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Hepatitis C Virus (HCV) - Market Insights, Epidemiology, and Market Forecast - 2030

https://marketpublishers.com/r/H092B2E8DCF0EN.html
Date: December 2020
Pages: 305
Price: US$ 6,950.00 (Single User License)
ID: H092B2E8DCF0EN

Abstracts

This report can be delivered to the clients within 24 Hours

DelveInsight's 'Hepatitis C Virus (HCV) - Market Insights, Epidemiology, and Market Forecast—2030' report delivers an in-depth understanding of the HCV, historical and forecasted epidemiology as well as the HCV market trends in the United States, EU5 (Germany, France, Italy, Spain, and United Kingdom), and Japan.

The HCV market report provides current treatment practices, emerging drugs, HCV market share of the individual therapies, current and forecasted HCV market size from 2017 to 2030 segmented by seven major markets. The Report also covers current HCV treatment practice/algorithm, market drivers, market barriers, and unmet medical needs to curate the best of the opportunities and assesses the underlying potential of the market.

Geography Covered

The United States

EU5 (Germany, France, Italy, Spain, and the United Kingdom)

Japan

Study Period: 2017–2030

Hepatitis C Virus (HCV): Disease Understanding and Treatment Algorithm

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Hepatitis C Virus Overview

Hepatitis C is a viral infection that causes liver inflammation and damage, sometimes leading to serious liver disorder. HCV spreads through contaminated blood or body fluids. High-risk settings include IDU and the transfusion of unscreened blood and blood products, unsafe injection practices, unsafe health care. Other possible but less well-characterized risk exposures include tattoos and piercings, needle sticks, and unsafe/traumatic sexual practices.

HCV can range from a mild illness lasting a few weeks to a serious, long-term illness. HCV can be acute or chronic. Acute HCV occurs within the first 6 months after the patient is exposed to HCV. Around 55-85% of infected persons develop chronic HCV infection. Chronic HCV can be a lifelong infection if left untreated. Chronic HCV can cause serious health problems, including liver damage, cirrhosis (scarring of the liver), liver cancer, and even death. Most patients with newly acquired HCV do not exhibit symptoms of infection within the first 6 months. For people who develop symptoms, they usually happen 2–12 weeks after exposure to the HCV and can include yellow skin or eyes, not wanting to eat, upset stomach, throwing up, stomach pain, fever, dark urine, light-colored stool, joint pain, and feeling tired. Most chronic hepatitis C people do not have any symptoms or have only general symptoms like chronic fatigue and depression.

HCV is distinguished into different categories called genotypes based on similar genes. HCV genotypes are 1 (1a and 1b), 2, 3, 4, 5, and 6. In the United States, genotypes 1, 2, and 3 are the most common. Genotype 3 is the second most common HCV subtype in the world and most hard to treat because of the rapid progression of liver disease, increased rates of steatosis (non-alcoholic fatty liver disease), and a higher risk for cancer (hepatocellular carcinoma).

Hepatitis C Virus (HCV) Diagnosis

HCV is diagnosed based on the patient's medical history, a physical exam, and blood tests. If a viral infection is confirmed, doctors may suggest additional tests to check the condition of the liver.

Initial testing for the diagnosis of hepatitis C infection uses serologic assays that detect human antibodies generated as a response to HCV infection. Blood tests for HCV include screening tests for antibodies to the HCV virus, HCV RNA test, Genotype test,

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etc.

In Chronic HCV, doctors may recommend additional tests to find out how much liver damage the patient has, or to rule out other causes of liver disease. These tests may include blood tests, Imaging Tests (Transient elastography, Ultrasound, MRI, and CT Scan), and Liver function Tests (ALT, AST, ALP, and total bilirubin). If the liver is damaged due to inflammation, enzymes pass out of the liver into the bloodstream, making ALT and AST levels higher than normal. The doctor may also recommend a liver biopsy if blood tests or imaging studies suggest the patient might have a liver problem. A biopsy can determine the extent of scarring, or fibrosis, in a liver affected by viral hepatitis

Hepatitis C Virus Treatment

New infection with HCV does not always require treatment, as the immune response in some people will clear the infection. However, when HCV infection becomes chronic, treatment is necessary.

