Access to hepatitis C medicines
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Abstract
Hepatitis C is a global epidemic. Worldwide, 185 million people are estimated to be infected, most of whom live in low- and middle-income countries. Recent advances in the development of antiviral drugs have produced therapies that are more effective, safer and better tolerated than existing treatments for the disease. These therapies present an opportunity to curb the epidemic, provided that they are affordable, that generic production of these medicines is scaled up and that awareness and screening programmes are strengthened. Pharmaceutical companies have a central role to play. We examined the marketed products, pipelines and access to medicine strategies of 20 of the world’s largest pharmaceutical companies. Six of these companies are developing medicines for hepatitis C: AbbVie, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Merck & Co. and Roche. These companies employ a range of approaches to supporting hepatitis C treatment, including pricing strategies, voluntary licensing, capacity building and drug donations. We give an overview of the engagement of these companies in addressing access to hepatitis C products. We suggest actions companies can take to play a greater role in curbing this epidemic: (i) prioritizing affordability assessments; (ii) developing access strategies early in the product lifecycle; and (iii) licensing to manufacturers of generic medicines.

Introduction
Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV). There is a global epidemic of hepatitis C, with approximately 185 million people estimated to be infected in 2005 and 350 000–500 000 deaths estimated annually. Over 80% of those affected by the disease live in low- and middle-income countries, especially in central, north and west Africa. Several middle-income countries such as Egypt, Nigeria and Pakistan have a high burden of hepatitis C. HCV is most often spread when infected blood enters the body. High-risk populations include intravenous drug-users and recipients of blood transfusions in poorly controlled environments; but the virus is also found in the general population. There are six genotypes of HCV, with distributions varying by region. It is possible for a person to be infected with multiple genotypes; 55–85% of people will develop chronic infection and about one third of these, if not treated, will eventually develop liver cirrhosis or hepatocellular carcinoma. Approximately 80% of newly-infected people are asymptomatic, which makes it difficult to diagnose and treat those who go on to develop chronic infection.

Newly-available drugs have revolutionized treatment. Previous treatments were poorly tolerated and had limited success. In contrast, the new treatments are easier to administer with shorter course durations and higher cure rates.

There are significant similarities between the hepatitis C epidemic and the human immunodeficiency virus (HIV) crisis of the late 1990s. Both involve global spread of underdiagnosed disease that can carry significant stigma and cause life-long illness and death. In both cases, there are new, effective products that can curb the global epidemic, held back by issues of affordability. The HIV crisis in South Africa resulted in a clash between civil society, government and the pharmaceutical industry, which led to the development of new ways of working, most notably with generic medicine manufacturers via licensing arrangements, creating a blueprint for access to medicine strategies for years to come.

However, there are also critical differences between the two epidemics that influence how pharmaceutical companies design access strategies. With HIV, the greatest disease burden is situated in lower-income countries and concentrated in sub-Saharan Africa. These countries were not viewed, in the earlier days of the epidemic, as representing market potential. In contrast, HCV is prevalent in some middle-income countries. Middle-income countries, though home to most of the world’s poor, have growing middle classes, representing economic opportunities for pharmaceutical companies. As a result, companies have an incentive to maintain exclusivity and charge higher prices in these markets. This may discourage donor, insurer and government investment in expensive new treatments, potentially slowing the adoption of new medicines.

Here we identify marketed products, product pipelines and access to medicine strategies of companies that make HCV medicines. We describe companies’ plans and activities to support greater access to HCV treatment and set out the criticisms, limitations and opportunities of these approaches. Finally, we present recommendations for companies to consider when developing access to medicine strategies for HCV-infected people.

Hepatitis C medicines
We used data from the Access to Medicine Index 2014 and other publicly-available sources such as company, patients’ organization and nongovernmental organization websites. The access to medicine index is created by the Access to Medicine Foundation, an independent initiative funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs, the United Kingdom Department for International Development, and the Dutch National Postcode Lottery. The Access to Medicine Foundation engages directly with 20 of the world’s largest pharmaceutical companies, requesting data biennially on selected activities via a detailed online questionnaire. The data are used to rank the companies in

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a biennial index. This index uses a set of 95 indicators to assess companies’ comparative performance in facilitating access to medicines in poor populations. A limitation of the data is that they are largely self-reported by companies. However, the data are reviewed by an external research partner (for the 2014 index, this partner was Sustainalytics, Amsterdam, Netherlands) and the foundation’s research team, clarified with companies and verified in some areas with external data sources.

