

Parallel trade

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Legal requirements - composition



Parallel and reference
product shall have

- ✿ Identical or sufficiently similar composition of formulation and active ingredient
- ✿ Same origin as the reference product

What is sufficiently similar?



Parallel product and its a.i. shall be similar to the authorised reference product as to its composition and effects i.e.

- any difference is within defined limits
- any difference shall be covered by the evaluation done for the reference product

Problems



Traceability?

- ☞ ECJ decisions and EC texts use the term „country of origin“ or „country of exportation“ which is unclear (CR „country of comparison“)
- ☞ Shall the paralel product reach the territory of country of origin or exportation???

Problems



- change of the batch number disables traceability (sometimes importer does not know the original batch number).
- mixing different batches
- expired products
- unknown sources of the active ingredients
- the original batch placed on the market under different batch numbers

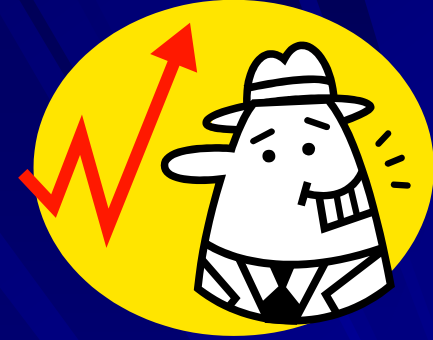
Problems



Difficulties with taking samples

- specific way of distribution
- re-packaging
- requirements on quick use and return of packagings
- troubles with documentation
- laboratory analysis necessary
- farmers do not co-operate

Possible improvement



- ➡ Cross - border co-operation
- ➡ System of information exchange for control purposes
- ➡ Implementation of good distribution practice and licensing of distributors
- ➡ Data on the origin and original batch number of all products available on request at distributor level
- ➡ Relevant provisions in the Regulation on labelling and packaging

Thank you for your attention!

