EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2016
EMA/630308/2016
Committee for Medicinal Products for Human Use (CHMP)

# Scientific conclusions and grounds for the variation to the terms of the marketing authorisation

Active substance(s): sofosbuvir

Procedure No. EMEA/H/C/PSUSA/00010134/201512

Period covered by the PSUR: 06/06/2015-05/12/2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for sofosbuvir, the scientific conclusions of CHMP are as follows:

Regarding the risk of bradycardia, further analyses indicated that this risk can occur when sofosbuvir is given with another direct-acting antiviral and amiodarone. In particular, interaction between sofosbuvir + simeprevir and amiodarone has also been identified. Since the existing wording restricted the warning only to the use of sofosbuvir + daclatasvir and amiodarone, it became outdated and had to be modified. Furthermore, patients who also take other medications known to cause bradycardia or those with underlying cardiac comorbidities and/or advanced liver disease were considered to be potentially at increased risk of symptomatic bradycardia with coadministration of amiodarone, based on post-marketing reports.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal product(s) containing sofosbuvir were warranted.

## Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for sofosbuvir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sofosbuvir is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.