

HARMONIZING LOCAL PV ACTIVITY TO IMPROVE EFFICIENCY

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CONTENTS

- Local QPPV
- More niche look towards a local scale – the Balkan non-EU countries
- Managing medicinal products and medical devices in the same database
- How to overcome differences in regulation across local regions
- Conclusion

LOCAL QPPV

- Differences in regulation
- PV knowledge
- Training
- Quality Management System
- Knowledge and understanding of English language
- Audits (internal/external)

HOW TO OVERCOME DIFFERENCES ACROSS LOCAL REGIONS

- All countries are following EU Regulation, but there are differences in-between countries
- Macedonia is the only country from the region which has developed own data processing network and management system
- Trainings and education/learning are essential
- Following international standards
- Develop strategies to increase ADR reporting by all stakeholders

CONCLUSION

- It is expected that all countries will develop similar network and management system in the near future
- Changes in PV regulation will improve risk communication and signal detection – proactive & solution finding
- Regional aspects are moving towards Global aspects – Harmonisation
- Aligning PV Regulation across different countries can be beneficial to streamline PV activities and meet local needs