1) Good pharmacovigilance practices (GVP) updates with relevance for PV writers

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp)

- Guideline on good pharmacovigilance practices (GVP): Module V – Risk management systems (Rev. 2). Last updated: 30/03/2017. Effective date: 31/03/2017

- Guideline on good pharmacovigilance practices (GVP): Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev. 2). Last updated: 30/03/2017. Effective date: 31/03/2017

- Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations II: Biological medicinal products. Last updated: 15/08/2016. Effective date: 16/08/2016

- Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev. 2). Last updated: 04/08/2016. Effective date: 09/08/2016

- Guideline on good pharmacovigilance practices (GVP) - Module VIII Addendum I – Requirements and recommendations for the submission of information on non-interventional post-authorisation safety studies (Rev. 2). Last updated: 08/08/2016. Effective date: 09/08/2016

2) Other EMA PV guidance updates with relevance for PV writers

- **Update RMP template (Rev. 2)**

  Guidance on the format of the risk management plan (RMP) in the EU – in integrated format (Rev. 2)

  Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp

- **Preparation of PSURs**

  Guidance document: Explanatory note to GVP Module VII

  Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/04/WC500225264.pdf

- **Assessment of PSURs**

  Guidance document: Assessors' Q&A guidance on PSUR single assessment (PSUSA)

  Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/04/WC500225265.pdf

- **Off-label use**

  Reflection paper on collecting and reporting information on off-label use in pharmacovigilance (DRAFT)
  Public consultation closed: 29/04/2016

  Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/04/WC500205499.pdf

- **Medication errors**
  - Good practice guide on recording, coding, reporting and assessment of medication errors.
    First published: 27/11/2015

Available
at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/11/WC500196979.pdf

- Good practice guide on risk minimisation and prevention of medication errors
  First published: 27/11/2015

  Available
  at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/11/WC500196981.pdf

- **Post-authorisation efficacy studies**

  EMA Scientific guidance on post-authorisation efficacy studies
  Effective date: 01/06/2017

  Available
  at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/12/WC500219040.pdf

- **Vaccines**

  The ADVANCE Code of Conduct for collaborative vaccine studies.

  Available
  at: http://www.sciencedirect.com/science/article/pii/S0264410X17302426?via%3Dihub

  This is the first module of the best practice guidance for vaccine benefit-risk studies (a project that was co-lead by the EMA). This code of conduct will be revised periodically. For revised versions visit ADVANCE website (http://www.advance-vaccines.eu/).

3) Announced GVP updates or developments with relevance for PV writers

Guidance under public consultation

- GVP chapter Product- or Population-Specific Considerations IV: Paediatric population was released for 2-months public consultation (until 13 October 2017) on 2 August 2017.

  Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/08/WC500232769.pdf

Updated guidance to be released as final in 2017

- GVP - Annex I - Definitions (Rev 4) is anticipated to be released in Q3 2017.
- GVP Module XV – Safety communication (Rev 1) and related templates in Annex II is expected in Q3 2017.
- GVP Module IX – Signal management (Rev 1) and revised guidance on statistical methods (addendum I), following the public consultation in 2016, will be released as final in Q3 2017.

Guidance under revision or development

- The pharmacovigilance guideline regarding use of medicines in pregnancy is under development to become a chapter of GVP.
- The pharmacovigilance guideline for medicines used by older populations is under development to become a chapter of GVP and is planned to be released for public consultation in 2017.
- GVP Module VII – Periodic Safety Update Reports (Rev 2) drafting is ongoing.