Breakfast Session:
Biosimilar Medicines

Biosimilar Medicines Cause New Risks

- **Higher degree of complexity of biological medicines is a tough challenge for production of generics**

- **Even smallest deviations in the manufacturing process of biologics could lead to severe risks for patients**

- **Biosimilar medicines need careful evaluation by regulatory bodies**

"Back in the 1990's, scientists thought that biosimilar products would be easy to achieve, but now we know that it is not that simple," Kurt Pfister said at an experts panel on biosimilar medicines at the European Health Forum Gastein, the EU's leading conference for health policy. Pfister – co-funder and managing director of the research institute PFC Pharma Focus – provided an overview of biosimilar medicines and the current scientific and regulatory issues surrounding them. Pfister illustrated how biopharmaceuticals differ from traditional chemical medicines. He emphasised the following three points:

- The manufacturing process in fact makes the biological product
- Any change in the production may change the product
- Any change in the product may change the efficacy and safety of the product

Patent protection for the first biotechnologically produced medications expires shortly. Fear that biosimilars might differ from the reference product raise concerns for patient safety and efficacy.

The regulatory bodies have so far maintained a cautious approach to biosimilars. The European Union is the first region in the world to have established a regulatory and legislative pathway for the approval of biosimilar medicines. The European Medicines Evaluation Agency (EMEA) is currently finalising a number of guidelines on the process of bringing different biosimilars to the market. *"Europe has a unique opportunity to make it right and ensure that patient safety is not compromised, when finalising guidelines for the approval of biosimilar products,"* Thomas Bols, Director of Government Affairs Amgen Europe, said at the breakfast workshop in Gastein.

The complexity of production of original biologicals coupled with the complexity of their structure clearly proves that biosimilar products are never identical to the original but only similar. *"It is very doubtful that we will ever come to a point when we can substitute one by another without any risk involved for the patient,"* Pfister concluded.

Further information and abstracts for the lectures
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