JUS-3

Implementation of the new transporter knowledge in the revised European drug Interaction guideline

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Drug regulation follows the scientific development. New knowledge is taken into the regulators' assessment both by directly applying knowledge gained from recent publications as well as by implementing the new knowledge in scientific guidelines. The area of transporters has been growing extensively. As more *in vivo* data became available supporting the importance of transporters *in vivo*, and enabling interaction predictions based on transporter knowledge, it was time to revise the guideline recommendations regarding transporter studies in the field of drug-drug interactions (DDIs). After an extensive and quite long work including external consultation and harmonisation discussions with the FDA, the final guideline has now been finalised and published. The DDI guideline, which got into force the 1st of January this year, recommends new investigational drugs to be tested for inhibition of a list of transporters, all observed to be of importance for the pharmacokinetics (absorption, elimination and distribution) of drugs *in vivo*. Furthermore, transport proteins involved in efflux or uptake processes likely to have clinically relevant effect on absorption or elimination of the new drug should be identified and their role quantified *in vivo* by DDI or PGx studies. Due to the fast development of the transporter field, detailed advice on in vitro methods, probe substrates and potent inhibitors are not given in the guideline. Only general advice on study design, controls etc are given. Instead, the company is referred to the scientific literature with a need to justify the approach chosen, both in vitro and in vivo, to the regulators based on the available science.