

# Timeline to

# SUCCESS

**O**n 1 March 2016, people in Australia living with hepatitis C will have equal access for the first time to all-oral, interferon-free, direct-acting antiviral treatments which lead to cure in more than 90% of cases. In an historic moment on 20 December 2015, Australian Health Minister Sussan Ley announced the new drugs are to be listed on the Pharmaceutical Benefits Scheme from 1 March, subsidised by the Australian Government.

The hepatitis C communities and their representative organisations advocated strongly all the way for approval and listing of these long-awaited treatments. Hepatitis NSW led the push for Equal Treatment Access: so that all people in Australia can receive the new treatments, without restriction based on treatment history or liver disease stage.

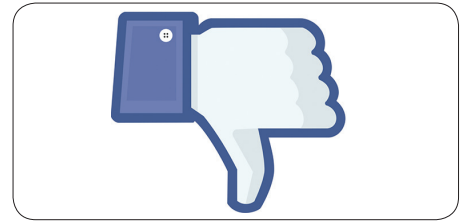
Hepatitis NSW sincerely thanks, in particular, our **C me Community Advocates** for the big part they played in this treatments advocacy and to the many people affected by hepatitis C who signed the **ETA Petition**, wrote submissions to the PBAC, wrote to and met with Parliamentarians, gave evidence at hearings and wrote submissions to the Parliamentary Inquiry, appeared in our ETA video and gave TV, radio and newspaper interviews.

Hepatitis NSW congratulates and thanks the Hon Sussan Ley MP, Minister for Health for her strong support for all people in Australia living with hepatitis C. What follows is a timeline of how advocacy and other events shaped this historic outcome.



## **December 2013** **Sofosbuvir approved by FDA**

US patients get first access to sofosbuvir. There is public outcry when the cost is revealed to be US\$84,000 for a 12 week course of treatment. Some health insurers and US state governments try to limit their exposure by restricting access to treatment for people with limited liver disease to reduce cost.



## **July 2014** **PBAC recommends simeprevir, but rejects sofosbuvir**

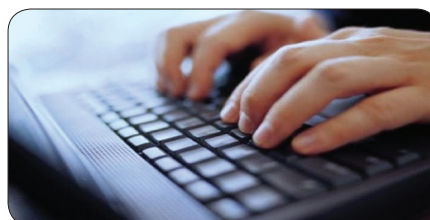
The PBAC rejected the submission for the listing of sofosbuvir on the Pharmaceutical Benefits Scheme (PBS) for the treatment of chronic hepatitis C on the basis of unacceptably high and likely underestimated cost-effectiveness and the high and likely underestimated impact on the budget. Simeprevir is, however, recommended.

## 2013

## 2014

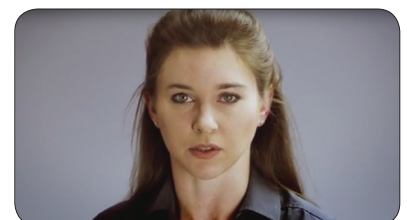
## **May 2014** **Hepatitis NSW calls for public submissions to PBAC: Round 1**

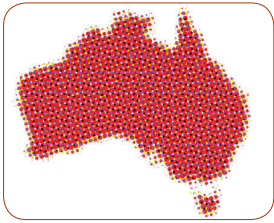
Hepatitis NSW calls on members of the public to make submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) in support of new drugs sofosbuvir and simeprevir. The PBAC is delighted although perhaps a bit unprepared for the level of public interest in their process.



## **August 2014** **Equal Treatment Access**

Five people with hep C, four hours of filming, three afternoons spent editing for a two minute video clip produced by one brilliant film maker JJSsplice, all to illustrate the case for **Equal Treatment Access**. A picture is worth a thousand words but on social media a good movie can be a powerful call to action.





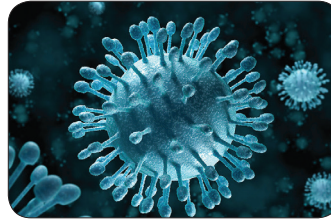
**October 2014**  
**Why is Australia so far behind?**

Over 110,000 people with hep C have already been cured in the United States and Europe where sofosbuvir has been approved. Which leaves Australians living with hepatitis C asking: Why are we so far behind?



