MEDICAL SCIENCE

Drug-trial data open to all

European Medicines Agency starts to publish warts-and-all clinical reports online.

BY ALISON ABBOTT

In a move lauded as a landmark for transparency in medical science, the London-based European Medicines Agency (EMA) has begun to release details of the full clinical-trial data that it receives from pharmaceutical companies.

On 20 October, the agency published around 100 clinical reports on two EMA-approved medicines — carfilzomib, a cancer drug, and lesinurad, a gout treatment — that together run to around 260,000 pages.

The disclosures make the EMA the first major drug regulatory agency to publish the warts-and-all results of clinical investigations that drug developers submit when they apply for approval to market medicines. These clinical-study reports (CSRs) are much more detailed than the papers that drug firms publish in scientific journals — which studies have shown are an "incomplete source of information on new medicines", says Larry Peiperl, the chief editor of *PLoS Medicine*. The CSRs include both positive and negative results, and details of drugs' adverse effects.

The EMA's CSR policy, which it adopted back in 2014, "will benefit academic research and the practice of medicine as a whole", says EMA executive director Guido Rasi. He says that it will help academics to independently reanalyse data, and also help drug developers to learn from the experiences of others. Previously, the EMA had released results only when third parties asked for them using freedom-of-information requests, under rules the agency brought in six years ago. Those rules led to some drug firms taking the agency to court to try to prevent their data from being released, arguing that the information was commercially confidential.

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"Patients and clinicians have been waiting a long time for clinical-trial data," says Yann Le Cam, chief executive of the rare-disease patient lobby group EURORDIS-Rare Diseases Europe and a member of the EMA management board. Some 700 medical and patient organizations had lobbied for the data release in the AllTrials campaign at the London-based campaigning group Sense About Science. The EMA says that it intends to release all CSRs in applications submitted since 1 January 2015, whether the applications were approved, rejected or withdrawn. Once it has cleared its backlog, the agency says that it expects to offer public access to around 4,500 clinical reports each year. It will redact some commercially confidential information and, to start with, individual patient data — until agreement is reached on how to guarantee patient confidentiality. "We all now hope that other global medicines regulators will follow the European Medicines Agency's great lead," says Síle Lane, who spearheads AllTrials.

Some drug firms are continuing to resist the EMA's release of their data to third-party freedom-of-information requests. In the latest legal battle, an interim judicial European Union court order this July blocked the EMA from releasing toxicity studies on a veterinary medicine called Bravecto (fluralaner) and CSRs on Translarna (ataluren), a treatment for Duchenne muscular dystrophy. The two drug firms concerned — Intervet and PTC Therapeutics — have argued that release of the data would infringe their rights to protect commercially confidential information. The EMA appealed against both decisions on 29 September, and says that it sees the cases as a test of its policy. ■

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POLITICS

Violence rocks South African universities

Student protests over rising tuition fees have stopped classes, closed institutions and slowed research.

BY SARAH WILD

A heavy security presence awaits academics at the University of KwaZulu-Natal campus in Westville, South Africa. After a library at the university's nearby Durban campus was torched last month, police officers now regularly search staff and their cars for petrol bombs, says Kavilan Moodley, an astrophysicist there.

Still, the institution remains open for research and teaching. On the other side of the country, all classes and lab-based research at the Cape Peninsula University of Technology (CPUT) in Cape Town have ground to a halt. The lockdown follows a non-fatal attack late on 11 October in which three men were locked in a university building that was then set on fire. "The physical lockdown has been about a week. Since the arson attacks, we could not guarantee staff and students' safety," says Mellet Moll, assistant dean for research in the engineering faculty.

Campus violence is affecting many of South Africa's 26 universities — and the impact is spilling over into research. Student protests against rising tuition fees began in 2015 as the #FeesMustFall campaign, which secured a freeze on fees for this academic year. But the protests flared up again and have become increasingly physically destructive since September, when the government announced that an 8% hike in fees would be permitted for the 2017 academic year. Many undergraduate classes around the country have been stopped, including those at the University of Cape Town (UCT), where face-to-face teaching has been suspended in all faculties. Last week, two security guards were attacked.

The effects on research are uneven. Scientists at the UCT, the University of the Witwatersrand in Johannesburg and the University of Pretoria say that, despite the distraction of protests and security, and difficulties in getting packages delivered, they are able to continue with their work. At the CPUT and the University of the Western Cape (UWC) in Cape Town, however, protests have been catastrophic for research. A senior academic at the UWC says that the situation is dire. With the