Study finds benefit to rapid drug licensing

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(Medical Xpress)—Paying too much heed to possible risks when licensing a medication can lead to a pharmaceutical of great benefit to patients either not being licensed or else having its use restricted. For this reason, medications of great benefit to patients should also be licensed when there is still some uncertainty about the risks. Furthermore, it would be advisable to involve patients much more closely in the decision-making process. These are the main findings of a current study by the European Medicines Agency with co-first time author Brigitte Blöchl-Daum of the University Department of Clinical Pharmacology at the MedUni Vienna.

The academic paper has now been published in the highly rated journal *Nature Reviews Drug Discovery*. The authors, the second first-time author is the former MedUni Vienna's vice-rector for research and currently Senior Medical Officer of the European Medicines Agency, the EMA, Hans-Georg Eichler, also resolutely point out the so-called "opportunity costs" here: "As a result of the unwillingness to accept a certain degree of uncertainty, resources are now lacking for the development of other medicaments which would have benefitted public health."

The decision to license a medication is based on the assessment of quality, safety and effectiveness. Normally, licensing duly ensues if the advantages of the new medication clearly outweigh the disadvantages. "Nothing comes on the market with a higher risk to benefit factor, but if it has a higher benefit factor then one should look at fast-tracking its licensing. And anyway there is no such thing as zero risk," says Brigitte Blöchl-Daum of the University Department of Clinical Pharmacology at the MedUni Vienna.

Cases have also been cited in the study – for instance, a medication for Parkinson's which was removed from the market due to undesirable side effects on the liver, but which was then later re-released as a result of vehement patient protests.

Of course, one should not leave patients to make these decisions on their own – but it would be worth taking a look at whether one should not include self-help groups more in reaching these decisions. At the same time experts are proposing to make medications, which do have a considerable benefit but also bring with them a certain risk, the subject of a continual evaluation and a particularly close monitoring once they are licensed.

More information: "The risks of risk aversion in drug regulation."

H.G. Eichler, B. Bloechl-Daum, D. Brasseur, A. Breckenridge, H. Leufkens, J. Raine, T. Salmonson, C.K. Schneider, G. Rasi. *Nature Reviews Drug Discovery* 12, 907–916 (2013) DOI: 10.1038/nrd4129