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WHY ARE THERE SO FEW NEW DRUG TREATMENTS IN EUROPEAN PSYCHIATRY?

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Those with psychiatric disorders have long suffered from prejudice, their illnesses and suffering often trivialised by journalists in their columns and by government agencies. Tougher regulations appear to be imposed on the licensing of new treatments in psychiatry and harsher criteria for their reimbursement by government agencies compared with other therapeutic areas despite clear evidence that these disorders are associated with the highest levels of suffering and disability according to the WHO.

For a new treatment for a psychiatric disorder to be licensed in the EU more studies meeting stricter conditions are required than is the case with equivalent licensing authorities such as the FDA. For example, in the EU a comparator arm is required in clinical trials in addition to the more scientific placebo control. There is no adequate justification for this demand which appears to confound the demonstration of efficacy and safety versus placebo with pricing issues. A further hurdle in the EU is the requirement that long term efficacy compared to placebo is established before a treatment can be licensed which causes delay in bringing the drug to the market and adds to the cost of development. The process might be eased if access to specialist advice by the licensing agencies, strictly limited in the CHMP in contrast to other agencies, were improved.

Difficulties in the licensing process and delays following the granting of a licence inevitably have a negative effect on the viability of developing new treatments. Even when a licence is granted transparency/pricing commissions are the source of serious delays before clinicians are allowed to prescribe the treatment. Delays in allowing access to treatment by EU citizens can be so long that medications become available only after they have come off patent. These issues have led some pharmaceutical companies to withdraw from the development of treatments in psychiatry for the EU market and to close their neuroscience laboratories. The resulting loss of expertise in neuroscience will not be easily reversed. Psychiatric patients in the EU will find that the options for new treatments of their serious disorders are declining compared with other countries.

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