The goal of hepatitis C treatment is a cure. HCV can be treated with antiviral medicines that attack the virus and can cure the disease in most cases. Several newer medicines, called direct-acting antiviral medicines, have also been approved to treat HCV. The four classes of DAAs, include NS5B nucleotide inhibitors, NS5B non-nucleoside inhibitors, NS5A replication complex inhibitors, and NS3/4A protease inhibitors (PI).

Harvoni (ledipasvir/sofosbuvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets), and Zepatier (elbasvir/grazoprevir) are the DAAs approved for different genotypes of HCV.

Pan genotypic treatments are drugs suitable for all genotypes of HCV. These drugs may simplify treatment by removing the need for genotype testing. Pan-genotypic regimens are recommended as first-line treatment for people with chronic hepatitis C infection. These include Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir and pibrentasvir), and Vosevi (sofosbuvir/velpatasvir/voxilapresvir).

HCV Epidemiology

The HCV epidemiology division provides insights about historical and current HCV patient pool and forecasted trends for every seven major countries. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of

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key opinion leaders. This part of the DelveInsight report also provides the diagnosed patient pool and their trends along with assumptions undertaken.

Key Findings

In the year 2017, the total prevalent case of HCV was 8,257,162 cases in the 7MM which are expected to grow during the study period, i.e., 2017–2030.

The disease epidemiology covered in the report provides historical as well as forecasted HCV epidemiology [segmented as Total Prevalent Cases of HCV, Total Diagnosed Cases of HCV, Gender-specific Cases of HCV, Age-specific Diagnosed Cases of HCV, Genotype-specific Diagnosed Cases of HCV, Diagnosed Cases of HCV by Impact on Liver and Treated cases of HCV] in the 7MM covering the United States, EU5 countries (Germany, France, Italy, Spain, and the United Kingdom), and Japan from 2017 to 2030.

Country Wise- HCV Epidemiology

Estimates show that the highest cases of HCV in the 7MM were in the United States, followed by Japan, Italy, Spain, France, Germany, and the United Kingdom in 2017.

> In the United States, the total number of prevalent cases of HCV was 3,251,471 cases in the year 2017 which are expected to grow during the study period, i.e., 2017–2030.
>
> In the year 2017, the total prevalent cases of HCV were 3,108,919 cases in EU-5 which are expected to grow during the study period, i.e., 2017–2030.
>
> In Japan, the total number of prevalent cases of HCV was 1,896,771 cases in the year 2017 which are expected to grow during the study period, i.e., 2017–2030.

HCV Drug Chapters

The drug chapter segment of the HCV report encloses the detailed analysis of HCV marketed drugs and late stage (Phase-III and Phase-II) pipeline drugs. It also helps to understand the HCV clinical trial details, expressive pharmacological action, agreements and collaborations, approval and patent details, advantages and

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disadvantages of each included drug, and the latest news and press releases.

HCV Approved Drugs

Mavyret (Glecaprevir and Pibrentasvir)/AbbVie

Mavyret is a pan-genotypic, once-daily, ribavirin-free, co-formulated next-generation HCV treatment including glecaprevir (broad-genotypic NS3/4A protease inhibitor) and pibrentasvir (NS5A inhibitor). Glecaprevir-pibrentasvir is the first pan-genotypic NS3/4A protease inhibitor-NS5A inhibitor combination to be approved that offers a potent ribavirin free option for the vast majority of patients with chronic hepatitis C, including a potential eight-week option for non-cirrhotic patients with renal disease or HIV co-infection. This drug is not an option for patients with decompensated cirrhosis given the presence of the protease inhibitor.

Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)/Gilead Sciences

Vosevi is the first pan-genotypic fixed-dose tablet that includes medications from three different HCV antiviral classes, specifically for patients with hepatitis C who were previously treated with certain advanced hepatitis C regimens, but could not achieve a functional cure. It is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C genotype with or without cirrhosis (compensated) who have previously been treated with an HCV regimen. Vosevi contains an active ingredient sofosbuvir, the medicine that has helped transform HCV treatment, combined with 2 additional medicines Velpatasvir and Voxilaprevir creating a highly effective HCV treatment.

