

EXPERIENCE WITH ARTICLE 34 APPLICATIONS

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CEUREG Forum XXIII.
Budapest, 14.-15. October 2019



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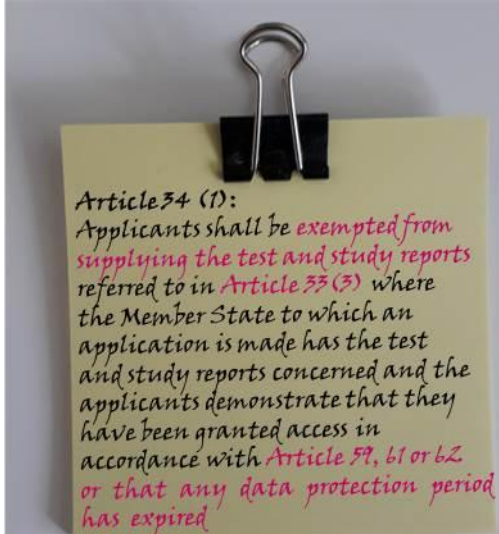
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Points to address

- Article 34 in different countries - Data requirements
- Experience with Article 34 applications
- Wishes

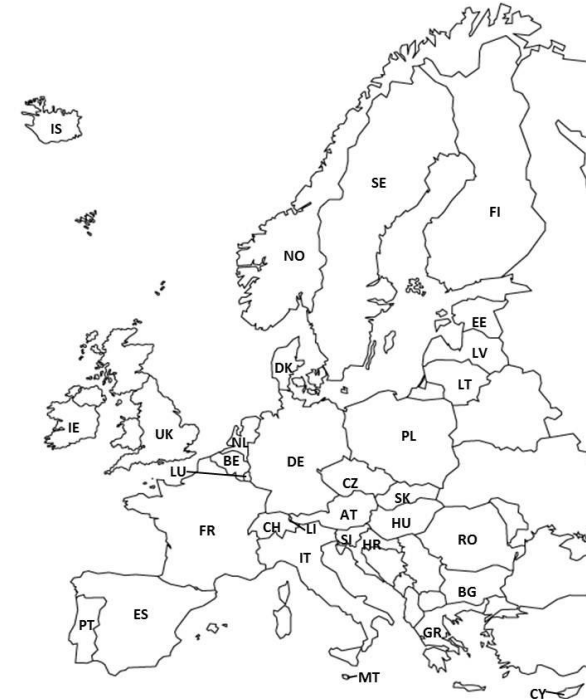


Article 34 (1):
Applicants shall be exempted from supplying the test and study reports referred to in Article 33 (3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired

ARTICLE 34 IN DIFFERENT COUNTRIES

DATA REQUIREMENTS

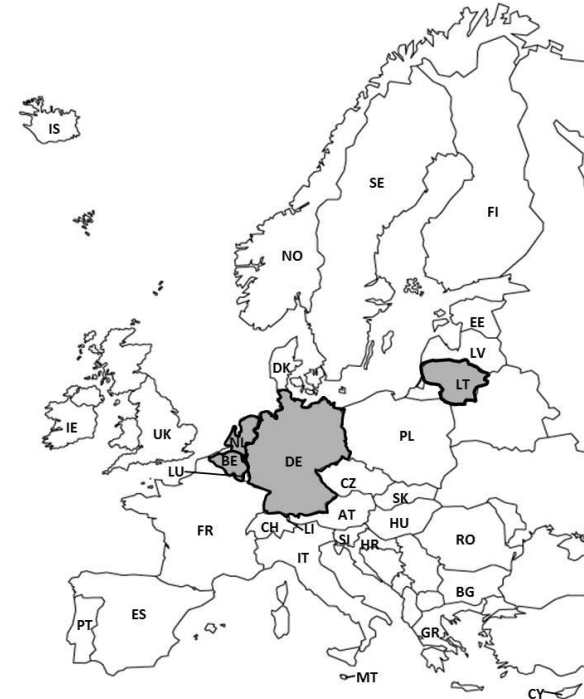
- General pre-requisites
 - Comparability to reference product
 - Reference to only one reference product
 - Studies available at MS and Data protection expired (or LoA)
 - Valid uniform principle authorisation



