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Immunogenicity guideline Pharmacovigilance

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Towards a risk-based approach

- Immunogenicity should, in principle, be discussed in RMP
- Knowledge on product and/ or product class should be described
- Drug-neutralizing antibodies should always be discussed in relation to clinical relevance

No specific risk for immunogenicity,
inclusion as potential or identified risk in RMP might not be needed

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Immunogenicity studies

- Challenges remain: drug-neutralising antibodies not routinely measured in clinical practice
- Immunogenicity studied in relation to clinical outcomes, e.g. hypersensitivity reactions
- Non-interventional observational studies might not provide the results needed
- Clinical trials or interventional observational studies needed → expensive, difficult to perform in clinical practice
- Use of standardised assays

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Spontaneous reporting

- Important tool for very serious consequences of immunogenicity, e.g. PRCA with Epoetin alpha
- Less value for detection of less serious consequences and drug-neutralising antibodies
- Development of an algorithm to identify potential cases of immunogenicity

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Risk minimisation activities

- Need should be assessed within RMP for identified and potential risks

- Activities for immunogenicity mainly related to guidance on anti-drug antibody and drug level measurements and methods to deal with immunogenicity

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Traceability

- Importance of traceability is recognized in all PhV guidelines
- Of specific importance in relation to immunogenicity due to batch-to-batch variability
- More specific guidance on traceability in GVP on biologicals

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Guideline in relation to GVP

- Guideline and GPV should be read in conjunction
- Guideline describes most important aspects for PhV of immunogenicity
- GVP describes issues in more detail
- Content of documents have been agreed between drafting groups