease, which goes in parallel with patients' suffering.

- In addition, **indirect costs** related to **loss of productivity** make the economic burden of the disease even more significant.

About Elimination

- Elimination of a disease is intended as the reduction to zero of the incidence of a specified disease in a defined geographical area as a result of deliberate efforts.
- HCV elimination was made possible by recent therapeutic advances, which have made HCV curable in the majority of instances - cure rates have progressed from 6% in 1991 (first interferon approved treatment for HCV) to over 90% in 2014 (directly acting antivirals introduced).
- Holistic approaches and strategies to improve overall awareness, increase testing for those at risk and link infected individuals to specific care pathways need to be developed.

About the "Hepatitis C Elimination Manifesto"

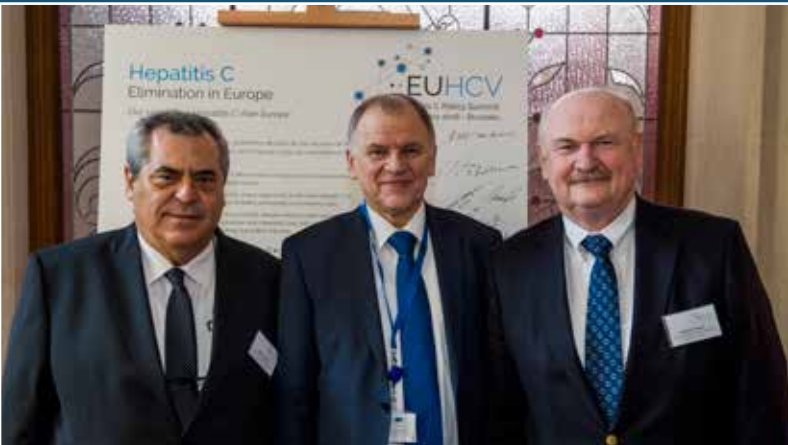
The main authors of the "Hepatitis C Elimination Manifesto" are:

- Prof Jeffrey V. Lazarus, University of Copenhagen (Denmark)
- Prof Mark Thursz, Imperial College, London (UK)
- Prof Pierre Van Damme, Viral Hepatitis Prevention Board, Vaccine and Infectious Disease Institute, Antwerp (Belgium)
- Prof Angelos Hatzakis, Athens University Medical School (Greece)

About the first EU HCV Summit

The Summit was organised by the Hepatitis B & C Public Policy Association in partnership with the European Association for the Study of the Liver (EASL), the European Liver Patients Association (ELPA), the Correlation Network, and the International Centre for Migration, Health and Development (ICMHD) with the financial support of AbbVie, Gilead, BMS and MSD. The Summit, which was attended by 140 policymakers and stakeholders from across Europe and beyond, was officially endorsed by the European Parliament's Friends of the Liver Group and the EMCDDA-European Monitoring Centre for Drugs and Drug Addiction.

Highlights from EU HCV Brussels Summit



European Health Commissioner Dr. Vytenis Andriukaitis with the HCV Policy Summit Co-Chairs



The first call of the Elimination Manifesto



Prof. Helena Cortez-Pinto, EASL explains why we must and can eliminate HCV



Dr. Stefan Wiktor WHO on the Elimination of hepatitis and the 1st WHO Global Strategy



Judith Kiton-Darling MEP signs the Elimination Manifesto

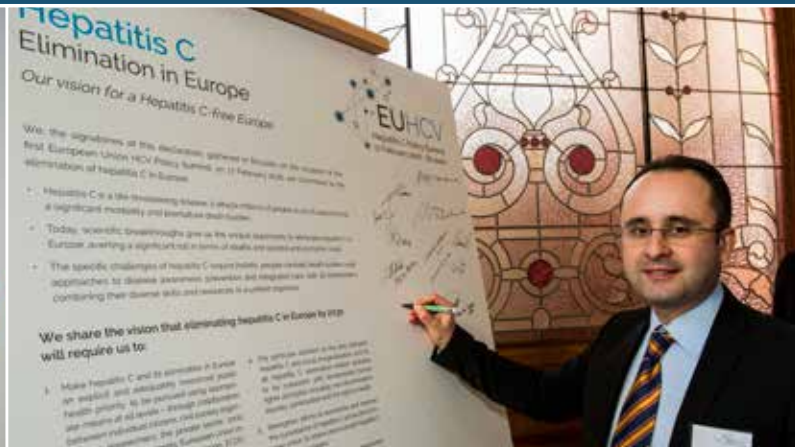


ELPA President Dr Tatjana Reic illustrates the HCV patient's perspective

Highlights from EU HCV Brussels Summit



EU Health Commissioner Dr. Vytenis Andriukaitis addresses the HCV Policy Summit



Dr CS Busoi MEP signs the Elimination Manifesto



The Elimination Manifesto



Dr. Yazdan Yazdanpanah presents Best Practice France: Screening



Dr. Homie Razavi states that it is feasible to eliminate HCV in the EU



Prof. A. Hatzakis, Co-Chair HepBCPPA kicks off the 1st EU HCV Policy Summit



Prof. Pierre Van Damme, Prof Angelos Hatzakis and Prof Jeffrey Lazarus, authors of the Elimination Manifesto

Highlights from EU HCV Brussels Summit



George A. Papandreou calls for the creation of a fund to eliminate Hepatitis C in Europe



George A. Papandreou signs the Elimination Manifesto



John F. Ryan DG Food and Health European Commission on EU Support for HCV Action



Dr. Cristian-Silviu Busoi MEP on why HCV must and can be eliminated in Europe



Goodbye from the attendees of the 1st EU HCV Policy Summit



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