## Report TOP TRENDS IN LIFE SCIENCES 2025

**SUMMARY** 

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**The Top Trends in Life Sciences 2025** conference confirmed that cooperation between the pharmaceutical sector and the public administration is crucial for the effective implementation of regulatory changes. The dynamic legal environment requires an open dialogue enabling a balance to be achieved between innovation and patient safety. The conclusions from the event can contribute significantly to further work on the reform of pharmaceutical legislation and the strategy for the development of the Life Sciences sector in Europe.

## Key takeaways from the different sections of the event:

- **Reform of pharmaceutical legislation in the EU** the discussions centred on the need for legislation to be adapted to a dynamically changing market and technological progress. Key areas of change include the digitalisation of regulatory processes, supply chain security and the introduction of more flexible registration regulations.
- EHDS and personal data protection the implementation of the European Health Data Space brings great hope, but also challenges related to privacy and the interoperability of health systems. Domestic regulations will need to be adapted and transparency ensured in access to patient data.
- Changes in the medicines reimbursement system the reform of the reimbursement system in Poland is focused on simplifying procedures, increasing transparency and better aligning reimbursement mechanisms with actual patient needs. Proposed changes include increasing price elasticity and creating new medicine availability categories. The draft of the new regulations, the so-called SZNUR (szybka nowelizacja ustawy refundacyjnej quick amendment of the Reimbursement Act) is nearing completion and may be published as early as March 2025.
- The impact of new technologies on the pharmaceutical sector AI development, digitalisation and automation of regulatory processes open up new horizons, but also give rise to legal and ethical challenges. The experts emphasised the need for clear guidelines to be created for the use of new technologies in the pharmaceutical sector.
- The role of in-house lawyer according to the experts, an in-house lawyer must be not only an adviser, but also a key business partner supporting risk management and strategic decision-making. It is important to find a balance between regulatory requirements and business needs.
- Workshop session conference participants, working in groups, discussed the most important regulatory challenges on the pharmaceutical market. Each of the discussions showed that, together, in a very short time, market experts are able to identify the main causes of and solutions to key challenges. The phrase "the law is not keeping up with market needs" was unfortunately heard repeatedly in the discussions.







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