The European Association of Urology, a membership organisation of more than 18 000 urologists from all over Europe, sees value in the use of Artificial Intelligence (AI) both in terms of the activities of our professional association (e.g and decision support and development of evidence based clinical guidelines), and in our clinical roles as medical professionals (e.g. in the early detection of cancer, treatment of tumours and other urological conditions, robotic surgery and for use in clinical trials).

In urology, we already have experience of this important interaction between the uptake / use of novel technology and medical practice in the field of robotic surgery.

In the use of AI technologies, medical professionals will often be users and/or deployers of these tools and will often be responsible for the 'human oversight' when they are used in care settings. It is therefore essential that these new technologies have checks and balances in place that ensure that they are safe and effective for their intended use, just as they would need to be in place for new medical devices or pharmaceuticals.

Many of the AI tools we use in a clinical setting are likely to fall under 'high risk' devices mentioned in option 3b. Indeed, many are likely to have important legal and physical impacts on our patients (supporting decisions on treatments, for example) and the general public (when it comes to decisions regarding risk based screening, for example). These technologies will have an important impact on the medical profession, requiring the need for new skills and training, and a clear legal framework outlining responsibility and liability when things go wrong. Just like any new technology or pharmaceutical, it must be clear what functions any new AI tool has been proven to be effective and safe in delivering. In the case of AI, the limitations of the tool will directly relate to the limitations of the data driving the tool in the first place. The limitations of the data used must be explained in a clear and transparent way.

A mandatory, stand alone, legal standard for high risk AI defined in 3b using a conformity assessment procedure (mentioned in the White Paper on AI) would give legal clarity on a number of these issues. For medical devices, this may also be achieved by updating of the relevant standards (ieg IEC 82304) linked to the Medical Devices Regulation.

In terms of application of such legislation in the health sector, it must make provision for feedback from experts from healthcare professionals, patients and the general public. The medical world is (rightly) highly regulated already. It is a sector well used to asking ethical questions. The risks and benefits will need to be defined by all actors, including healthcare professionals and patients, payers and industry. There will be interaction with data protection, pharmaceutical and medical device legislation and the boundaries and complementarity must be carefully defined. It will be essential to understand the human oversight and control/ responsibility over which aspects of the AI device and this information must be clearly described to the user by the manufacturer.

For this reason, there must be provision for opinions from healthcare professionals and experts imbedded into the AI conformity assessment process in the health sector. The Medical Devices

Regulation, for example, has a included the creation of Medical Expert Panels through the JRC who will play a role in the assessment process of new medical devices. This model could be considered as a model to be replicated in any proposed AI legislation.

The new regulatory approach must go hand in hand with a broader package of education, training and skills for medical professionals so that these tools can be safely deployed in the most effective manner, as outlined in the AI White Paper. European medical societies such as the EAU have a long tradition of training, disseminating knowledge/skills and developing multi-disciplinary guidelines and look forward to engaging with the Commission on next steps to bring benefits for patients.