Commentary: Vincenzo Salvatore

The role of AI in pharmaceuticals

Artificial intelligence (AI), or the ability of a machine to perform functions usually associated with the human mind, has featured prominently in public discussions in recent weeks. In the US, the White House issued an executive order on 30 October setting new standards for AI safety and security that will require developers of these systems to share information from safety tests and other critical information with the US government. The order was issued in accordance with the Defense Production Act, traditionally used to regulate private industry in the context of national defence. Not long afterwards, the British government convened an international summit at Bletchley Park, UK, to discuss AI safety. The meeting concluded on 2 November with a declaration recognising the potential for serious harm from AI, but saying that these risks are best addressed through international co-operation.

Just about every industry in the world – including pharmaceuticals – is potentially affected by AI. But not all countries are taking the same approach to AI regulation. In Brussels, the European Commission has taken a different path from the US by proposing formal legislation. This is embodied in the proposal for a *Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act)* which was published on 21 April 2021. This regulation is now navigating its way through the European Parliament and the EU Council with an expected approval in early 2024, according to the Commission.

The *AI Act* is one of a number of EU legislative initiatives under consideration affecting the pharmaceutical and healthcare sectors including revisions to supplementary protection certificates, compulsory licensing, and new methodology for the conduct of clinical trials. But the *AI Act* is unique in that it is a risk-based horizontal regulation covering all prospective uses of the technology. It is also aligned with the European Health Data Space, a proposal to create common standards and rules for the potential secondary use of health data. This is intended to foster knowledge sharing and to reduce duplication of procedures in clinical trials. The Health Data Space in turn builds on the General Data Protection Regulation which was adopted by the EU in 2016 to give individuals more control over their personal data.

Under the EU's risk-based approach, AI systems will be classified according to their risk to users and to other individuals. AI systems that present 'unacceptable' risks would be banned. Those classified as 'high-risk' would be authorised but subject to a set of requirements and obligations to gain access to the EU market. AI systems with only a 'limited risk' would be required to meet light transparency rules.

An example of a prohibited AI practice would be systems that use real-time remote biometric identification systems for law enforcement purposes. Another would be systems that exploit people with specific physical or mental disabilities. Examples of high-risk systems include those that create biometric identities of natural persons or those that manage critical infrastructure. Limited risk systems would include systems that interact with humans such as chat-bots on company websites. AI systems that manipulate an audio or video would have limited reporting, or transparency requirements. Generative AI systems like ChatGPT would be classified as limited risk systems.

Suppliers with AI systems classified as high-risk products would have to register them in a database managed by the Commission before placing them on the market. Systems that are already covered by existing EU safety rules would be monitored similarly to the rules governing medical devices. Surveillance at the level of the EU member states would be done by a national supervisory authority. At the union level, the regulation would be overseen by a European Artificial Intelligence Board composed of representatives of the member states and of the Commission.

Having said this, challenges lie ahead. Even a limited risk system like generative AI is a potentially powerful player in the healthcare sector. This is because it can go beyond data analysis to offer services such as diagnosis and clinical notes. It is essential to wield AI cautiously as the outcomes from its use can vary substantially depending on the inputs it receives. The generative AI market is projected to reach approximately $120 billion by 2030, which will most likely drive pharmaceutical companies to forge collaborations with AI firms in order to stay competitive across many sectors including drug discovery, the design and conduct of clinical trials, patient recruitment, and monitoring the performance of products after they have reached the market. Notably, there are concerns about the accountability and reliability of AI algorithms.

In this complex and evolving landscape, the biggest risk lies in the possibility of an incorrect diagnosis. Diagnoses depend on the inputs of data into a system, and which data are accessible to users as outcomes can vary. Other relevant risks concern security, as these systems can be altered by anyone with intent to misuse them, or to employ them for illegal purposes.

Finally, we must consider the risks that could arise by the inconsistency of data put into a system, or the lack of relevant data, which in turn, could lead to erroneous evaluations. Ultimately, responsibility lies with the human being that uses the system, thus the healthcare professional. It is critically important that these professionals are well trained for the use of these systems.

This commentary was prepared by Vincenzo Salvatore, leader of the Healthcare & Life Sciences Focus Team at the law firm BonelliErede.