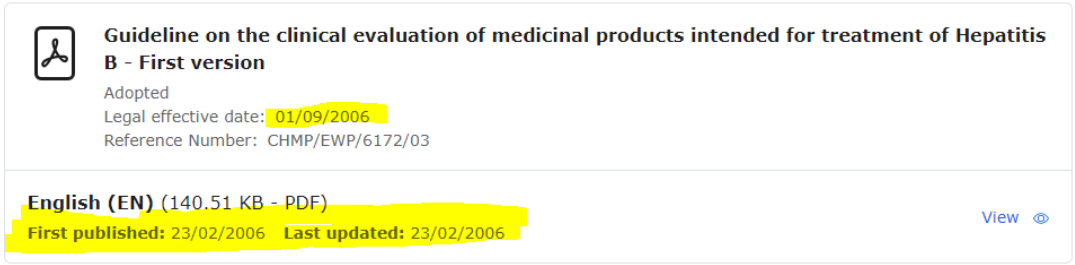
Concept Paper:
Revision of the EMA Guideline on the “Clinical evaluation of medicinal products intended for the treatment of Hepatitis B” (CHMP/EWP/6172/03)

HBV Forum 12 Meeting

Presented by Stephanie Buchholz on 03 June 2024
SNE, Public Health Threats department, EMA

Reasons for the guideline revision



Guideline on the clinical evaluation of medicinal products intended for treatment of Hepatitis B - First version

Adopted
Legal effective date: 01/09/2006
Reference Number: CHMP/EWP/6172/03

English (EN) (140.51 KB - PDF)
First published: 23/02/2006 **Last updated:** 23/02/2006
View

[Guideline on the Clinical Evaluation of Medicinal Products intended for Treatment of Hepatitis B (europa.eu)]

- Current Hepatitis B guideline (CHMP/EWP/6172/03) was **published in September 2006**
  - Addresses clinical study designs and endpoints applying to **Nucleos(t)ide analogues** and **interferons**
  - The treatment goal of **functional cure** has evolved → **changed** the **development landscape** of agents

→ Current guidance **does not address** agents with **other mechanisms of action** and **combination regimens** aiming at achieving **functional cure** of CHB infection.

- **Combined endpoint** of sustained suppression of HBV DNA and sustained HBsAg loss → **accepted** as **surrogate markers** for efficacy

→ **Change of acceptable** and **recommended primary endpoints** for clinical trials

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Topics to be revised/added

- **Clinical trial requirements** including trials that aim to demonstrate the efficacy of treatments aiming at **achieving functional cure**, including finite and combination treatment regimens.
- Update **recommendations for primary efficacy endpoints** to include endpoints relevant to achieving sustained viral suppression or functional cure.
- **Efficacy and safety considerations** when **stopping suppressive NUC treatments** in clinical trials aimed at evaluating regimens intended to achieve functional cure.
- **Considerations specific** to the development of agents with **novel mechanisms of action**.
- **Statistical analyses** in trials that evaluate **finite treatment regimens**.
- **Definitions** of HBV cure, diagnostic criteria, and patient characteristics.

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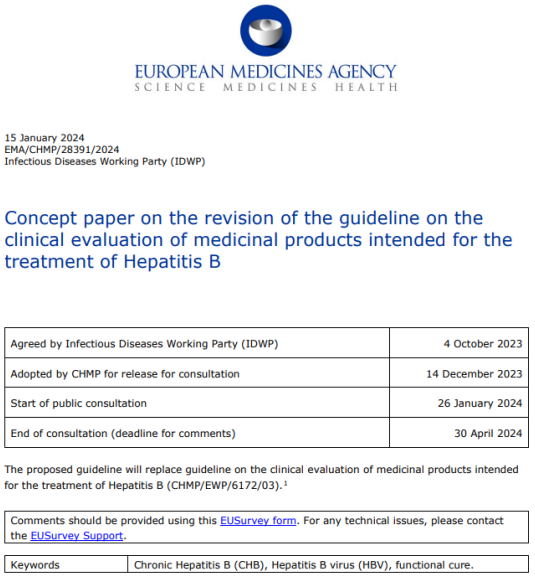
Current status

- The concept paper is currently out for **public consultation**
- Deadline for comments: **30 April 2024**
- Comments are **currently revised** by the Drafting group
- Upcoming awaited **EASL HBV clinical treatment guideline** and **publications** will be considered

Link to the **EMA concept paper:**

- Concept paper HBV adopted at PROM Jan2024 (europa.eu)
- **Finalisation** of **Draft guideline** in **2025**



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 January 2024
EMA/CHMP/28391/2024
Infectious Diseases Working Party (IDWP)

Concept paper on the revision of the guideline on the clinical evaluation of medicinal products intended for the treatment of Hepatitis B

Agreed by Infectious Diseases Working Party (IDWP)	4 October 2023
Adopted by CHMP for release for consultation	14 December 2023
Start of public consultation	26 January 2024
End of consultation (deadline for comments)	30 April 2024

The proposed guideline will replace guideline on the clinical evaluation of medicinal products intended for the treatment of Hepatitis B (CHMP/EWP/6172/03).[1]

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	Chronic Hepatitis B (CHB), Hepatitis B virus (HBV), functional cure.

Any questions?

Further information

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