

## Statement on antimicrobial resistance and requirement to secure the development of new antibiotics before the last two last-resort antibiotics lose their efficacy

*Antimicrobial resistance (AMR) rapidly develops into the biggest threat to public health ever. The United Nations General Assembly of September 2016 devoted one full day to address the brewing AMR crisis. In September 2019, it will receive an advisory report of the UN Interagency Coordination Group (IACG). In several world regions multiple and even totally drug resistant bacteria have emerged while one of the two last effective antibiotics, colistin, is losing its efficacy. This may lead to the start of a post-antibiotic era, as feared by then-Director-General of the WHO Margaret Chan. The European Union is right to prioritise and lead the fight against AMR, which can only be won if public and private partners come together, pool expertise and resources, and prioritise joint action to – in time – develop new antibiotics. We are fortunate to have, in the European Lead Factory (ELF), a pre-competitive partnership that has demonstrated its capacity to develop new medicinal inventions. ELF is established, has AMR-projects running, and is ready to scale up in partners and projects. Established under the Innovative Medicines Initiative (IMI) public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), ELF holds the promise of developing new antibiotics inventions at a time when the pharmaceutical industries abandon such development due to today's lack of economic incentives. We urge all relevant European Union authorities to make up for lost time and prioritise the adequate funding of the search for new antibiotics through the European Lead Factory.*

### **Antimicrobial resistance kills and wipes out 4% of global GDP**

The overuse of antimicrobials in people and animals breeds resistance in bacteria, viruses, fungi and parasites to the drugs that treat infectious diseases. Antimicrobial resistance (AMR) already kills at least 33.000 Europeans each year – as much as influenza, tuberculosis and HIV/AIDS combined.<sup>1</sup> If trends continue, common infections will once again kill, rendering interventions like organ transplantations, joint replacements or chemotherapy too dangerous to undertake, while diseases thought conquered, such as tuberculosis or gonorrhoea, will return with a vengeance.<sup>2</sup> The European Union is therefore right to turn its energy and resources towards fighting it.<sup>3</sup> Left unchecked, by the year 2050 AMR could cause as much as 10 million deaths a year<sup>4</sup>, surpassing today's leading causes of death (ischemic heart disease, 9.4 million, and cancer, 2 million). The financial impact will also be considerable – an AMR crisis could hit the global economy as badly as the 2008 financial crisis, wiping out almost 4% of global GDP (more than 5% in low-income countries), increasing healthcare costs by USD 1 trillion (EUR 875 billion) and pushing up to 28 million people into poverty.<sup>5</sup> Investments into AMR research by ELF will provide a huge return in health and wealth, since ELF is capable to efficiently mobilize the collective intelligence in Europe in drug discovery to combat AMR. The usual funds for the development of a new antibiotic amount to USD1 billion and may

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<sup>1</sup> This figure is likely an underestimate, as reported deaths for the UK and France alone already add up to 24,500.

<sup>2</sup> Dr Margaret Chan, Director-General of the World Health Organization: 'Remarks at the G7 Health Ministers Meeting. Session on antimicrobial resistance: realizing the "one health" approach.' Berlin, Germany (October 8, 2015).

<sup>3</sup> The EU has published an AMR action plan in 2017 and the European Parliament resolution of September 13, 2018 calls for new legislation to stimulate the development of new antimicrobials for humans.

<sup>4</sup> The UK review on AMR chaired by Jim O'Neill (final report, 2016): *Tackling Drug-Resistant Infections Globally: final report and recommendations*.

<sup>5</sup> The World Bank (2017): *Drug-Resistant Infections: A Threat to Our Economic Future*. Figures for the high-impact AMR scenario.

take more than a decade.<sup>6</sup> ELF as a pre-competitive and publicly co-funded institution is committed to develop up to 80 new medicinal inventions in 10 years with a budget of EUR 650 million.

**ELF is a proven platform that brings together European science and the private sector in collaborative R&D that demonstrably accelerates the development of novel medicines – including for AMR**

ELF was co-initiated and co-funded by the European Commission and EFPIA under IMI. Launched in 2013 with a budget of EUR 196 million, it opened the proprietary compound collections of seven large pharmaceutical companies to universities and SMEs in search for drug discovery starting points ('leads'). By 2018, ELF and its partners expanded this combined library to over 500,000 compounds and delivered close to 200 'hit lists' for diseases like cancer, diabetes, Alzheimer's, neglected tropical diseases – and AMR. Further achievements include the establishment of 2 biotech companies, 2 partnering deals, and 5 patents, including patents to fight multidrug resistant infections. ELF projects have already brought a potential new antibiotic with a novel mechanism of action to preclinical development and could further lead to new drugs that restore the effectiveness of penicillin and other antibiotics. ELF achievements and impacts have been repeatedly recognised by the Commission, most notably by European Commissioners Carlos Moedas and Neven Mimica of DG RTD and DEVCO in February 2019, citing the output of ELF as high quality and important for innovative drug discovery.

ELF has developed and demonstrated a partnership model that allows even direct competitors to share knowledge and increase the speed and success of drug discovery. It has also proven capable of killing dead-end projects and reallocating resources to more promising approaches. This strength enables ELF to scale up quickly in partners and projects and manage a potential European AMR drug discovery programme as few or no others could.

**In ELF, Europe has a rare opportunity to immediately turn policy ambition into innovation reality, with the confidence of proven performance and full inclusion of partners – saving valuable time and money**

Traditionally, policy ambitions must be translated into appropriate funding programmes and procedures for application and evaluation, disbursement and oversight – an approach that consumes time and resources. Moreover, top experts from science and the economy refer to the lack of alternatives for ever less effective antibiotics as a *market failure*. By making use of ELF, an established, successful tool, the EU can consolidate its investments of time and money – and apply them where they matter most, without sacrificing EU excellence.

We believe ELF, a success story of EU policy and partnership, provides a rare opportunity to put the collective intelligence of Europe to work, today, to accelerate the discovery of novel medicines against possibly the biggest public health threat on our horizon.

**Supported by:**

Professor Mark Eyskens, former Prime Minister of Belgium;

Mr Louis Michel, former European Commissioner for Development Cooperation;

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<sup>6</sup> DRIVE-AB report, January 2018

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Professor Derek Butler, Chair of the Board MRSA Action UK;

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Professor Beatriz Silva Lima, University of Lisbon, Former Chair of the Scientific Committee of the Innovative Medicines Initiative, Former Chair of the Safety Working Party, European Medicines Agency;

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