Innovation and the regulatory environment

There is an increasing demand for innovation in order to guarantee economic growth and the wellbeing of citizens. In healthcare, despite tremendous progress in science and increasing investment in research and development by the pharmaceutical industry, the rate of introduction of innovative medicines has remained roughly stable over the past 30 years.

Although discovery of innovative drugs mainly reflects the capacity of industry, therapeutic innovation itself is the result of a more complex system, including politicians, scientists, investors, regulators and payers. It is also clear that the ability of industry to innovate is affected by the law, cost-constrained health systems and increasing regulatory requirements for product authorization.

We at the European Medicines Agency (EMA) have been reflecting carefully on the potential constraints that limit innovation in medicines. We have tried to counteract these constraints by adapting our organization and activities to changing business models, to the development of new technologies, and to current and emerging health needs. This new regulatory environment requires a common integrated vision between the EMA and national agencies, with the ultimate goal of protecting public health while ensuring that patients have timely access to innovative medicines, particularly for unmet needs and rare diseases.

- Firstly, patients have been involved in the regulatory process since the early stages of drug evaluation.
- Since we have found that innovation mainly comes from academia and small and medium-sized enterprises (SME), we have enhanced relationships with these groups, particularly by providing support to SMEs through a dedicated office.
- With adaptive licensing (AL), we are starting to explore a new marketing-authorization pathway to facilitate access to medicines by patients. AL replaces the approval/non-approval magic moment with iterative phases of evaluation of a drug through evidence gathered during its entire life-cycle, also taking advantage of elements introduced by the new pharmacovigilance legislation, post-authorization efficacy and safety – including real-life – studies, and ad hoc registries.
- Finally, while trying to reduce the time taken by the marketing-authorization process, joint scientific advice / health technology assessment (HTA) expands the role of the regulatory network and may avoid the significant delays in access to approved medicines currently caused by the time required for HTA and payers' decisions.

We are fully aware that, in addition to the above, the recent Clinical Trials Regulation and the new EMA policy on publication of clinical trials data will result in the release of 'big data' that will facilitate the application of new knowledge in future research provided that it will be managed appropriately, especially the commercially confidential information and individual patient data.

Guido Rasi
Executive Director
European Medicines Agency

Artikkeli on julkaistu Sic!-lehden ja -verkkolehden numerossa 4/2014.

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NICE TO KNOW

Andreas Pott, the Deputy Executive Director, has taken responsibility for the management and operations of European Medicines Agency from 13 November 2014 onwards.

More information: www.ema.europa.eu