



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency advises on compassionate use of sofosbuvir

Conditions of use defined for patients with chronic hepatitis C infection before or after liver transplantation

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has given an opinion on the use of sofosbuvir, a medicine for chronic (long-term) hepatitis C virus (HCV) infection, in a compassionate-use programme. It is the third time a compassionate-use programme has been assessed at the European Union (EU) level.

Such programmes, set up at the national level, are intended to give patients with a life-threatening, long-lasting or seriously disabling disease who have no available treatment options access to treatments that are still under development and that have not yet been authorised. An application for authorisation of sofosbuvir was submitted by Gilead in April 2013. While it is currently under evaluation by the CHMP, Sweden has requested a CHMP opinion on the conditions under which early access to sofosbuvir in combination with other agents could be given specifically for patients before or after liver transplantation.

HCV infection is a major European public health challenge. It occurs in between 0.4% and 3.5% of the population in different EU Member States and is the most common single cause of liver transplantation in the EU.

There is currently no standard-of-care therapy available for patients with chronic HCV infection awaiting liver transplantation or for those who have undergone liver transplantation. For most of these patients, there are currently no approved treatment options. Many patients with HCV infection in the pre- and post-transplant setting are therefore in urgent medical need of therapy to prevent graft reinfection or to treat recurrent HCV infection in the graft.

The opinion concerns the use of sofosbuvir as part of a compassionate-use programme, for the treatment of adults infected with chronic HCV who are also:

- actively on the waiting list for liver transplantation and require treatment to prevent graft reinfection with HCV;



- or who have undergone liver transplantation and have aggressive, recurrent HCV infection resulting in progressive and worsening liver disease and are at high risk of death or decompensated liver failure within 12 months if left untreated.

The aim of the CHMP assessment and opinion on a compassionate-use programme of new medicinal products is to ensure a common approach, whenever possible, regarding the criteria and conditions of use under Member States' legislation. The opinion provides recommendations to the EU Member States that are considering setting up such a programme, and its implementation is not mandatory. In addition to describing which patients may benefit from the medicine, it explains how to use the medicine and gives information on safety. The assessment report and conditions of use of sofosbuvir in this setting will be published shortly on the Agency's website.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A questions-and-answers document on the compassionate use of medicines in the European Union can be found here:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500069898.pdf
3. More information on compassionate use and programmes already assessed can be found here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000293.jsp&mid=WC0b01ac058007e691
4. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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