PRESS RELEASE

Can adaptive licensing bridge the gap between regulatory and HTA evidentiary standards?

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The prospect of a new model for drug approval based on 'acknowledged uncertainty' provided for a lively debate at the European Medicines Agency Review of the Year and Outlook for 2013, an annual meeting organised with TOPRA. The concept of adaptive licensing is not revolutionary, but rather a natural step in the evolution of drug approval, explained the EMA's Senior Medical Officer, Hans-Georg Eichler. Nonetheless, not all parties were in agreement.

The idea of adaptive licensing (or staggered approval) was introduced in the EMA's Road Map to 2015 as a possible solution for earlier approval of drugs to meet an unmet medical need, for those drugs not eligible for conditional marketing authorisations or marketing authorisations under exceptional circumstances.

It is seen as a possible way to address the constant 'access vs evidence' dilemma that regulators face on a daily basis. The vision is to allow products onto the market sooner, but perhaps with a more restricted indication to begin with. Post-authorisation, the target population could be broadened when more real-life data became available. This might also be a way to bridge the gap between the evidentiary standards required by regulatory agencies and HTA bodies for assessing the benefits and risks of a therapy.

Dr Eichler made it clear that it would be a prospectively planned approach to the regulation of drugs, through 'iterative phases of evidence gathering followed by regulatory evaluation and licence adaptation'. He hastened to add that it was not without its challenges and would not be a one-size-fits-all solution to solve all the problems of the pharmaceutical industry.

Tomas Salmonson, Chair of the EMA's CHMP, agreed that this was 'not a way of rescuing drug development programmes that have gone wrong'. He said that the time had come to pilot the idea and that everything was in place to do so. One of the main prerequisites for success, however, is to make sure all decision makers are on board, and this of course includes HTA bodies.

Although Carole Longson of the UK National Institute for Health and Clinical Excellence appeared to be more open to adaptive licensing, Thomas Müller of Germany's Federal Joint Committee (G-BA) was less convinced. He expressed concern that adaptive licensing could be perceived as a lowering of standards and said that this in turn could erode trust in the drug regulatory system. He emphasised that unmet medical need should not be a reason for lowering the required level of certainty, but rather it should be an incentive for greater investment in research. 'The danger is that you substitute evidence with hope,' he said. Florian Schmidt of the European Commission (DG SANCO Unit D5) also weighed in at the end of the session with doubts about the legality of adaptive licensing. 'I want to give this very hesitant message from the Commission that we aren't convinced this is the best way forward,' he said.

The following morning, discussion of the HTA-regulatory gap continued on a slightly different tack with a session on scientific advice from the EMA and HTA bodies. Jane Moseley of the EMA said that overall the experience had been positive and that it had been valuable to have multi-party views. The EMA takes a flexible approach to this process, she noted.

Mira Pavlovic of French HTA agency HAS pointed out that the current system lacks a follow-up procedure, meaning that companies could potentially leave the meeting with different advice from the EMA and multiple HTA bodies. Though she said that the EMA scientific advice experience was working, it could be optimised. To this end, HAS and other HTA agencies have been involved in multi-HTA early dialogue pilots in the context of EUnetHTA (the European Network for Health Technology Assessment). 'We can't do joint EMA-HTA advice if we can't do it among ourselves,' she noted.

EFPIA's Director General, Richard Bergström, also said that industry was trying to foster greater dialogue with HTA bodies and that he had seen some positive changes in this regard. However, he added that there was still a need to align priorities and expectations. Greater alignment is one of seven themes that will be discussed further in a scientific paper due to be released by the industry federation in the near future.

NOTES FOR EDITORS

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