

Fighting Excessive Pricing Medicines



With the support of the
Erasmus+ Programme
of the European Union

Fighting Excessive Pricing Medicines

Gene-based medicines (CAR-Ts) promising but highly expensive

Effectiveness price-reducing options life-saving medicines: anecdotal evidence

Toolbox price-reducing measures:

- (i) **Compulsory licensing**: 'patent flexibility'
'nuclear option', hardly used for gene-based therapies: too controversial;
despite 'data-exclusivity waiver': disclosure clinical test data (Art. 18(2) EU Reg. 816/2006)
- (ii) **Pharmacist's exemption**: justified exception national patent law
liability risk patent infringement considerable
- (iii) **Abuse dominant position** excessive pricing (EU competition rules)?
Competition authorities unfit as price regulators
- (iv) **cross-border purchasing medicines** (e.g. Beneluxa - Spinraza case):
joint procurement CAR-T medicines (EU Dir 2014/24/EU, art.39): **attractive option EU MS**

Conclusion: Despite obstacles *voluntary* CB purchasing innovative medicines is potentially promising price-reduction option