**26 November 2014**  
**Local & International support for ETA petition**

1,300 people sign the ETA petition in just ten days. Hundreds of Australians and people from all over world including the US, UK, India, Vietnam, New Zealand, Canada, Singapore, the Philippines, Israel, Norway, the Netherlands and Saudi Arabia support the petition because they believe in Equal Treatment Access.



**12 December 2014**  
**New treatments could eradicate hepatitis C**

Experts believe new treatments could mean the eradication of Hepatitis C "within our lifetimes". But they say their vision will only become reality if there's a worldwide effort to make the new remedies available to all. The global call comes as top clinicians from around Europe gather ahead of the first Five Nations Conference on HIV and Hepatitis in London.



**22 January 2015**  
**Commonwealth Parliament holds inquiry into hep C**

The Commonwealth Parliament's House of Representatives Standing Committee on Health conducts an inquiry into hepatitis C. This inquiry calls for public submissions on important hep C matters including: prevalence and testing; treatment in primary care, acute care, Aboriginal Medical Services and in prisons; long and short term impacts of hepatitis C; prevention of new infections; stigma and discrimination. Hepatitis NSW helps community members to make submissions, and on 22 January, we support half a dozen people tell their own experiences of living with hepatitis C to a public hearing in Sydney.

**2014**



**2015**



**13 November 2014**  
**ETA petition launched**

Hepatitis NSW Campaigns Coordinator, David Pieper, launches the online Equal Treatment Access petition. Hepatitis Australia and the other State and Territory Hepatitis organisations jump on board and share it with people living with hepatitis C across Australia. Partners from across the Blood Borne Virus Sector, including NUAA, also lend a hand.

**1 December 2014**  
**Small Step forward as simeprevir is listed on PBS**

The Australian Government lists simeprevir on the PBS. Simeprevir will go on to benefit a small number of people then waiting for treatment, with use limited given it still required the use of interferon injections. However, the much larger gains which are possible with other new interferon-free drugs, such as sofosbuvir, continue to be denied to Australians living with chronic hepatitis C.

**8 January 2015**  
**New Health Minister**

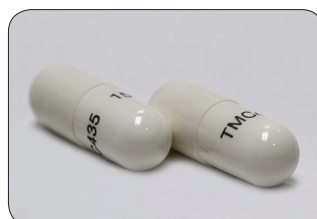
Sussan Ley, MP for Farrer, is appointed as Federal Health Minister replacing Peter Dutton. The ETA petition has reached over **3,600 signatures**.



**28 January 2015**  
**PBAC to reconsider sofosbuvir, and consider other new treatments: Round 2**

Three new hep C treatments (asunaprevir, daclatasvir, ledipasvir + sofosbuvir and sofosbuvir) are on the agenda for the March meeting of the PBAC, as well as sofosbuvir (again). Hepatitis NSW encourages community members to take this first opportunity since the rejection of sofosbuvir last July let the PBAC know that all Australians living with hep C deserve **Equal Treatment Access**.

**EQUAL TREATMENT ACCESS**





### 10 March 2015 PBAC meets to consider hep C drugs

Hundreds of community members have made PBAC submissions in support of sofosbuvir, asunaprevir, daclatasvir and Harvoni for the treatment of 230,000 Australians living with hep C. Hepatitis NSW CEO Stuart Loveday, and community member and C me advocate Bill Lehane (above), have the rare opportunity to directly address Committee members, and explain just why these drugs are so important to more than 80,000 people living with hepatitis C in NSW alone.



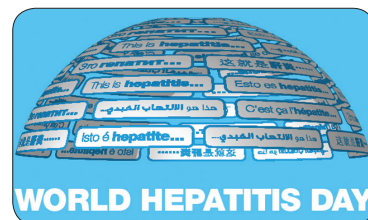
### April 2015 ongoing Limited access through trials, and compassionate access schemes

With the new drugs recommended by the PBAC but with an uncertain wait until PBS listing, the main options for people trying to access them within Australia is through clinical trials, although these are now thin on the ground, or, for people with advanced liver disease, through compassionate access schemes. All hep C pharmaceutical companies seeking PBS listing offered these programs, although the numbers were small (especially when compared to the more than 230,000 people waiting for treatment access overall).