Epclusa (sofosbuvir/velpatasvir)/Gilead Sciences

Epclusa is a pan-genotypic drug used to treat adults and children 6 years of age and older or weighing at least 37 lbs (17 kg) with chronic (lasting a long time) HCV genotype 1, 2, 3, 4, 5, or 6 infections without cirrhosis or with compensated cirrhosis and with advanced cirrhosis (decompensated) in combination with ribavirin. It also provides a much-needed option for patients with HCV genotype 3 infections. Epclusa contains a combination of sofosbuvir and velpatasvir. Sofosbuvir and velpatasvir are antiviral medications that prevent HCV from multiplying in the body.

Harvoni (ledipasvir and sofosbuvir)/Gilead Sciences

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Harvoni is a fixed-dose combination containing ledipasvir and sofosbuvir for oral administration. Sofosbuvir is a nucleotide analog HCV polymerase inhibitor, and it blocks the polymerase enzyme which the virus must use to reproduce. Ledipasvir is an HCV NS5A replication complex inhibitor that interferes with another protein HCV uses to reproduce. The fixed-dose combination of ledipasvir-sofosbuvir provides an effective and well-tolerated one-pill once-a-day option for treatment of genotypes 1, 4, 5, and 6 chronic HCV infection. This direct-acting antiviral regimen was the first FDA-approved interferon- and ribavirin-free regimen to treat hepatitis C.

Note: Detailed Current therapies assessment will be provided in the full report of HCV

HCV Emerging Drugs

CC-31244 (Cocrystal Pharma)

CC-31244 is an investigational, oral, non-nucleoside inhibitor (NNI). It is a potential best-in-class pan-genotypic inhibitor of NS5B polymerase for the treatment of hepatitis C infection. It has the potential to be an important component in an all-oral ultra-short duration HCV combination therapy. It has been designed and developed using the Company's proprietary structure-based drug discovery technology to have a high barrier to drug resistance and to be a highly potent, selective NNI that is active against all HCV genotypes (1-6) with low-level cytotoxicity in multiple cell types. Currently, CC-31244 is under development and has recently completed its phase IIa stage in the US.

AT-777 (Atea Pharmaceuticals)

AT-777 is a novel NS5A inhibitor, being developed as a treatment for HCV. AT-777 is a purine nucleotide prodrug, which is being developed as an orally administered, direct-acting antiviral therapy for the treatment of patients with HCV. The use of nucleoside and nucleotide analogs to inhibit the viral RNA polymerase, thereby preventing propagation of the virus, is a well-documented and historically successful approach to the treatment of various viral diseases, including HCV infections.

Other than the previously mentioned candidates, AT-527 and AT-777, Atea Pharmaceuticals is also developing AT-787 as the lead candidate for the treatment of HCV patients. AT-787 is Atea's proprietary pan-genotypic product candidate. This direct-acting antiviral is a single fixed-dose tablet that combines AT-527 and AT-777 (purine nucleotide prodrug NS5B polymerase inhibitor and novel NS5A inhibitor, respectively) that has potent pan-genotypic activity against HCV replication in vitro. AT-787 is

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believed to have the potential to offer a short duration protease-sparing regimen for HCV-infected patients with or without cirrhosis. Due to this potential, Atea Pharmaceuticals has announced that rather than AT-527 and AT-777, AT-787 is the selected product candidate for the treatment of HCV.

Note: Detailed emerging therapies assessment will be provided in the final report.

HCV Market Outlook

Currently, treatment strategies for HCV mainly include Direct-Acting Antiviral agents. The development of new generation DAAs with much higher SVR rates has dramatically improved the prospects for people infected with HCV. DAAs directly target the HCV in different ways to stop it from reproducing. There are four classes of direct-acting antivirals that combine in various ways to make up the different HCV DAA treatments. NS3/4A protease inhibitors work by blocking a viral enzyme (protease) that enables the HCV to survive. NS5A Inhibitors block a virus protein, NS5A, which HCV needs to reproduce. Non-Nucleoside NS5B Polymerase Inhibitors inhibit HCV from reproducing. Nucleoside and Nucleotide NS5B Polymerase Inhibitors directly target the HCV to inhibit making copies of itself in the liver. Oral antiviral medications include Zepatier (elbasvir and grazoprevir), Harvoni (ledipasvir and sofosbuvir), Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Mavyret (glecaprevir and pibrentasvir), Epclusa (sofosbuvir and velpatasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir).

