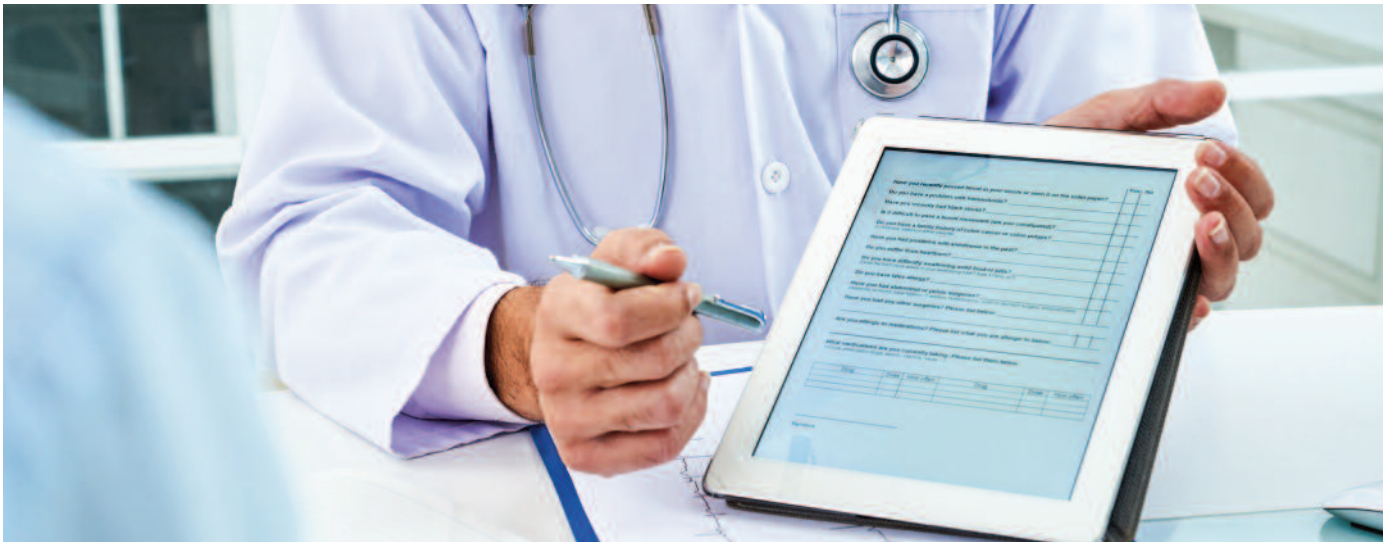

Writing for patients: Foreword from the EMA

In recent years, regulators across the globe have improved the way they communicate to patients and the general public about their activities and how medicines are regulated.

In particular, how to best communicate the benefit and risk of medicines has been the focus of much debate and of many efforts, often involving different parties. Overall, this has resulted in an improvement of the information we offer to patients and citizens about their medicines. However, there is still a need to invest further in this field, as we navigate through an evolving landscape in medicines regulation, dominated by innovation and the explosion of new (digital) technologies.

For regulatory authorities to deliver our mission to protect public health, we need to address stakeholders' concerns and communicate the science behind our decisions. The main focus of regulators is to evaluate medicines for approval and to monitor their safety afterwards. To succeed in this important task, it is crucial that the public health recommendations that we issue are well understood and trusted by patients, healthcare professionals, and the public. However, as new methodologies and innovative treatments enter into clinical practice, it is increasingly more important to move from simply pushing out regulatory information, to explaining to society the scientific work of regulatory authorities.

One good example of an area where regulators must strive to engage and communicate better with society, and a major focus of public attention, particularly in view of the current pandemic, is vaccines. Over the past years we have seen how vaccination, an incredibly successful medical intervention that has not only saved millions of lives but eradicated some deadly diseases, is put into question, not just by anti-vaccine groups, but by parents who develop genuine concerns following harmful narratives in social media and elsewhere, and even by academics and members of the medical profession. The unavoidable challenges of bringing new vaccines for COVID-19 in a shorter timeline may be seen by these groups as a further opportunity to raise levels of scepticism, which will need to be counteracted with high-quality, evidence-based information, and transparency.

> To be trusted, we need to explain the science and facts in ways that the public can understand.

Digitalisation is becoming an increasingly routine aspect of our daily activities. New technologies have prompted new ways for society to communicate, share, and gather information. And the speed at which information – and disinformation – can travel implies additional challenges for regulators and providers of authoritative information, who aim at ensuring that our voice and messages are heard through the platforms that people use.

Accompanying this technological revolution have been many changes in the nature of our society, making it more critical of any type of authority than ever before. The term 'fake news' has become part of our daily conversation. With so many voices, people find it hard to distinguish reliable information from unreliable, and communities of belief often found through social media can sustain people in following harmful narratives. In such an environment, regulators must work harder than ever to win public trust and to remain a reference source of reliable information.

We have seen over the years an increasing demand from civil society for the rationale underpinning our decisions. Regulators are becoming more open and keener to collaborate with those challenging accepted ideas and asking for the evidence on which decisions were based. Regulators and decision makers should be prepared to explain why we have acted in a particular way and provide the evidence and reasoning behind our decisions.

But it is not enough to be transparent about our decisions. As explained before, to be trusted we need to explain the science and facts in ways that the public can understand. If we fail to explain and connect with the EU citizens whom we serve, other less trustworthy sources may fill the gap with misinformation and inaccurate facts. High-quality, and clear information becomes a critical element of the regulatory process, an essential one to deliver our mission to protect the health of EU citizens.

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