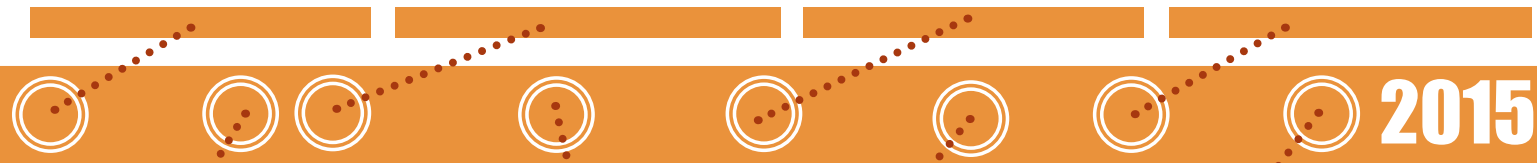
### 20 May 2015 Health Minister shows first sign of support

Health Minister Sussan Ley tells her local paper that she "will support recommendations for several new hepatitis C treatments to be listed on the Pharmaceutical Benefits Scheme". Ms Ley told *The Border Mail* "she would begin working toward their inclusion on the PBS after the July meeting".



### 28 July 2015 World Hepatitis Day (WHD)

Hepatitis NSW, Hepatitis Australia and other state and territory hepatitis organisations say that it's Time For Action to stop rising death toll from viral hepatitis. Globally, the World Hepatitis Alliance highlights the alarming statistic that 4,000 people die every day from hepatitis-related liver disease. Hepatitis NSW's key message is that "Now is the time for all Governments to help ensure all people living with hepatitis B and C who need treatment are able to access it".



### 27 April 2015 Positive recommendations from PBAC

**Good news!** The PBAC recommends that new hepatitis C treatments sofosbuvir, sofosbuvir/ledipasvir and daclatasvir/sofosbuvir should be listed on the PBS. But there's a catch: acceptable prices for these drugs still need to be negotiated between the Government and the companies involved. Government then needs to agree to list them on the PBS, which means we could be months, or even years, away from PBS listing.

### 15 May 2015 Greg Jefferys blogs about personal impor- tation of hep C meds

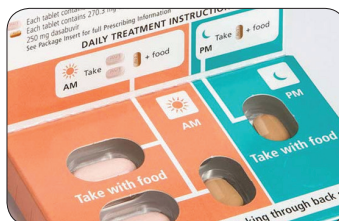
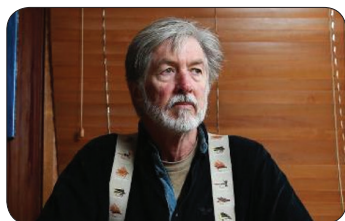
Frustrated at the high prices of sofosbuvir internationally and the lack of availability in Australia, Tasmanian Greg Jefferys heads to India to investigate potential sources of generic versions of sofosbuvir to cure his hep C. He blogs his journey in the hope that the information he discovers will be helpful to other people who also want to pursue personal importation, and that it put pressure on the big drug companies to lower their prices.

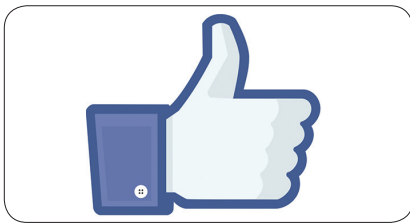
### 1 June 2015 More new treatments on the PBAC agenda: Round 3

Another new treatment called Viekira Pak is on the agenda for the July meeting of the PBAC. Hepatitis NSW once again encourages people to make a submission telling PBAC why it should be approved – and despite an understandable level of 'submission-writing fatigue', many community members answer the call (thank you!). More treatments mean more choice for people with different genotypes, different levels of cirrhosis and different treatment histories, as well as those who are co-infected with HIV or hep B.