At present, some companies have indulged themselves in initiating clinical trials that investigate new treatment options or studying how to use existing treatment options better. Current ongoing trials evaluate combinations of antivirals with high genetic barriers and investigate optimal treatment doses and durations. Key players such as Cocrystal Pharma (CC-31244), Atea Pharmaceuticals (AT-527, AT-777, and AT-787), PRISM Pharma and Ohara Pharmaceuticals (PRI-724), GeneCure Biotechnologies (HCVax (Therapeutic HCV vaccine)), and several others are investigating their candidates for the management of HCV in the 7MM. Companies like Medivir are investigating their candidate in the early stages of clinical development.

Key Findings

The HCV market size in the 7MM is expected to change during the study period 2017–2030. The therapeutic market of HCV in the seven major markets was USD 10,445 million in 2017 which is expected to decline during the study period

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(2017–2030). According to the estimates, the highest market size of HCV is found in the United States followed by Japan in the year 2017.

The United States Market Outlook

In 2017, the total market size of HCV therapies was USD 6,929 million in the United States which is expected to decline in the study period (2017–2030).

EU-5 Countries: Market Outlook

In 2017, the total market size of HCV therapies was USD 2,330 million in the EU-5 countries which is expected to decline in the study period (2017–2030).

Japan Market Outlook

The total market size of HCV therapies in Japan was USD 1,187 million in 2017 which is expected to decline in the study period (2017–2030).

HCV Pipeline Development Activities

The drugs which are in pipeline include:

CC-31244 (Cocrystal Pharma)

AT-527 (Atea Pharmaceuticals)

PRI-724/OP-724 (PRISM Pharma and Ohara Pharmaceuticals)

AT-777 (Atea Pharmaceuticals); AT-787 (Atea Pharmaceuticals)

HCVax/Therapeutic HCV vaccine (GeneCure Biotechnologies)

Note: Detailed emerging therapies assessment will be provided in the final report.

HCV Drugs Uptake

Currently, the HCV market is almost entirely dominated by direct-acting antiviral agents (DAAs) which represent a revolution in HCV drug discovery. DAAs were developed to

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improve the SVR rates, reduce adverse events, and improve adherence to therapy among HCV patients. Among DAAs, the majority of the market is currently dominated by Mavyret, Epclusa, and Harvoni. Among emerging therapies, Cocrystal Pharma (CC-31244) and Atea Pharmaceuticals (AT-787) are evaluating the potential of their regimens in the HCV market.

Access and Reimbursement Scenario in HCV Therapies

Glecaprevir–pibrentasvir was recommended by NICE in 2018, within its marketing authorization, as an option for treating chronic hepatitis C in adults, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit. Glecaprevir–pibrentasvir is suitable for all genotypes and has a shorter treatment duration than most other direct-acting antiviral treatments. Also, Elbasvir–grazoprevir was recommended by NICE, within its marketing authorization, as an option for treating genotype 1 or 4 chronic hepatitis C in adults.

KOL-Views

To keep up with current market trends, we take KOLs and SME’s opinion working in the HCV domain through primary research to fill the data gaps and validate our secondary research. Their opinion helps to understand and validate current and emerging therapies treatment patterns or HCV market trends. This will support the clients in potential upcoming novel treatment by identifying the overall scenario of the market and the unmet needs.

Competitive Intelligence Analysis

We perform Competitive and Market Intelligence analysis of the HCV Market by using various Competitive Intelligence tools that includes – SWOT analysis, PESTLE analysis, Porter’s five forces, BCG Matrix, Market entry strategies, etc. The inclusion of the analysis entirely depends upon the data availability.

Scope of the Report

The report covers the descriptive overview of HCV, explaining its causes, signs and symptoms, pathophysiology, and currently available therapies.