**Current treatment**

The World Health Organization (WHO) released new treatment guidelines for hepatitis C infection in April 2014. Given that most patients will not realize they are infected, screening is recommended for high-risk groups. In countries with high prevalence and low infection control, screening is recommended for the whole population, if resources allow this. However, diagnostic capacity is limited in many low- and middle-income countries. The size of the population requiring treatment for hepatitis C is difficult to gauge. As noted, not all of the 185 million people estimated to be infected will progress to chronic infection, and there are no conclusive predictors of disease progression. There is currently no vaccine against HCV. In higher-income countries where treatment is available, all persons diagnosed with chronic HCV infection are typically considered suitable for treatment. In countries where treatment availability is constrained, treatment is prioritized for patients in more advanced stages of the disease. Different treatment regimens are advised depending upon HCV genotype. Older HCV treatments comprised combination antiviral therapy with pegylated interferon (weekly injections) and ribavirin (tablet, capsules, or oral solution). Pegylated interferon, which remains on patent in most countries, was added to WHO’s essential medicines list in 2013. Ribavirin is off-patent and generic versions exist. Two companies (Merck & Co. and Vertex) now have multiple drug approvals expected from alternative manufacturers.

**New treatment options**

New antiviral drugs for HCV infection, known as oral directly-acting antiviral agent therapies, are now available on the market. They are more effective, safer and better-tolerated than existing therapies: 90% of people are cured. The therapies are orally administered and have shorter treatment courses (12–24 weeks depending on regimen and genotype), which decreases monitoring requirements. Five currently-marketed therapies were added to WHO’s essential medicines list in 2015 (Table 1).

| Company          | Brand name             | Class                  | Market approval | EML |
|------------------|------------------------|------------------------|-----------------|-----|
| AbbVie           | Viekira Pak®           | Direct acting antiviral | 2014            | No  |
| AbbVie           | Viekirax®              | Direct acting antiviral | –               | Yes |
| AbbVie           | Exviara®               | Direct acting antiviral | –               | Yes |
| Bristol-Myers Squibb | Daklinza®         | Direct acting antiviral | –               | Yes |
| Gilead           | Sovaldi®               | Direct acting antiviral | 2013            | Yes |
| Gilead           | Harvoni®               | Direct acting antiviral | 2014            | Yes |
| Johnson & Johnson | Olysio®               | Direct acting antiviral | 2013            | Yes |
| Johnson & Johnson | Incivo®               | Direct acting antiviral | 2011            | Yes |
| Merck & Co.      | Victrelis®             | Direct acting antiviral | 2011            | No  |
| Merck & Co.      | Peginteron®            | Interferon             | 2001            | Yes |
| Roche            | Pegaspov®              | Interferon             | 2002            | Yes |
| Roche            | Copegus®              | Nucleoside analogue    | 2002            | Yes |

EM: European Medicines Agency; EML: World Health Organization Essential Medicines List; FDA: US Food and Drug Administration; INN: international nonproprietary name.

*Now discontinued in the US market.

Note: Only FDA and EMA drug registrations are tracked.

**Table 1. Currently marketed hepatitis C medicines from pharmaceutical companies, 2015**
Kadmon and Medivir AB (Stockholm, Sweden) are also involved in marketing HCV products.18

Table 1 and Fig. 1 show, respectively, currently marketed HCV products (FDA and EMA registrations only) and an overview of products in research and development, up to date at the time of this paper’s submission. Table 1 indicates the presence of several new products on the market. Fig. 1 summarizes the progress in development of HCV medicines, with many products in phase III of clinical trials. Future competition may play an important role in enhancing affordability, contingent on the relative efficacy of competitors and how broadly companies choose to register them.

