Useful links and resources in PV

Please note: this list includes a personal selection of links and materials that some of the PV SIG members deemed useful or interesting. It is not exhaustive and not regularly updated. Feel free to use it to get some insights in the pharmacovigilance world!

European Medicines Agency (EMA)

https://www.ema.europa.eu/en

EMA - SCOPE training materials

https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/pharmacovigilance-training-materials

Guidance on pharmacovigilance requirements, processes, and documents in the EU

- EMA – Pharmacovigilance:
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac05800241de

- EMA - Good Pharmacovigilance Practices (GVP):
  https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices

- EMA – Risk Management Plans (RMP):
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp&mid=WC0b01ac058067a113

- EMA – European public assessment reports (including public RMP summaries):
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

- CMDh- Risk Management Plans (RMP) and List of safety concerns per approved RMP of active substances per product
  http://www.hma.eu/464.html

- EMA – Signal Management : For list of Designated Medical Events (DMEs)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000587.jsp

- EMA – PRAC recommendations on safety signals
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000375.jsp&mid=WC0b01ac0580727d1c#section1

- EMA – Periodic Safety Update Report (PSUR):
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910

- EMA- Periodic safety update report single assessments
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/psusa_search.jsp&mid=WC0b01ac0580902b8d

- ICH – Periodic Benefit-Risk Evaluation Report (PBRER):
  http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

- CMDh- MRI product index (Public Assessment Reports for products authorised via MRP/DCP procedures)
  http://www.hma.eu/mriproductindex.html

- ICH – Development Safety Update Report (DSUR):
  http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/development-safety-update-report.html

- EMA – ICH guideline E2F on DSUR:
  http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/09/WC500097061.pdf

- CIOMS- Pharmacovigilance
  https://cioms.ch/pharmacovigilance/

- Reports of CIOMS Working Groups: Pharmacovigilance
  https://cioms.ch/shop/?filterby=pharmacovigilance

- ENCePP- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
  http://www.encepp.eu/

- The European Union electronic Register of Post-Authorisation Studies (EU PAS Register)
  http://www.encepp.eu/encepp_studies/indexRegister.shtml

- ENCePP Guide on Methodological Standards in Pharmacoepidemiology. http://www.encepp.eu/standards_and_guidances/methodologicalGuide.shtml

Information on agenda, minutes, and highlights from the PRAC

https://www.ema.europa.eu/en/committees/prac/prac-agendas-minutes-highlights

Information on the contents and requirements for Addendum to Non-clinical Overview, Addendum to Clinical Overview, Clinical expert statement

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-processing-renewals-centralised-procedure_en-0.pdf

Information on the contents and requirements for Periodic Adverse Drug Experience Report (PADER)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6463498/

Post Marketing Reporting of Adverse Drug Experiences, Code of Federal Regulations, 21CFR314.80. Food and Drug Administration (FDA) 2017. [Last accessed on 2018 Aug 17]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.80 .

Information on the contents and requirements for Risk Evaluation and Mitigation Strategies (REMS)

https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

https://www.fda.gov/media/77846/download

https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

Information on the contents and requirements for targeted risk management plans and follow-up commitments for prescription opioid-containing products in Canada

Submission of targeted risk management plans and follow-up commitments for prescription opioid-containing products - Guidance for industry. Available from https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/submission-targeted-rm-plans-commitments-prescription-opioid-containing-products-guidance-industry/document.html

Information on the contents and requirements for issue-related summary reports in Canada

Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products - Guidance Document for Industry https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/preparing-submitting-summary-reports-marketed-drugs-natural-health-products-guidance-industry.html

Non - EU Regulatory Health Authorities

- ***Japan: Ministry of Health, Labour and Welfare: Pharmaceuticals and Medical Devices***

https://www.mhlw.go.jp/english/index.html

- **Health Canada**

https://www.canada.ca/en/health-canada/services/drugs-health-products.html

- **New Zealand Medicines and Medical Devices Safety Authority (resources for education and learning)**

https://medsafe.govt.nz/safety/education-and-information.asp

- **The Therapeutic Goods Administration (TGA), Australian Public Health Authority Australian Public Assessment Reports for prescription medicines (AusPARs)**

  https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

- **FDA US Food and Drug administration**
  www.fda.gov