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Celebrating its past, European Medicines Agency looks to the future of public communication

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Abstract

As the European Medicines Agency (EMA) marks its 30th anniversary with a series of events at its offices in Amsterdam, one area in the spotlight is EMA's communication with the public. The Agency has made significant strides in this area over the past three decades, and it faces new challenges today. There are also exciting opportunities brought about by changes to the pharmaceutical and technological landscape.

As the European Medicines Agency (EMA) marks its 30th anniversary this year with a series of events at its offices in Amsterdam, one area in the spotlight is EMA's communication with patients and the public.

It is an area in which EMA's practices have evolved considerably over the past 30 years and one which, given ongoing societal and technological trends, could be on the cusp of an even greater transformation.

From its creation in the 1990s, the decade during which the internet became commercialised and available to everyday people, the Agency has had to contend with the challenges and opportunities of transparency from the start.

The European public assessment report

Early on, EMA introduced the concept of the European public assessment report (EPAR). A world first, the EPAR generated significant disquiet at the time, with some industry insiders certain that it would sound the death knell for the pharmaceutical industry in Europe. Up to that point, the ins and outs of a marketing authorisation application were considered secret and the careful weighing of the evidence by regulators something that should be beyond the gaze of the wider public. Absurdly, some even considered the summary of product characteristics (SmPC), which contains valuable information for healthcare professionals, to be proprietary information not for publication on a regulator's website.

> European public assessment reports were a sea change in how the Agency saw its role in connecting with the public.

Today, the EPAR is a standard transparency tool underpinned by EU legislation. Each centrally authorised medicine has an assessment report, detailing the Agency's evaluation of the medicine, accompanied by a short summary in lay language, the SmPC and package leaflet as well as other authorisation details, all published as part of an EPAR.

To meet the goal of reaching the lay public, EMA hired professional medical writers who produce "medicine overviews" – previously called EPAR summaries – which are available in all official EU languages and serve as landing pages for each medicine on EMA's website.

EMA took the EPAR concept further with the publication of assessment reports, which include plain-language question-and-answer summaries, for medicines that were refused authorisation or for which companies decided to withdraw their applications.

This was a sea change in how the Agency saw its role in connecting with the public. If a patient had the right to know why a medicine was authorised, they should also have the right to know why a medicine might have been denied to them. Sometimes a medicine might miss out on an authorisation because of less-than-robust efficacy or safety data. Sometimes it could be because the company had failed to address some uncertainties or because they encountered good manufacturing practice (GMP) problems and could therefore not guarantee the quality of the medicine. Today, the Agency releases information of this kind routinely, but it had to overcome stiff resistance from an industry not used to having information on failed applications freely available to the public.[1]

The principle behind the EPAR has been extended to other major procedures at EMA, such as EU-wide safety, harmonisation, and arbitration procedures (also known as referrals). For each of these, the Agency publishes an assessment report detailing the basis for the opinion of its committees (the Committee for Medicinal Products Human Use [CHMP] or Pharmacovigilance Risk Assessment Committee [PRAC]), preceded by a lay language document or news item for the public.

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The concept of the EPAR has now grown beyond the European Union to become a global standard. Many types of public assessment reports (PARs) are published today by different regulators across the world. And a PAR, with or without a lay summary, for approved and rejected applications is now a requirement of the WHO's benchmarking tool for national regulatory systems.[2]

Current communication challenges

But publishing information is just the start of the challenge. As the Agency, along with other regulators around the world, has increased its output, including information targeted at the public, so have other sources. The rise of social media platforms has changed how public information gets shared and received.

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While the proliferation of sources of information can be of great value, it also brings the risks of misunderstanding as well as mis- and disinformation, which can negatively impact people's health and their trust in the regulatory system. The challenge is particularly acute in times of crisis, such as during pandemics when heightened interest in the regulation of medicines comes face-to-face with direct concerns about government policies and fears for the future.

And just as the internet brought challenges and opportunities for transparency about medicines regulation in the 1990s, so also, and perhaps to a greater degree, will artificial intelligence (AI) come with its own unique challenges and opportunities. Sources of information – both credible and not – are already increasing as more people use AI to generate and search for information. In this new setting, AI could be used to help guide people through the vast amount of information that regulatory authorities provide.

In some ways it feels just like the 1990s again with a new technology coming into widespread use, except that the stakes seem higher. We operate in a society with higher expectations and more distrust of authorities than 30 years ago. And while it is easier to find reliable information about medicines, it is also easier to come across information that is unreliable, misleading, or intentionally false, and harder than ever to tell them apart.

EMA prioritises communication with the public

Difficulties in telling reliable information from false information is why the latest strategy of EU regulators prioritises communication with the public and the use of technologies such as AI.[3] EMA is also looking for ways to improve the readability of the materials it publishes and to ensure that they are easily accessible to the public. A prime example of work on accessibility is the electronic product information (ePI) initiative, which aims to make the production information (including SmPC and package leaflet) more accessible and searchable in all EU languages. A recent ePI pilot programme has paved the way for implementation in routine regulatory processes.

EMA's strategy for the coming years goes beyond communication and focuses too on engaging effectively with stakeholders, building on the work already done

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with them throughout the medicines lifecycle.[4] EMA intends to continue increasing the participation of patients and consumers in a variety of pre- and post-authorisation activities, even as more patient involvement is expected following the proposed revision to the EU pharmaceutical legislation.[5]

Industry also has a critical role to play. Medical writers working in the private sector produce many of the documents that patients will eventually read, including lay summaries for clinical trials.

Final remark

If we want to avoid mis- and disinformation and anti-science narratives taking over, work with all stakeholders will remain crucial. It is important that the European public is not only adequately informed about the medicines they use but can also be confident in the regulatory system that authorises them.

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Disclosures and conflicts of interest

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