**Access to medicine strategies**

For the 2014 access to medicine index, companies were asked to disclose plans for making HCV products available in low- and middle-income countries. We refer to these as company access strategies. Companies shared information about equitable pricing strategies (which take affordability into account for poor populations), voluntary licensing agreements, donations of products and capacity-building initiatives. Johnson & Johnson and AbbVie disclosed no access to medicine strategies. Several new HCV products and access strategies were launched after the period of analysis ended. A summary of the access strategies identified is provided in Table 2.

Disclosure of access to medicine strategies for products that were still under development was limited across in-house and collaborative projects. This may reflect intense competition in HCV medicines. Only Gilead disclosed access strategies for products under development, having agreed licensing conditions for two products before registration.

Access strategies are in place for two newly marketed products: sofosbuvir and ledipasvir (Gilead) and were also in place for boceprevir (Merck & Co, now discontinued). Three companies are active in pricing strategies (Gilead,
will place downward pressure on prices.

Merck & Co. and Roche). Only Gilead is currently actively licensing HCV products. In late 2014, Bristol-Myers Squibb announced an intention to engage in both licensing for HCV products and tiered pricing (in which different price points are set depending on the market in which the product is sold).

Discussion

Ensuring access to medicines is a joint responsibility of governments, companies, multilateral agencies and non-governmental organizations (NGOs). Pharmaceutical companies, being private entities, must also be able to justify their access to medicine activities to shareholders.

We have highlighted two key points of entry for pharmaceutical companies to help to address access to HCV medicines. First, affordability: the high prices attached to new medicines may be deterring donors (international or bilateral), health insurers and governments from committing sufficient funds to curbing the epidemic.9,10 Where drugs are paid for out-of-pocket, ensuring affordability is also critical. Second, generic manufacturers can scale up and distribute new medicines. Generating sufficient competition among generic manufacturers will place downward pressure on prices.

Affordability

Manufacturers of new HCV medicines will benefit from market exclusivity until around 2025.15 For Gilead, this monopoly has been magnified by the dominance of sofosbuvir. However, this lead will be increasingly challenged as other new entrants compete for market share. This effect is already being seen as prices for sofosbuvir in the United States are being increasingly discounted in the face of competition.

Companies should develop, with governments, mechanisms for significant price discounting based on rigorous, well researched, transparent assessments of affordability in low- and middle-income countries, clearly taking account of the needs and abilities of payers and the presence or absence of subsidies.

Separate pricing policies within countries can make sound business sense and improve access.21 In middle-income country markets with greater economic value to companies, private and public systems can be offered different brands and prices. This is known as market segmentation. Proposed strategies from Gilead for enforcing market segmentation of sofosbuvir requiring patient identification and limited dispensing were criticized for risking confidentiality and adherence.22 For poorer populations, high-volume, low-cost approaches may prove more profitable: in the United States, Gilead appears to be shifting to a higher-volume/lower-price model as competition from AbbVie intensifies.23,24

Gilead initially charged US$ 84 000 for a course of sofosbuvir in the United States. The lowest identified price for that treatment in a developing country was US$ 900 in Egypt.25 These prices are much higher than the drug’s production cost, which is US$ 68 to US$ 136 for a 12-week course.26 We were not able to estimate the research and development costs for this drug, and Gilead states publicly that they do not track this expenditure per product.27 High prices may be deterring bilateral, international and national funders from allocating funding at the scale required for the widespread rollout of new HCV treatments.

Generic partners

The lessons from scaling up HIV/AIDS medicines have shown that the capacity of generic medicine manufacturers to produce high-quality medicines and their knowledge of local regulatory requirements are important for manufacture, distribution and treatment. Equally important is the impact of sufficient competition from generic medicine manufacturers on prices: the average price of a first-line adult antiretroviral regimen dropped from US$ 414 per person per year in 2003 to US$ 74 in 2008.27

 Licensing can also make business sense. For example, efficiencies may exist in engagement with generic manufacturers who understand local regulatory requirements well, have an existing network of contacts with developing country governments and regulators and can rapidly scale up production. Manufacturers may derive income from the application of royalties to licence agreements, for example 7% royalties were attached to the licences agreed by Gilead for sofosbuvir.28

