



Importation of generic hepatitis C therapies: bridging the gap between price and access in high-income countries

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Lancet 2017; 389: 1268–72

Published Online

November 7, 2016

[http://dx.doi.org/10.1016/](http://dx.doi.org/10.1016/S0140-6736(16)32051-7)

[S0140-6736\(16\)32051-7](http://dx.doi.org/10.1016/S0140-6736(16)32051-7)

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An estimated 80–150 million people are infected with hepatitis C virus (HCV) worldwide, with the highest prevalence in low-income and medium-income countries of Africa and Asia. HCV-related liver disease mortality is estimated to be half a million per annum.^{1,2}

Chronic HCV treatment was interferon based for two decades, with the addition of ribavirin,³ pegylated-interferon,⁴ and initial protease inhibitor direct acting antiviral (DAA) therapies (telaprevir, boceprevir)^{5,6} subsequently providing stepwise improvements in the rate of sustained virological response (SVR). Despite these improvements, interferon-containing HCV therapy uptake remained low in most countries, ranging from less than 1% to a maximum of 5% of people with chronic HCV starting therapy each year.⁷ Fortunately, the past 5 years have seen a revolution in HCV therapeutic development, with the advent of interferon-free DAA therapies, which disrupt replication through inhibition of HCV protease, polymerase, and NS5A function.⁸ Simple (single daily dosing oral regimens), highly tolerable, short-duration (8–24 weeks) regimens with extremely high efficacy (cure rates >95%) have been developed and registered internationally. Used in various combinations depending on HCV genotypes and previous treatment exposure, these include: sofosbuvir and ledipasvir;^{9–11} paritaprevir, ritonavir, ombitasvir, and dasabavir with or without ribavirin;^{12–14} sofosbuvir and daclatasvir;^{15,16} elbasvir and grazoprevir;^{17,18} and sofosbuvir and velpatasvir.

There is clear evidence that HCV cure affects the risk of HCV-related liver disease and hepatocellular carcinoma.¹⁹ Early treatment might have greater benefit. Furthermore, as a result of the high efficacy and tolerance, and ease of delivery of these drugs, HCV treatment as prevention is being explored in some countries, particularly treatment of high-prevalence populations, such as people who inject drugs and incarcerated populations.²⁰ The broad implementation of these therapeutic regimens has the potential to dramatically affect the burden of HCV-related disease globally. Indeed, new HCV treatments have been deemed so important that some (sofosbuvir, daclatasvir) were added to the 2015 WHO Essential Medicines List along with a number of their combinations.²¹

High drug pricing for interferon-free DAA regimens (up to US\$93 000 per 12 week course) has limited broad implementation in the vast majority of settings, with restrictions based on liver disease stage generally introduced to reduce budget impact.²² Other restrictions, including those based on ongoing drug and alcohol use, have further limited access in many settings, particularly

within the USA.²² Even in high-income countries, there is considerable diversity in access to and pricing of new HCV therapies.

In the UK, spending on HCV treatment increased almost five-fold between 2014 and 2015, to £190 million. Estimates suggest that it would cost more than £4 billion to treat the estimated 214 000 people with chronic HCV in the UK at a cost of £20 000, so access has generally been restricted to those with advanced liver disease.²³ The Australian Government has allocated AUS\$1 billion to the Pharmaceutical Benefits Scheme to fund HCV DAA therapies for the next 5 years, with no restrictions based on liver disease stage. This is a volume-based pricing deal between the government and pharmaceutical companies.²⁴ Although details are not publicly available, it is understood that this deal is expected to provide treatment for approximately 60 000 individuals. However, there is also a risk-sharing arrangement in place, so that if more individuals are treated then the cost would be borne by the pharmaceutical companies rather than the by government, which would mean that the cost-per-treatment would fall. In the initial 5 months of the DAA programme (March–July, 2016), an estimated 26 360 patients initiated therapy, with possibly 40 000 to be treated in 2016, representing 17% of the total population with chronic HCV infection in Australia.²⁵

Patients who live in countries that do not have universal government funding schemes, or who do not fit specific criteria for subsidisation, must wait until these medicines are funded by their public or private insurers, or find other ways to access medicines such as through clinical trials, industry access schemes, or personal fundraising. All these means of accessing medicines are, however, ad hoc and many patients miss out. This not only affects the individuals concerned, but also greatly limits the public health effect of new HCV therapies.²⁶

In some lower-income countries, voluntary licenses have been issued, which allow generic versions of patented medicines to be manufactured, providing greater access to new HCV medicines. In India, 11 generic companies signed voluntary licenses with Gilead for sofosbuvir and ledipasvir plus sofosbuvir, and are permitted to supply these medicines to more than 100 low-income and middle-income countries.²⁸ However, this agreement explicitly prohibits supply to several middle-income and high-income countries. The resulting discrepancy between prices in high-income countries and those in lower-income countries can be taken advantage of by patients in wealthier countries. Patients may, for example, travel to countries where medicines are less expensive (so-called medical

tourism). Alternatively, they can import less expensive versions of the medicines that they need. Australia, for example, has legislation permitting individuals to import up to 12 weeks of unlicensed medicines at their own risk. While a prescription and consent are needed, no further regulatory oversight is required for most classes of medicines. Importantly for patients with HCV, a 12 week supply of medicines is generally sufficient for HCV treatment.