ARTICLE 34 IN DIFFERENT COUNTRIES

EXAMPLES FOR FULL DATA REQUIREMENTS

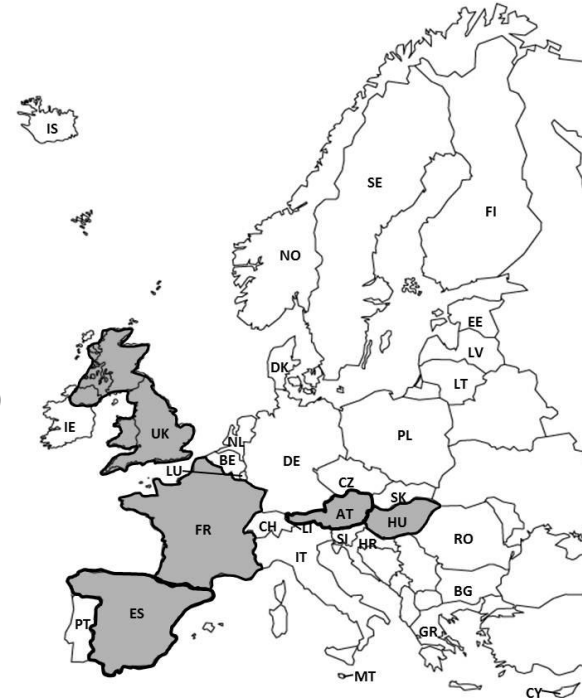
- General pre-requisites
 - Comparability to reference product
 - Reference to only one reference product
 - Studies available at MS and Data protection expired (or LoA)
 - Valid uniform principle authorisation
- Full dossier needed (dRR part A, B and C), e.g.
 - Germany
 - Lithuania
 - Netherlands
 - Belgium



ARTICLE 34 IN DIFFERENT COUNTRIES

EXAMPLES FOR REDUCED DATA REQUIREMENTS

- General pre-requisites
 - Comparability to reference product
 - Reference to only one reference product
 - Studies available at MS and Data protection expired (or LoA)
 - Valid uniform principle authorisation
- Only some dossier parts or short dossier
 - Austria: dRR Part A and C
 - Hungary: dRR Part A, PhysChem, Efficacy studies (SE-EPPO zone)
 - Spain: Short dRR part A, B, C (only comparability)
- Administrative process
 - France: BIS-procedure; No dossier needed. Identical uses claimed
 - UK: No need to submit data (BREXIT?)

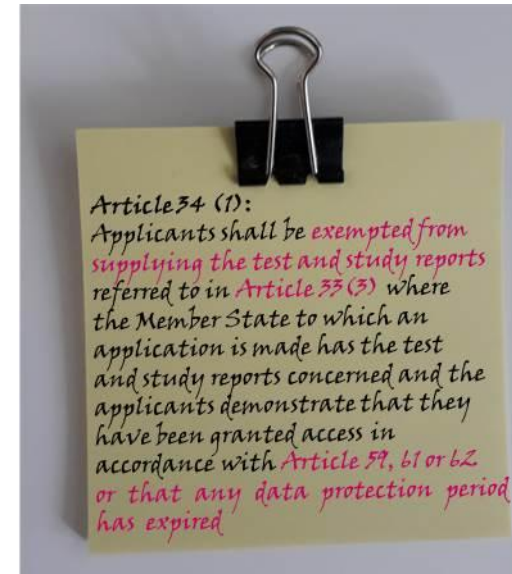


EXPERIENCE WITH ARTICLE 34 APPLICATIONS COMBINATION WITH ARTICLE 33

- Zonal procedure
 - zRMS with reduced requirements, cMSs with full requirements? => **Acceptance?**

- New data requirements
 - Authorisations of reference products acc. to old data requirements
 - New studies for Article 34 application => dRR part B?
=> **Only combination of Article 34 with 33!**

