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Strengthening EU's Regulatory System for Medicines

A new report from Escher, the independent TI Pharma platform for regulatory innovation, shows that the current regulatory system for medicines in Europe can be used in a more efficient and effective manner. André Broekmans, chairman of Escher: " Overall, the EU regulatory system operates well, however important recent changes had not yet been evaluated. One of our conclusions is that pathways that were intended to bring important new medicines faster to the market are not used in the right way. We are therefore missing opportunities to make medicines available to patients earlier."

Escher collaborated with researchers from Utrecht University to look into a number of areas that might be improved: pharmacovigilance, conditional approval, paediatric investigation plans and decentralized authorisation procedures. The research shows that some parts of the regulations are not yet fully achieving the effects they were intended to have. For example, the conditional marketing authorisation pathway was intended to bring much-needed products, for example for cancer treatment, to the market faster. The researchers found, however, that in practice it has often been used as a back-up for the 'normal' approval pathway, because requesting conditional approval had some perceived drawbacks (e.g. potential reimbursement issues and the level of post-marketing obligations). The researchers also identified opportunities for making the regulatory system more efficient, without compromising public health, for example by adjusting the timing of the submission and the level of detail of plans for the investigation of medicines in children."

Broekmans states that these discrepancies between the initial objectives of legislation and the effects of regulatory instruments in real-world practice should be better monitored: "The way in which formal assessments of regulatory instruments are conducted needs to be strengthened. Also, one of the main messages from the report is that the effectiveness of regulatory instruments can be increased by reflecting on the interpretation and implementation of the primary legislation. Companies and authorities need to learn together how to better use the opportunities that the current system provides. This is especially important as we are heading towards a future with more adaptive approaches to regulation and medicines with different profiles and characteristics."

Richard Bergström, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), notes: "Our latest learning from genomics and our improved understanding of human biology have resulted in a record number of promising break-through medicines in development. Entering a new era of personalised medicine, the current model for medicines development and approval may not be appropriate. Against this background EFPIA decided to provide an unrestricted research grant to the Escher platform to explore if the model is fit for purpose."

Hubertus Cranz, Director General of the Association of the European Self-Medication Industry (AESGP) who also funded the research, says that another important conclusion of the report is that “the research from Escher shows that many areas can be improved without having to adapt the legislation itself, but by working on a better implementation.”

Escher chairman André Broekmans: “There was a real value in working together with multiple stakeholders through the Escher platform: we were able to carry out the research independently but still work closely with companies, regulatory authorities and other societal stakeholders. Their contributions with data, expertise and experience enabled us to gain valuable insights into the development and authorisation process for new medicines.”

Source: Escher
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