### 22 August 2015 FixHepC opens for business

Tasmanian Dr James Freeman and his father (also a doctor) set up **FixHepC Buyers Club** to provide affordable treatment for hepatitis C in Australia for around \$2,000. The Club assists Australians to import the Approved Pharmaceutical Ingredient (API) in sofosbuvir, ledipasvir and daclatasvir from China and have them compounded (made into tablets) in Australia. Taking advantage of the regulatory framework in Australia, where it is legal for a patient to import a 12 week supply of medication for their own use, the Buyers Club assisted people who were not prepared or able to wait for PBS listing to navigate this process.





### 24 August 2015 PBAC Recommends Viekira Pak

More good news! Another interferon-free drug combination has been recommended for inclusion on the PBS. This makes four interferon-free drugs/ combinations supported by the PBAC. But, Australians are STILL waiting for the first interferon-free hepatitis C treatment option to be made available on the PBS. Hepatitis NSW calls for Government to act as this situation is unacceptable, and it is unconscionable.



### October 2015 Equal Treatment Access Petition delivered

The online ETA petition, containing over 5,000 signatures and hundreds of comments, was delivered to Federal Health Minister Sussan Ley, together with a cover letter urging her, and the Federal Government, to list new hepatitis C treatments on the PBS urgently. In that letter we also reiterated the need for these new treatments to be made accessible without restriction based on treatment history or liver disease stage so that as many people can benefit from them as possible.



### 20 December 2015 Turnbull government to spend \$1 billion on hepatitis C 'miracle cures' for all

The best news of all! Sussan Ley announces \$1 billion over 5 years in funding for new treatments for hepatitis C – sofosbuvir, sofosbuvir+ledipasvir and daclatasvir will all be listed on the PBS from 1 March 2016. The move will make Australia one of the first countries in the world to publicly subsidise the drugs for their entire population of people with hep C, no matter what the condition of a patient's liver. No listing date is yet proposed for Viekira Pak.

2015



2016



### 1 October 2015 Time for Action – Time for new cures campaign

Hepatitis Australia, Hepatitis NSW, state and territory hepatitis organisations and other groups from across the sector write an open letter to Health Minister Sussan Ley indicating the urgent need to end the impasse, and to list the new hep C drugs on the PBS, so that the process of saving lives – and ultimately ending the hepatitis C epidemic in Australia – can begin.



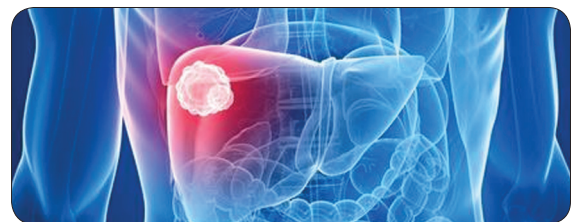
### October - November 2015 Community joins Time for New Cures call

In the absence of action from Federal Government, Hepatitis NSW supports the nation-wide social media campaign providing images to share on Facebook & Twitter to let the Health Minister, the Hon Sussan Ley MP, know that it's #TimeforAction. We also encourage the community to make its voice heard by writing to their local Member of Parliament to support the urgent listing of new hep C cures on the PBS. We provide a link to help find local MPs and a draft letter to download and send.



### 1 March 2016 PBS Listing

The day that the community has been waiting for is finally here – new, all oral, direct acting antiviral interferon-free hepatitis C treatments are available on the Pharmaceutical Benefits Scheme (PBS). Now is the time for people living with hepatitis C to talk to their doctor or liver specialist to find out how you can benefit from the new drugs.



### Still to come

The treatment landscape will change forever on 1 March 2016, but that doesn't mean it will stand still. Hepatitis NSW will continue to advocate for Viekira Pak to be listed on the PBS, as an additional option depending of different genotypes or coinfection with HIV. We hope to see more hepatitis C direct acting antiviral drugs in the PBAC pipeline during 2016, while sofosbuvir+velpatasvir (a pan-genotypic treatment option) has already been submitted for US FDA approval. As always, Hepatitis NSW will push for these drugs to be accessible to all, so as many people as possible can be cured of hepatitis C.