EUROPEAN MEDICINES AGENCY
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**Press release**

# Opening up clinical data on new medicines

## EMA provides public access to clinical reports

As of today, the European Medicines Agency (EMA) gives open access to clinical reports for new medicines for human use authorised in the European Union (EU).

Vytenis Andriukaitis, European Commissioner for Health and Food Safety, said "Transparency is an essential component in clinical research. Its outcome – whether positive or negative – should be made publicly available. EMA's transparency initiative will make Europe a true front runner with respect to release of data concerning clinical trials. It will create a bridge from now until the new Clinical Trials Regulation - which foresees additional milestones towards transparency, becomes applicable."

For every new medicine, citizens, including researchers and academics,will be able to directly access thousands of pages from clinical reports submitted by pharmaceutical companies to EMA in the context of marketing-authorisation applications. Clinical reports give information on the methods used and results of clinical trials conducted on medicines.EMA is the first regulatory authority worldwide to provide such broad access to clinical data.

"Transparency on clinical datais a longstanding commitment from EMA and today, we are delivering on our promise to give access to the data on which our recommendations are based", explained EMA's Executive Director Guido Rasi. "Our initiative has shaped the global debate towards more transparency. It will benefit academic research and the practice of medicine as a whole."

With EMA's proactive approach to providing access to the data, patients and healthcare professionals will be able to find out more information about the data underpinning the approval of medicines they are taking or prescribing.

It will also facilitate the independent re-analysis of data by academics and researchers after a medicine has been approved. This will increase scientific knowledge, and potentially further inform regulatory decision making in the future.

Increased transparency will also benefit innovation. The shared knowledge about a medicine helps developers learn from the experience of others and can lead to more efficient medicine development programmes.

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"Patients and clinicians have been waiting a long time for clinical trial data. This new approach will at last provide transparent information on all results of clinical trials, positive or negative, as submitted to the EMA", commented Yann Le Cam, Chief Executive Officer of EURORDIS-Rare Diseases Europe and member of the EMA's Management Board. "We expect this to enhance trust in the medicines approval system. Access to this new knowledge base can help to accelerate innovation by reducing duplication of research and de-risking some new developments."

**Innovative policy on proactive publication of clinical data**

The publication of the clinical reports follows the adoption by EMA of a policy on the publication of clinical data for human medicines. During the development process the Agency extensively consulted with all stakeholders concerned, making sure to integrate their sometimes divergent views.

The website, available at [LINK], will include the clinical reports contained in all initial marketing-authorisation applications submitted to the Agency on or after the policy's entry into force on 1 January 2015. The policy also applies to applications submitted on or after 1 July 2015 to vary a marketing authorisation for an extension/ a modification of indication or a line extension. The documents are published once the European Commission decides whether or not to grant a marketing authorisation; the documents will also be published when applications are withdrawn before an EMAopinion has been given.

As a first step, EMA is publishing today data for two medicines, representing approximately 260,000 pages of information for over 100 clinical reports. Data will be progressively added online for all applications concerned since the policy entered into force. This is will be a learning curve for the Agency and all its stakeholders, as they start to apply the policy for the first time. While the policy gives an unprecedented proactive access to clinical data, it also demands the highest standard of protection of patients' personal data. The process will evolve over time as more experience is gainedand may lead to adaptations of EMA's guidance.

Once the process is fully implementedand the backlog has been dealt with, EMA aims to publish the reports 60 days after a decision on an application has been taken, or within 150 days after the receipt of the withdrawal letter. EMA is committed to these timelines. However, given the volume of work in publishing these reports, which will have to be undertaken with existing resources, EMA may need to re-assess their feasibility. According to current forecasts, EMA expects to offer access to approximately 4,500clinical reports per year.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The clinical data website is accessible here. More information on how to register to have access to it is available here.
3. The two medicines for which data is published today are Kyprolis (carfilzomib), an orphan cancer medicine for the treatment of multiple myeloma, and Zurampic (lesinurad), a medicine for gout.
4. More information on EMA's policy on publication of clinical data is available on our website here.
5. On the basis of the data submitted to EMA, now available on the clinical data website, the Agency provides recommendations on whether a medicine should be authorised for use in the EU. The assessment reports for all these scientific opinions are available here on our website.

6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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