Before the commencement of the HCV treatment programme funded by the Australian Government in March, 2016, an estimated 1400 Australian patients received treatment with the assistance of FixHepC, a web-based platform for the importation of HCV therapies.²⁸ Through importation and compounding of the active pharmaceutical ingredients (APIs) for sofosbuvir, ledipasvir, and daclatasvir from India, patients were able to access a course of 12 weeks of therapy for AUS\$1500–2000—a fraction of the market price for these treatments. More recently FixHepC has sourced these medicines from generic companies in India and Bangladesh.

Importation schemes were supported by professional bodies such as Australasian Society of HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).²⁹ The ASHM released a position statement in October, 2015, which outlined their support for the new treatments, making recommendations about specific antivirals and the methods by which they may be procured—including purchase of these medicines from overseas or over the internet. In addition to having obvious appeal to people with HCV, importation schemes can have an indirect role in securing greater discounts within government and large payer-funded HCV treatment programmes.

This raises the question, why are large-scale personal importation schemes not more widely implemented? While importation per se is generally legal, in some settings there are regulations that preclude the importation or prescribing of cheaper imported medicines. The USA, like Australia, permits personal importation, but officially excludes importation of medicines from overseas that are cheaper than those that are available locally.³⁰ In some countries, while personal importation may be permitted, there can be limits regarding what medicines physicians can prescribe. For example, in Europe, prescribing off-label or unlicensed medicines on the basis of cost-saving alone is illegal, and the UK's General Medical Council supports this position.³¹ How well this is, and can be, policed is another matter. The FixHepC website provides access to DAA therapy to patients in the UK, overcoming this barrier by providing patients an online consultation with an Australian doctor, who provides prescriptions from Australia.

While safety is no doubt a major reason why many hold reservations about personal importations of medicines, it is also likely that economic factors and

political pressure play a part. For example, when Thailand issued a compulsory licence for some cancer drugs, the USA responded by downgrading their trading status.³² When France used its “Temporary Recommendations for Use” regulation to support the off-label use of Avastin for aged-related macular degeneration at a fraction of the price of the registered alternative, they faced stiff opposition from the European pharmaceutical lobby.³³ Although these cases are not examples of personal importation, they show that even governments aiming to provide access to affordable medicines for their citizens in goodwill can face stiff challenges from industry or foreign governments.

There are also barriers to organised forms of personal importation, such as FixHepC. For example, in Australia there seems to be unresolved legal, political, and operational complexities when it comes to large-scale forms of importation, in which physicians, exporters, prescribers, and compounding pharmacists collude to treat patients with cheaper, unlicensed versions of a medicine. This is no doubt, partly because of legitimate concerns about the purity of APIs, and the fact there is no guarantee that the manufacturing process meets national standards. Indeed, Australia's Therapeutics Goods Administration recently ordered the FixHepC website to cease advertising prescription-only medicines, and in response its operations have subsequently moved to Myanmar.³⁴ This order was, however, dated to May, 2016, after Australia had already started subsidising HCV medicines for the general public, and therefore would have had little effect on access.

Despite the reservations that many countries seem to have about personal importation schemes, the Australian experience suggests that, if done well, organised importation of unlicensed HCV medicines do not expose patients to unnecessary risks and provides access to effective therapies. In the recent Australian REDEMPTION study (n=412) using DAA HCV therapy accessed through the FixHepC website, outcomes were equivalent to those using branded treatments.³⁵ The quality of APIs was assessed with liquid chromatography, nuclear magnetic resonance, and mass spectroscopy. The interim week 12 SVR for genotype 1 HCV was 95% with imported sofosbuvir and ledipasvir or imported sofosbuvir and daclatasvir. The cohort included 28% of individuals with cirrhosis. Across all genotypes the SVR was 94%, showing equivalent clearance rates at one-hundredth the cost.³⁵

Whether or not countries choose to support personal importation schemes for legal, economic, and practical reasons, the fact is that there is demand for such schemes, and this demand is not specific to HCV therapy. A case in point is the *I Want PreEP Now* website, which provides recommendations and guidance to UK residents about how and where to buy generic versions of unsubsidised medicines for pre-exposure prophylaxis for HIV. Whereas the brand name medicine is available

For the *I Want PreEP Now* website see <http://www.iwantprepnnow.co.uk>

through private clinics at a cost of £400 for 30 pills, generic products are available through the website at a tenth of the price. And in the US state of Maine, laws passed in 2013 permitted residents to purchase cheaper medicines online from countries deemed to have equivalent or greater licensing regulations, until this state law was overturned in 2015 because it was deemed to compromise federal regulation.³⁶ This tension between what people seem to want, and what countries are willing to support, suggests that there must be strong moral and sociopolitical arguments both for and against personal importation.