Comprehensive insight has been provided into the HCV epidemiology and treatment in the 7MM.

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Additionally, an all-inclusive account of both the current and emerging therapies for HCV is provided, along with the assessment of new therapies, which will have an impact on the current treatment landscape.

A detailed review of the HCV market; historical and forecasted is included in the report, covering drug outreach in the 7MM.

The report provides an edge while developing business strategies, by understanding trends shaping and driving the global HCV market.

Report Highlights

In the coming years, the HCV market is set to change due to declining patient populations due to high DAA cure rates, lower average net selling price due to payers pressure; which would compress the size of the market to enable the drug manufacturers to penetrate more into the market.

The companies and academics are working to assess challenges and seek opportunities that could influence HCV R&D. The therapies under development are focused on novel approaches to treat/improve the disease condition.

Major players are involved in developing therapies for HCV.

A better understanding of disease pathogenesis will also contribute to the development of novel therapeutics for HCV.

Our in-depth analysis of the pipeline assets across different stages of development (Phase III and Phase II), different emerging trends, and comparative analysis of pipeline products with detailed clinical profiles, key cross-competition, launch date along with product development activities will support the clients in the decision-making process regarding their therapeutic portfolio by identifying the overall scenario of the research and development activities.

HCV Report Insights

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Market Attractiveness

Market Drivers and Barriers

Key Questions

Market Insights:

What was the HCV Market share (%) distribution in 2017 and how it would look like in 2030?

What would be the HCV total market size as well as market size by therapies across the 7MM during the study period (2017–2030)?

What are the key findings of the market across the 7MM and which country will have the largest HCV market size during the study period (2017–2030)?

At what CAGR, the HCV market is expected to decline in the 7MM during the study period (2017–2030)?

What would be the HCV market outlook across the 7MM during the study period (2017–2030)?

What will be the resultant market size in the year 2030?

How would the market drivers, barriers, and future opportunities affect the market dynamics and subsequent analysis of the associated trends?

HCV patient types/pool where unmet need is more and whether emerging therapies will be able to address the residual unmet need?

How emerging therapies are performing on the parameters like efficacy, safety, route of administration (RoA), treatment duration, and frequencies based on their clinical trial results?

Among the emerging therapies, what are the potential therapies which are expected to disrupt the HCV market?

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Epidemiology Insights:

What are the disease risks, burdens, and unmet needs of the HCV?

What is the historical HCV patient pool in the seven major markets covering the United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan?

What would be the forecasted patient pool of HCV in the 7 major markets covering the United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan?

What will be the growth opportunities in the 7MM concerning the patient population about HCV?

Out of all the 7MM countries, which country would have the highest prevalent population of HCV during the study period (2017–2030)?

At what CAGR the population is expected to grow in the 7MM during the study period (2017–2030)?

What are the various recent and upcoming events which are expected to improve the diagnosis of HCV?

Current Treatment Scenario and Emerging Therapies:

What are the current options for the treatment of HCV?

What are the current treatment guidelines for the treatment of HCV in the US, Europe, and Japan?

How many companies are developing therapies for the treatment of HCV?

How many therapies are developed by each company for the treatment of HCV?

How many emerging therapies are in the mid-stage and late stages of

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development for the treatment of HCV?

What are the key collaborations (Industry–Industry, Industry-Academia), Mergers and acquisitions, licensing activities related to the HCV therapies?

What are the recent novel therapies, targets, mechanisms of action, and technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for HCV and their status?

What are the key designations that have been granted for the emerging therapies for HCV?

What is the global historical and forecasted market of HCV?

Reasons to buy

The report will help in developing business strategies by understanding trends shaping and driving the HCV market.

To understand the future market competition in the HCV market and Insightful review of the key market drivers and barriers.

Organize sales and marketing efforts by identifying the best opportunities for HCV in the US, Europe (Germany, France, Italy, Spain, and the United Kingdom), and Japan.

Identification of strong upcoming players in the market will help in devising strategies that will help in getting ahead of competitors.

Organize sales and marketing efforts by identifying the best opportunities for the HCV market.

To understand the future market competition in the HCV market.

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