To date, Gilead is the only manufacturer of new HCV medicines to have completed agreements with generic medicine manufacturers. The number of manufacturers29 is, arguably sufficient to engender competition and the full agreements have been publicly disclosed.30 Although the scope of the licences appears broad, they do not include key middle-income country markets with high HCV burdens, such as Brazil, China, Georgia, Mexico, Thailand and Ukraine.31 Further, it is not yet clear on what scale generic manufacturers will enter the market, nor what discounts will be realized, though NATCO, Hyderabad, India, has disclosed a price of 19 900 Indian rupees for 28 400 mg tablets in Nepal.32 On a 12-week course of treatment, this equates to approximately US$ 900. So, although Gilead’s licensing activities represent leading practice among the companies included in the access to medicine index, this approach has limitations in geographic scope and improvements in affordability are not yet clear. Bristol-Myers Squibb has also announced its intention to engage with generic medicine manufacturers, detailing the geographic scope of future licences.
Regarding licensing, it is important that pharmaceutical companies agree to the most flexible terms possible, for example, minimizing royalties, not placing restrictions on supply of active pharmaceutical ingredients and allowing supply to as broad a range of countries as possible. This provides generic medicine manufacturers with the greatest potential to compete and keep prices low.

Market segmentation can broaden the geographic scope of licences. Where patent-holders may wish to retain monopoly over higher income segments, licences can limit markets generic manufacturers can sell to. GlaxoSmithKline and Pfizer, via their joint-venture Viiv Healthcare, have tested this approach in the context of HIV medicines with the Medicines Patent Pool, segmenting public and private markets for dolutegravir and introducing a tiered royalty structure that enabled the inclusion of more middle-income countries.

Plan access strategies early

Research-based companies should consider developing access strategies such as equitable pricing or voluntary licensing earlier in a product’s lifecycle (for example, in the later stages of research and development). This could reduce the time taken for products to reach those in need. In the case of voluntary licensing, agreeing terms with generic manufacturers early extends the time available for technology transfer, thereby enabling licencees to start production as soon after product registration as possible. Gilead has licensed medicines before product registration. To our knowledge, no other pharmaceutical company has engaged in pre-registration licensing for HCV products.

Supporting awareness and diagnosis

Since most HCV infections are initially asymptomatic, it is also important to raise sufficient awareness, reduce stigma, and build screening and diagnostic capacity to curb the epidemic. In addition to pricing and licensing, some companies disclosed details of programmes for supporting local screening and diagnostic capacity. It should be noted that such activities bring with them a significant risk of conflict of interest associated with direct contact with patient organizations or health-care professionals. Companies may seek to manage this conflict through the involvement of established NGOs and/or WHO, aligning with the needs of ministries of health and integrating with existing programmes.

Merck & Co. is building screening capacity in Latin America, aimed at reducing the time taken for results to be received. Likewise, Roche, with strength in diagnostics, is engaged in building screening capacity in central Europe, and has engaged in pre-registration licensing for HCV products.

Conclusion

It is clear that treatment of hepatitis C is undergoing a revolution. It is not enough however, to develop effective treatment. All actors in the global health community need to ensure that these new products are available, accessible and affordable for all in need. This goal ultimately requires a multi-actor, multi-pronged approach.

The lack of access strategies disclosed for products under development is concerning, especially those in phase II clinical trials, which bear the greatest chance of market entry. It is also concerning that some companies disclosed no access strategies for either currently marketed products or products in the pipeline.

As described, pharmaceutical companies have central roles to play, particularly with regard to ensuring affordability and voluntary licensing. The available evidence provided by companies so far suggests a need for more concerted, broader engagement in access strategies.

Competing interests: None declared.
Hepatitis C medicines

Danny J Edwards et al.

Policy & practice

Resumen

Acceso a los medicamentos para tratar la hepatitis C

La hepatitis C es una epidemia global. Se estima que, en todo el mundo, hay 185 millones de personas infectadas, la mayoría de las cuales viven en países de ingresos bajos y medios. Los recientes avances en el desarrollo de antivirales han producido terapias más efectivas, seguras y de mejor tolerancia que los tratamientos para la enfermedad existentes.

