Position paper on the European Pharmaceutical Strategy - Timely patient access to affordable medicines

To achieve the goal of safe and affordable medicines and to support the European pharmaceutical industry to remain an innovator, the EU must put innovation in humane nonclinical safety and efficacy assessment at the heart of this strategy. The pharmaceutical sector will continue to struggle to respond to both long term health issues such as our aging population and new pandemics like coronavirus unless it invests in better, human-relevant methodologies to predict the safety and efficacy of new pharmaceuticals.

Drug development is in crisis. Currently 90% of drugs fail in clinical trials despite the prior conduct of extensive animal tests suggesting that these medicines were safe and effective; 55% of failures are due to lack of efficacy while 28% are due to toxic effects in humans[1]. This general failure rate is bad enough, but for drugs aimed at treating complex and poorly understood conditions, failure is almost a certainty. For example, the failure rate for Alzheimer's drugs is estimated to be higher than 99%[2].

Only a handful (approximately 20) of novel medicines are released onto the market every year[3] and withdrawals and warnings of adverse effects commonly follow as the drug is tested in the wider population[4]. The efficacy of the drug can also prove to be more limited than initially thought based on the animal test data. For example, out of 48 cancer drugs approved by the European Medicines Agency from 2009 to 2013 to treat 68 types of cancer, almost half showed no survival benefits and even in cases where benefits were seen, the difference was judged to be 'clinically insignificant'[5]. This tells us that the animal testing paradigm, on which the pharmaceutical industry relies heavily on, is failing.

In addition to the low approval rates, the discovery and development of new drugs is an excruciatingly long and expensive process and typically takes an average of ten to 15 years to complete[6], at a cost of $2.6 billion per drug[7].

The scientific literature is replete with concerns over the current drug testing paradigm, as well as calls to transition to more predictive and more human-relevant approaches as a matter of urgency. These calls are getting more desperate as the industry struggles and have now reached a tipping point with our continued failure to tackle unexpected health crises like the COVID-19 pandemic.

The public also does not support animal experiments. According to our latest poll, almost three quarters (72%) of EU citizens think that Europe should set targets and deadlines to phase out animal testing while 66% supported an immediate end to all animal tests[8].

It is time for leaders to listen and take decisive action.

The EU must create a framework to incentivise new and modern non-animal approaches that prove meaningful for the protection of citizens and the environment and foster innovation and growth. There also needs to be increased funding for and prioritisation of human-relevant and humane science to make the EU the world-leading powerhouse for animal-free research.

In conjunction with this new pharmaceutical strategy, we urge the Commission to consider the development of a separate strategy or 'roadmap' that will set out a comprehensive plan to end

reliance on outdated and unreliable animal research. The roadmap should contain agreed milestones, targets and timetables, like those seen in other EU sectors, such as climate emissions and pollution. Other countries and regulatory agencies are leading the way with strategies to replace animal testing to help bring about real change, for example the EPA, FDA and ICCVAM strategies in the US. This is not just an animal welfare issue; humans are also suffering because of serious adverse effects (some even fatal) that were not predicted in animal tests, because of the lack of satisfactory treatments for countless conditions and because of the ongoing failure in the understanding of complex human disease like Alzheimer's that cannot be accurately 'modelled' in animals.

The urgent need for this EU roadmap was recently supported by a broad range of stakeholders from the EU and US, including decision-makers, academics, scientists and industry representatives, at a pan-European conference that took place virtually on the 10th of September. The focus of the workshop was on 'building back better' in a 'post-COVID19 world' and how this could be accomplished through increased collaboration and investment in sustainable research and innovative human-relevant technologies[9].

In conclusion, Cruelty Free Europe recommends that innovation in non-clinical safety and efficacy and specifically the replacement of animal testing be included in the EU's pharmaceutical strategy. The importance of regulatory change and increased investment in non-animal methods should form the backbone of the EU's plan to build back resilience and competitiveness post-COVID-19 and be integrated into the EU Green Deal and the Next Generation EU.

We also urge the Commission to develop a separate comprehensive strategic plan, with agreed milestones, targets and timetables, to deliver the EU's existing commitment to replace all animal experiments and to help bring about safer and more effective medicines for humans and an end to the needless suffering of animals in Europe's laboratories.

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