26 October 2022

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Re: Notification of "withdrawn product"

Gilead Submission No: ADV-22-21056

Dear Sir/Madam,

Please find herewith enclosed our notification for a

- √ Centrally authorised medicinal product in accordance with Article 13 and 14b of Regulation 1027/2012
- □ Nationally Authorised medicinal product in accordance with Article 23a and 123 of Directive 2012/26/EC

Product Name: Hepsera; INN: Adefovir Dipivoxil; MAH: Gilead Sciences Ireland UC;
EV Code: PRD1612276, PRD1612286, PRD4141149, PRD3458789, PRD3458661, PRD3458333, PRD3458662, PRD3458332

To take the following action(s):

- □ Cease the marketing of a medicinal product (permanently or temporarily)
- □ Suspend the marketing of a medicinal product
- □ Withdraw a medicinal product from the market
- √ Request the withdrawal of a marketing authorisation
- □ Not to apply for the renewal of a marketing authorisation

I declare that the reason(s) for such action(s) are:

- □ Based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC;
- √ Not based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC.

I herewith confirm that together with this cover letter an Excel spread sheet (template EMA/445787/2013) entitled Gilead Sciences – Hepsera Notification Report Table is submitted containing all the required information related to the medicinal product concerned.

Yours sincerely,

[redacted]

[redacted]

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