Estas terapias presentan una oportunidad para poner freno a la epidemia, siempre y cuando sean asequibles, aumentar la producción genérica de dichos medicamentos y reforzar los programas de sensibilización y detección. Las empresas farmacéuticas juegan un papel central. Se examinaron los productos comercializados, la producción de medicamentos généricos y las estrategias de acceso a dichos medicamentos para permitir el tratamiento de la hepatitis C.

Résumé

Accès aux médicaments permettant de soigner l’hépatite C

L’hépatite C est une épidémie mondiale. On estime à 185 millions le nombre d’individus infectés par ce virus dans le monde, la plupart vivant dans des pays à revenu faible ou intermédiaire. Les récents progrès dans la mise au point de médicaments antiviraux ont conduit à des traitements plus efficaces, plus sûrs et mieux tolérés que les traitements existants pour soigner cette maladie. Ces traitements permettraient de freiner l’épidémie, à condition que leur coût soit abordable, que la production de médicaments génériques soit intensifiée et que les programmes de sensibilisation et de dépistage soient renforcés. Les sociétés pharmaceutiques ont, à cet égard, un rôle central à jouer.

Résumé

Access to Hepatitis C Medications

Hepatitis C is a global epidemic. It is estimated that 185 million people are infected with the virus, mostly in low- and middle-income countries. Recent advances in the development of antivirals have led to more effective, safer and better-tolerated treatments than existing ones for this disease. These treatments could slow the epidemic, provided they are affordable, that generic production be increased and that programmes of awareness and screening be strengthened. Pharmaceutical companies play a central role in this.

Summary

Access to Hepatitis C Medications

Hepatitis C is a global epidemic. It is estimated that 185 million people are infected with the virus, mostly in low- and middle-income countries. Recent advances in the development of antivirals have led to more effective, safer and better-tolerated treatments than existing ones for this disease. These treatments could slow the epidemic, provided they are affordable, that generic production be increased and that programmes of awareness and screening be strengthened. Pharmaceutical companies play a central role in this.

Zusammenfassung

Zugang zu Medikamenten für die Behandlung der Hepatitis C

Die Hepatitis C ist eine globale Epidemie. Schätzungen zufolge sind weltweit etwa 185 Millionen Menschen von diesem Virus betroffen, die überwiegend in Ländern mit niedriger und mittlerer Einkommenskategorie leben. In den letzten Jahren wurden effektivere, sicherere und verträglichere Therapien entwickelt, indem Medikamente gegen die Hepatitis C entwickelt wurden. Diese Therapien bieten eine Möglichkeit, die Epidemie zu bremsen, sofern sie wirtschaftlich verfügbar sind, die Produktion von Generika aufgeweitet wird und die Programme der Sensibilisierung und der Screening-Studien verstärkt werden. Pharmazeutische Unternehmen spielen eine zentrale Rolle in diesem Prozess.

摘要

丙型肝炎药物的可及性

丙型肝炎是一种全球性流行病。据估计, 全世界约有 1.85 亿人受到感染，其中大多数人居住在中低收入国家。目前，抗病毒药物研制取得了新进展，推出了新疗法。该疗法比现有的疾病疗法更加有效、安全且耐受性更高。如果这些疗法价格实惠、这些药物的仿制药生产规模扩大并且公众意识和筛查项目增强，此类疗法就为抑制该流行病提供了一种可能。

制药公司在其中发挥着核心作用。我们调查了世界上最大的 20 家制药公司销售的产品、渠道和药物可及性策略。其中六家公司正在研制丙型肝炎药物: 艾伯维 (AbbVie)、百时美施贵宝 (Bristol-Myers Squibb)、吉利德 (Gilead)、美国强生 (Johnson & Johnson)、默克集团 (Merck & Co) 和罗氏 (Roche)。这些公司采用一系列的方法支持丙型肝炎治疗，包括定价策略、自愿授权、能力建设和药物捐赠。我们概述了这些公司在解决丙型肝炎产品可及性方面所采取的措施：一、将负担能力评估放在首位；二、在产品生命周期各阶段制定药物可及性策略；三、向仿制药制造商提供授权。
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