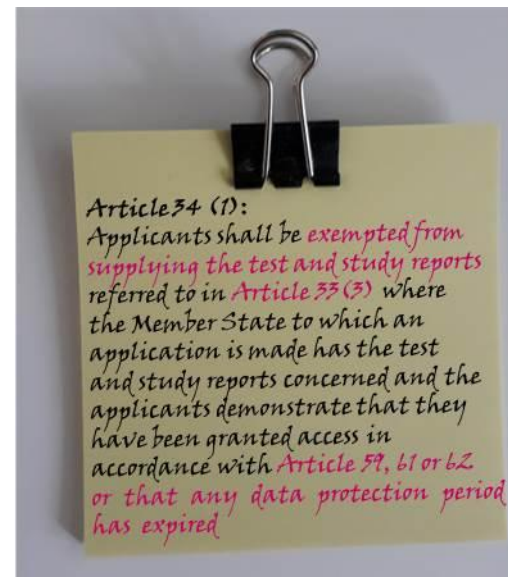
- Valid uniform principle authorisation
 - Often old authorisations of reference product
 - Uniform principle status of reference product unclear
=> **Clear public information needed!**



EXPERIENCE WITH ARTICLE 34 APPLICATIONS

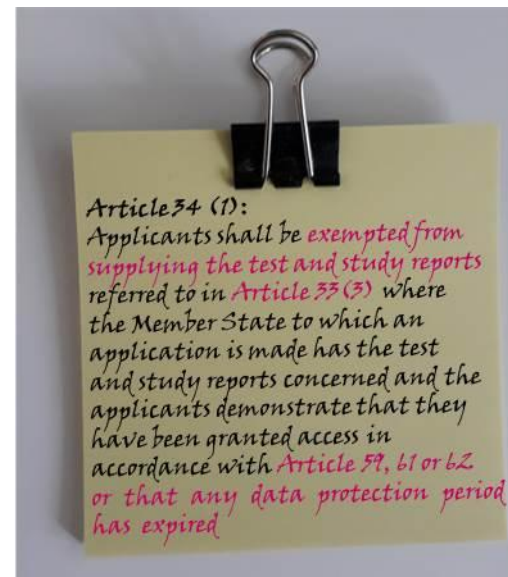
DATA PROTECTION AND AVAILABLE DATA

- Reference lists often not public available
 - Difficult to check available studies (non-data protected)
 - Avoidance of duplicative testing
 - Avoidance of additional vertebrate studies
- Difficult to check data protection status
 - Often data protection expiry date not clear
 - study already used in first authorisation?
 - First usage of data
 - a.s. data, PPP data?



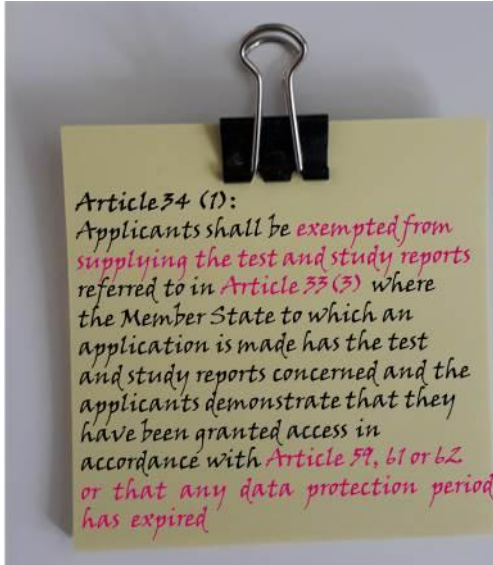
EXPERIENCE WITH ARTICLE 34 APPLICATIONS COMBINATION WITH OTHER ARTICLES

- Mutual recognition (Article 40)
 - Availability in both MSs of
 - same reference product
 - same studies
 - Acceptability?
 - MS of origin with reduced requirements, MR-MS with full requirements?
- Low risk (Article 47)
 - Desired: More and more low risk products
 - Combination Art. 47 & Art. 34 not mentioned in the Regulation
 - => Guidance needed



ARTICLE 34 WISHES

- Zonal procedure and Mutual recognition
 - Acceptance of the zRMS/ MS_{Orig} authorisation in the cMS/ MR-MS
=> Although zRMS/ MS_{Orig} with reduced requirements
- Combination of Art. 34 with other articles
 - Art. 33 with new data requirements (Statement) & reduced requirements
 - Guidance Art. 47 and Art. 34 combination
- More transparency, i.e. publication of ...
 - ... the uniform principle authorisation status for each product
 - ... the full reference lists of each product
 - ... the data protection expiry date for each study (a.s. and PPP)



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or that any data protection period
has expired

**THANK YOU FOR
YOUR KIND ATTENTION**

In case of questions, please contact me:
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