Against such schemes, it could be argued that patients in high-income countries should not have access to cheaper medicines available in low-income countries because price discrepancies are legitimate responses to the ability of different markets to pay for medicines. Importing of medicines from low-income countries could compromise the discounting schemes provided to these countries if the practice becomes too widespread. This could mean that the most vulnerable patients suffer as pharmaceutical companies refuse to discount prices to protect their investments, or refuse to contribute to schemes such as the Medicines Patent Pool that aims to make medicines more accessible in low-income and middle-income countries (eg, Bristol-Myers Squibb has added daclatasvir to this pool).³⁷ It could also be argued that these practices undermine intellectual property laws and threaten current and future investment in drug development, which would have negative long-term consequences worldwide.

On the other hand, the fact that medicines can be sold at massive discounts in many parts of the world (and presumably not at a loss) calls into question the legitimacy of prices charged in many high-income countries—eg, in Egypt, sofosbuvir sells at a 99% discount to the US price,³⁸ and it has been estimated that HCV treatments could be manufactured for less than US\$200 per patient.³⁹ Although the issue of drug pricing is complex, and prices cannot be determined solely on the basis of manufacturing costs, concerns about the legitimacy of HCV drug prices have been buttressed by the results of a recent investigation of Sovaldi's pricing in the USA. The resulting US Senate Report concluded that Gilead aimed to set high pricing precedents in early launch markets and to set a high baseline price for successor products.⁴⁰ Additionally, it found that the price of Sovaldi was aimed at maximising revenue based on expectations of how payers would react to the price, rather than being connected to underlying costs of development, or investment returns. The Attorney-General of Massachusetts has threatened to take legal action against Gilead for the pricing of its medicines, arguing that it “may constitute an unfair trade practice”.⁴¹ In this regard it is worth noting that between 2013 and 2015, Gilead's sales revenue for Sovaldi and Harvoni was more than US\$31 billion, with \$19 billion of these products sold in 2015 alone.^{42,43}

It is important to keep in mind that the practice of personal importation is driven by the very same imperative that allows companies to charge high prices for life-saving medicines—hope. When hope fades because the cure is too expensive, no one can blame patients for seeking other avenues to access treatments. While it is not an ideal solution, and governments do have options available to them,²⁷ the case of HCV shows that under certain circumstances, personal importation can work as a stop-gap measure until better and longer-term solutions are found. We also need to keep in mind that the problem is a global one—although personal importation can provide hope to people in relatively wealthy countries, universal access will not be achieved in this way. While the cost of manufacturing DAAs is rapidly decreasing, raising the prospect that more people who need these treatments will be able to access them,⁴⁴ there are many other commercial forces at play, which mean that prices will not necessarily fall according to standard market logics.

The generic importation of HCV medication thus highlights the problems of drug cost, regulation, and access in both high-income and low-income countries. What is needed in this situation, where values conflict on so many levels, is greater clarity about the threshold at which the wellbeing of patients and societal health should outweigh corporate interests. To achieve this clarity, we need far greater transparency around why medicines cost the amount that they do. In cases where large populations of patients are denied access to life-changing medicines because of prices that cannot be justified, we need to have legal frameworks and mechanisms in place that allow patients to access these treatments (on a large scale if necessary) from elsewhere without fear of personal or societal repercussions. Where current legislation and regulation does not permit affordable access to life-saving treatments, governments need the political will to take action and change legislation. When mechanisms exist within current legal frameworks for accessing medicines, governments need to leverage them. In short, we need to replace amoral market-logic with fair-mindedness and compassionate rationality.

Contributors

NG conceptualised and wrote the Viewpoint. WL participated in the conceptualisation and writing of the Viewpoint. AH, RD, MD, and GJD critically reviewed and contributed to writing the Viewpoint.

Declaration of interests

NG is a researcher on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines. WL is Chief Investigator on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines. RD is an Assistant Investigator on a National Health and Medical Research Council funded project relating to improving funding of high cost cancer medicines. GJD is a consultant/advisor and has received research grants from Abbvie, Bristol-Myers Squibb, Gilead, Merck, Janssen, and Roche; personal fees from Gilead, Abbvie, Merck, Bristol-Myers Squibb, and Roche; and travel support from Abbvie, Merck, Bristol-Myers Squibb, and Roche. AH has received

personal fees from Gilead and Jansen. MD has received support for lecturing and travel bursary from AbbVie, Bristol-Myers Squibb, and MSD.

Acknowledgments

This work was supported by funding through a grant from the National Health and Medical Research Council. The funding body had no role in the writing or decision to submit for publication.

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