



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on GVP XVI rev3

PCWP/HCPWP joint meeting

Presented by Núria Semis-Costa on 21 September 2021
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An agency of the European Union



Update GVP XVI rev3

- Feedback from meeting in June 2020 incorporated
 - Terminology, use of tools...
- Draft published for public consultation early 2021
- Deadline comments April 2021 – 700 comments received on module alone
- Still analysing... halfway there
- Expect to publish guidance Q2 2022
- In the meantime: GVP XVI.AddIII on Pregnancy prevention plans adopted by PRAC
 - We will initiate consultations right away



Any questions?

Further information

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