



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

“EMA ready to address challenges ahead”

Support to innovative medicines, transparency and patient involvement will be among the priorities of new EMA Executive Director Guido Rasi

Executive Director Guido Rasi outlined his vision for his five-year mandate at the helm of the European Medicines Agency (EMA), at a press briefing today.

Among the current shifts in medicines development, Professor Rasi mentioned the vast progress made in the understanding of the human body and the underlying science, the increased globalisation of medicines development and manufacturing, as well as the current pressure on healthcare systems. "I am confident that EMA, working closely with the national competent authorities in Member States, is ready to successfully address these new challenges", said Guido Rasi.

Professor Rasi highlighted five building blocks on which EMA's response to these shifts is built:

- **Focusing on research & development for medicines that address public health needs:** "We want to focus our efforts on those medicines which have the potential to really improve patients' lives – so that innovation clearly translates into public health benefits."
- **Commitment to transparency:** "We have a pioneering approach to transparency. We are the first regulator in the world to allow researchers and academics, and the public as a whole, access to the clinical data on which marketing authorisations are based."
- **Patient involvement:** "All that we do must ultimately benefit patients. This is why we involve them more and more in our work, to ensure their views and needs are taken into account at every step of the process."
- **Best use of all available evidence:** "In Europe, with a population of over 500 million citizens, the opportunities to study the impact of medicines in real life and monitor their safety and efficacy are enormous. Integrating all available data enables real-time monitoring of the safety and efficacy of medicines."
- **Global reference authority for the regulation of medicines:** "Development and manufacturing of medicines is now global and regulatory authorities cannot work in isolation. We are reinforcing our role as a global reference authority, to provide the regulatory oversight that our citizens expect."



To address these challenges, Professor Rasi noted the importance to strengthen the cooperation with Member States, the European Commission and other European and international partners, and to bring communities and stakeholders involved closer together for a more holistic approach to medicines evaluation and surveillance across the whole lifespan of a medicine.

Guido Rasi took office as Executive Director of EMA on 16 November 2015. Professor Rasi was nominated as Executive Director for a five-year mandate by the Management Board of the Agency on 1 October 2015.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Professor Rasi is the third Executive Director of EMA. His predecessors were Fernand Sauer (1994-2000) and Thomas Lönngren (2001-2010); Professor Rasi was previously Executive Director of EMA from November 2011 to November 2014.
3. As result of a judgment issued by the EU Civil Service Tribunal that annulled for procedural reasons the 2011 selection and appointment process for the position of Executive Director of the Agency, Deputy Executive Director Andreas Pott led the Agency between November 2014 and mid-November 2015. During this period, Professor Rasi continued to work for the Agency as Principal Adviser in Charge of Strategy.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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