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ASSOCIATION OF MEDICAL RESEARCH CHARITIES

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Ensure people can access effective therapies faster

Make the EU the primary destination to discover and develop safe and effective treatments for patients by creating a flexible regulatory and licensing system

The emerging generation of treatments are increasingly personalised and can bring huge health benefits. They will also aid growth in our already-strong pharmaceutical industry, attracting global investors.

Research regulation and the licensing of medicines must evolve to enable us to trial these new treatments and speed up patients' access to innovations that will save and improve their lives.

We must act now to build on the EU's rich science base and create a fertile environment for developing new treatments that can put us at the forefront of the next age of biomedical innovation.

Case study

Adaptive licensing offers a new way to trial increasingly personalised treatments

New regulatory processes to enable adaptive licensing are being explored by the European Medicines Agency, the agency that licenses medicines for use across all member countries of the EU. Adaptive licensing means a drug is granted a license early in its development for a specific group of patients and/or treatment settings. The safety and effectiveness is closely monitored as the drug is developed and this information is used to adapt the drug's license. Adaptive licensing allows patients access to promising treatments at an earlier stage and offers alternative routes to trial new treatments where patient groups are very small.

Fact...

Developing new treatments needs long-term investment

It takes around 12 years of research and drug development and £1.15 billion before patients benefit from new medicines.[1]

Case study

The Innovative Medicines Initiative pools public and private funding to boost EU innovation

Jointly funded by the European Commission and the European Federation of Pharmaceutical Industries and Associations, the Innovative Medicine Initiative has a €2 billion budget making it the largest biomedical public-private partnership in the world. It aims to make the EU a more attractive place to conduct pharmaceutical research by removing potential bottlenecks in the drug development process. It supports collaborative research projects and builds networks of industrial and academic experts throughout the EU to boost innovation.

Fact...

Animal research is an important part of the research process

63% of people in the UK can accept the use of animals in medical research where there is no alternative and suffering is minimised.[2]

Take opportunities to join-up health research across the EU where co-ordination can benefit patients

People across the EU share a number of common health conditions that researchers are working on. Research resources can be pooled and activity coordinated. Some research projects have very large databases or equipment that can be valuably shared by EU countries.

Case study

European co-ordination reduces the number of animals needed for medical research

The laboratory mouse is one of the most important mammalian models for studying genetic and multi-factorial diseases in man. The European Mouse Mutant Archive (EMMA) is an international repository for mice used in medical research. It is supported by EU funding through the FP7 Capacities Specific Programme. Mouse eggs, sperm and embryos are stored frozen, meaning animals aren't used unnecessarily in breeding to continuously maintain a colony. EMMA therefore has animal welfare benefits and protects against the loss of valuable mouse strains, many of which have been genetically modified at great effort and expense. The resources of EMMA support basic biomedical and preclinical research, providing the foundation for the development of diagnostics and treatments that save and improve lives.

Case study

European co-ordination to develop and sustain information infrastructure for life sciences research

The EMBL European Bioinformatics Institute (EMBL-EBI) is one of the world's leading centres of excellence for bioinformatics, providing freely available data from life science experiments covering the full spectrum of molecular biology. Based on the Wellcome Trust Genome Campus in Cambridgeshire, EMBL-EBI develops and maintains many of the database resources that underpin life sciences research across Europe and internationally, and provides services and tools to enable researchers from academia and industry to access and use this information to advance knowledge and its application for health benefit.

Case study

EU policy on rare diseases helps encourage research into new treatments

Rare diseases are those that affect less than 1 in 2,000 people. Leadership from the EU has been hugely valuable for patients and industry. Europe-wide policies and legislation have been implemented to support the development of 'orphan' drugs which offer promising treatments for rare diseases but have a low commercial value due to the small patient group that will benefit from them. The European Commission has also developed a Communication on Rare Diseases which sets out proposals for a comprehensive, EU wide strategy on research, diagnosis, treatment and care for rare disease patients. This called on all EU member countries to develop plans for rare diseases by 2013 to increase integration of strategies across Europe.

Rare conditions affecting only a handful of people in the UK affect many handfuls of people across the EU as a whole. Researchers across the EU can valuably work together on initiatives to investigate specific rare conditions and coordinate the sharing of information across borders.

Case study

European funding encourages the building of a pan-European collaboration for research into a rare condition

The AKU Society works internationally to enable research into the rare disease Alkaptonuria (AKU). With only 406 affected individuals across Europe, an international collaborative approach is the only way to recruit enough participants for the study of the disease and to test potential treatments. In 2013 the AKU Society and the Royal Liverpool University Hospital led a pan-European Consortium to successfully bid for a £4.6 million FP7 grant to conduct clinical trials of the drug nitisinone. The trials are taking place at centres in the UK, France and Slovakia. This example demonstrates how co-ordination between member countries can access EU funding for research into an area of high unmet need which will ultimately benefit patients.

1. Association of the British Pharmaceutical Industry (2014), *Delivering value to the UK: the contribution of the pharmaceutical industry to patients, the NHS and the economy*. http://www.abpi.org.uk/our-work/library/industry/Pages/310114.aspx

2. Ipsos MORI (2012), *Views on the use of animals in scientific research*. http://www.ipsos-mori.com/researchpublications/publications/1512/Views-on-the-use-of-animals-in-scientific-research.aspx