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Global regulatory challenges and current hot topics in the regulatory world

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The pharmaceutical industry is a highly regulated industry. The regulatory requirements are permanently growing to ensure supply of high pharmaceutical quality, safety and efficacy of medicinal products. The factor time is now playing a more important role to allow expedited patient's access to innovative medicinal products to treat their disease and improve their life. In the EU regulatory pathway for advanced therapy medicinal products (ATMP) and further, adaptive pathway and accelerated approval as well as conditional approval, hospital exemption, lead to an expedited access of patients to the medicines where there is an unmet medical need. Personalized medicine, individualized medicine and breakthrough designation are on the move in the US and Europe. Japan has created the priority review "sakigake" that allows expedited approval of significant innovative medicines offering priority consultations and priority reviews and assessment. Regenerative medicine such as stem cell therapy is moving forward and will revolutionize the way diseases are treated. Treatment of ageing macular degeneration (AMD) has almost become routine with cell therapy. Others like arthritis, hepatitis, diabetes are progressing. If you can regenerate the kidney, then no need for dialysis anymore.

Currently there is a move towards multi-regional clinical trials (MRCT) following ICH guideline E 17 notably in Asia, following the initiative of Japan, China, Taiwan and Korea. This initiative will put more light on the ethnic factors to be considered in drug development for the relevant drug classes. A revision of the ICH "E 5" guideline on ethnic factors is on the radar screen as well as new ICH guideline "E17" on general principles on planning and designing MRCTS. The ICH E17 guideline reached step 2b and entered the consultation period (step 3).

Pharmacovigilance and drug safety has gained more and more focus from regulatory agencies with eudravigilance in Europe, risk evaluation and mitigation system (REMS) in the USA, drug safety in japan; and more and more agencies are putting more emphasis on ICSRS, ADES and ADRS reporting. Periodic safety update reports (PSURS) are becoming periodic risk-benefit evaluation reports (PRBERS), pharmacovigilance risk assessment committee (PRAC) in the EU is (re-) evaluating safety of marketed products and is involved in safety evaluation of new drugs prior to approval. Post approval safety studies (pass) and post approval efficacy studies (PAES) are becoming part of the regulatory decision outcome. Special monitoring is adding to strengthen safety of medicines in the EU.

The falsified medicines directive in Europe has led to increased regulatory requirements. By 1st of January 2018: a 2d bar code on each pack will become mandatory, the creation of a european hub to check the packs before dispensing to the patient, identification of medicinal products (IDMP), among other requirements will add-on the challenges.

Biosimialrs approvals in Europe since more than 10 years are now taking place in the USA with the first products approved as biosimilars including monoclonal antibodies. The 4 letter rule added to the inn distinguishes the biosimilar from the reference listed biologic allowing traceability. The US-FDA requests an "interchangeability" application to grant the regulatory status "interchangeable" to the approved biosimilar. Once the first interchangeable product of a reference listed biological (RLB) is approved what will be the market future of further biosimilars of the same RLB? The change in the presidency in the USA and the drug pricing discussions, revoking and replacing Obama care will have an impact on the future of medicines in the USA. New requirements are evolving for compounding pharmacies in the USA.

Europe is relaxing the biosimilars approval allowing the global reference product, introducing the 3 principle for animal studies: reduce, replace and refine, encouraging *in vitro* studies to replace *in vivo* animal studies, also allowing extrapolation of indications for the same mode of action.