Medicines regulatory harmonisation

The term regulatory harmonisation identifies a process by which countries located in a region or belonging to a regional organization pursue a stronger alignment in terms of regulation. This process can concern various fields, including health. Patient groups are already involved in harmonisation initiatives across the world, but additional efforts from all stakeholders are still required to make patient engagement more stable and effective. IAPO identifies implications and opportunities of patient-led harmonisation.

Definition

The challenges and opportunities brought about by technological advancements in the medical field cross national boundaries and are, in their own nature, global. This has induced many and diverse healthcare stakeholders to call for regulatory approaches to be adjusted accordingly. In this regard, it has been claimed that greater harmonisation, meaning greater "alignment and coordination of regulatory rules", would likely benefit all healthcare stakeholders (see Zerhouni and Hamburg, 2016).

Given the nature of the process of regulatory harmonisation, one of the key conditions to be met for it to unfold successfully is for the process itself to be imbued with an appropriate degree of legitimacy and authority. commitment to pursuing harmonisation and taking appropriate steps for it to deliver. Key actors who can play a leading role in ensuring that this condition is fulfilled are national governments and authorities. Legitimacy, in this respect, can only be achieved if these actors exhibit true willingness of and commitment to pursuing harmonisation and taking appropriate steps for it to deliver.

In this context, delivering means providing the possibility for new medicines to be more easily accessible to higher number of patients and applying, at the same time, levels of safety, efficacy, and quality of the highest standards.

Examples of regulatory harmonisation

One of the most relevant examples of regulatory harmonisation is represented by the European Medicines Agency (EMA). The EMA seeks to promote timely patient access to new medicines and provides recommendations on medicines for human and veterinary use. If applications for marketing authorisation of a medicine are submitted through the **centralised procedure** and are approved, that medicine will be authorised for all of the member states of the European Union and the European Economic Area. In terms of patient involvement in the EMA, the two key milestones are represented by the Framework for interaction with patient and consumers organisations (the Framework) and the Patients and Consumers Working Party (PCWP). The **Framework** was issued in 2005 and revised in 2014. It lays the foundation for regular and systematic interaction between the Agency and patient and consumer organisations across Europe. The Framework identifies a series of objectives and outlines a working methodology in order to ensure that a transparent and accountable relationship is in place with patients and consumers.

The **PCWP** was founded in 2006. It is a structured platform within the EMA in which patient and consumer representatives can engage in discussions around key issues concerning the use of medicines, patient information and communication. In the PCWP, patient representatives can also liaise with representatives of EMA's scientific committees and provide recommendations on multiple themes.

Other world regions, too, have started working towards the creation of more harmonised regulatory environments. In Africa, the New Partnership for Africa's Development (NEPAD), the African Union, and the World Health Organization have launched the African Medicines Regulatory Harmonization (AMRH) Initiative. The Initiative aims to strengthen patient access to safe, efficacious, and quality assured medicines in the African Region by pursuing stronger regulatory harmonization amongst the African Union member states. This process will result in the establishment of the **African Medicines Agency** (AMA) by the end of 2018. The topic of how to ensure that the future AMA is truly and effectively patient-oriented was at the centre of IAPO's African Regional Meeting, which took place in Entebbe, Uganda, on 4-5 July 2017.

As for the Americas, in 1999 the Pan American Health Organization (PAHO) and national regulatory authorities in the Region launched **the Pan American Network for Drug Regulatory Harmonization** (PANDRH). According to the PANDRH's statute, which was approved in December 2015, the Initiative aims to strengthen cooperation among countries and among the Region's key stakeholders in order to develop and implement common proposal "for the regulation of health technologies". PANDRH also aims at supporting good regulatory practices in the Americas. The technical work within PANDRH is coordinated by the national regulatory authorities participating in the consortium.

Advocating for patient-centric harmonisation

Regulatory harmonisation can be an effective tool whereby patients living in different countries (and under diverse regulatory contexts) can access and use medicines that are equally safe, efficacious and quality assured. However, regulatory harmonisation in itself is not the silver bullet for all of the challenges facing patient communities worldwide. This is why patient advocates have a role to play in order to ensure harmonisation has patients' needs and perspectives at its centre. To achieve this goal, patient representatives must get across clear messages.

- **Patient engagement in regulatory harmonisation must take place as early as possible and be nurtured over time.** In the mid-2000s the EMA gave itself a set of tools (such as the Framework and the PCWP) to fuel and support stable interaction with patients and consumers over time. In Africa and in the Americas, regulatory harmonisation is on-going and, in the African case, will result in the establishment of AMA by the end of 2018. Patients are today considerably more structured and organised than they were in the mid-90s (when the EMA was founded). Patient groups have therefore an unprecedented opportunity to be part of the conversation from the start, and be co-drivers of the harmonisation process even prior to the birth of a medicines agency. Due to that, early engagement would enable patients to have a meaningful say not only on aspects related to medicines regulation, but also with regard to the strategic direction and practical functioning of the entire harmonisation journey.

- **"Leave no-one behind" means more than access to medicines. In fact, it also, and most importantly, means access to decision-making.** It is crucial that every patient has a real opportunity to access and use high-quality health services. At the same time, patients cannot truly take responsibility as equal healthcare stakeholders if they are left behind in key decision-making processes and only called on-board once the rules are set and the procedures approved. Patient involvement must not be seen as a concession that other stakeholder grant to patients on a discretionary basis. Patient involvement is rather a primary way of empowering patients to take their share of responsibility.

- **Harmonising does not mean ignoring differences.** Regulatory harmonisation does not aim to nullify the differences that exist among countries and patient communities. Rather, an harmonisation process that is patient-led and oriented serves to ensure that countries with varying degrees of wealth and with ununiformed regulatory provisions in place can benefit from the enforcement of the same high standards in terms of medicines' safety, efficacy, and quality, which stands at the core of the principles of equity and equality.

How to move forward

Following our African Regional Meeting, IAPO is committed to working with its African members towards the development of an Entebbe Statement on how to develop a patient-centric AMA. At the same time, we are continuing contributing our input within EMA's PCWP, of which IAPO is part, and playing an active role in the various EMA's patient engagement initiatives. Our long-term objective is to make sure that patients are at the centre of the harmonisation processes unfolding in the various world regions. This is the primary way through which patients' voice can be truly integrated in decision-making mechanisms, processes, and outputs.