



Fifty years of the European medicines regulatory network: reflections for strengthening intra-regional cooperation in the Region of the Americas

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ABSTRACT

This report considers how the experience of the European regulatory system might be applied to help strengthen the regulatory systems for medicines in the Region of the Americas. The work of the European Medicines Agencies (EMA) is carried out through its scientific committees, composed of members from European Economic Area countries. A robust legal framework allows EMA to coordinate resources from Member States' competent authorities, including, for example, assisting candidate countries as they prepare to join the European Union (EU). Capacity-building programs help countries adjust their regulatory systems ahead of full participation in the European medicines regulatory network. These programs facilitate adoption of common technical requirements, identify areas where action might be needed to ensure the smooth transposition of EU pharmaceutical law into national legislation, and prepare candidate countries for participation in EMA committees and the European regulatory network.

The methodology of these programs could be of potential interest to the Pan American Health Organization (PAHO), the Regional Office of the World Health Organization for the Americas. Given resolutions adopted by the World Health Assembly and the PAHO Directing Council, there is a strong indication that the countries of the Region of the Americas wish to assemble a system that uses the existing regulatory capacity of some countries to strengthen local regulatory capacities in others.

Key words

Legislation, drug; drug approval; drug and narcotic control; health care coordination and monitoring; health surveillance; European Union; Americas.

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At the 67th World Health Assembly on 24 May 2014, the World Health Organization (WHO) Member States approved the resolution, "Regulatory systems strengthening for medical products" (WHA67.20), which acknowledges that "effective regulatory systems are an essential component of health system strengthening and contribute to better public health

outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective, and quality medical products and effective regulatory systems are necessary for implementing universal health coverage, responding to the dual burden of infectious and non-communicable diseases" (1).

This WHO Resolution urged Member States to take actions at several levels, including:

- Strengthening their national regulatory systems;
- Engaging in global, Regional, and sub regional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious, and affordable medical products;
- Promoting international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;
- Supporting regulatory systems for medical products with appropriate funding as an essential component of the health system;
- Supporting regulatory system strengthening as an essential component of the development or expansion of local or Regional production of quality, safe, and efficacious medical products; and
- Achieving access to and rational use of quality, safe, efficacious, and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious, and affordable medical products.

Over the years, Europe has built its own medicinal product registration process on the basis of these principles. Striking similarities can be drawn between the aims and objectives of the European medicines system and those of the Pan American Health Organization (PAHO). It has been suggested that the unique experience of the European Union (EU) in strengthening the regulatory capacity of its Member States could provide some insight into the strategies, procedures, and tools that the Region of the Americas might need to strengthen the capacity of its national regulatory authorities and to designate Regional regulatory authorities. In particular, the EU experience may be relevant to establishing cooperation mechanisms for strengthening the steering role of other national regulatory authorities, as highlighted by the 50th PAHO Directing Council in Resolution CD50.R9 (2).

BACKGROUND OF THE EUROPEAN REGULATORY SYSTEM

The EU was first formed by the political will of a small number of European countries dealing with the economic aftermath of World War II, and with an industrial policy that foresaw that countries who trade with one another become economically interdependent and are therefore less likely to engage in conflict. Only upon the basis of such pillars and principles could the EU have built its current state of partnership, mutual trust, and collaboration.

In 1951, six countries—Belgium, France, Germany, Italy, Luxembourg, and the Netherlands—founded the European Coal and Steel Community, and later, in 1957, the European Economic Community and the European Atomic Energy Community. This was the basis for what became known as the European Union in 1993. Another 22 countries joined the EU through five subsequent waves of accession, including a historic expansion in 2004 marking the re-unification of Europe after decades of division. Today the EU is composed of 28 Member States (3).

The European Medicine Agency (EMA) was created in January 1995 with a clear legal mandate (4) to carry out the scientific evaluation of marketing authorization applications, with the European Commission taking the final decision on granting marketing authorization for the whole EU. Initially, the scope of the centralized evaluation process was focused on innovative and technologically-advanced medicines. It was set up for optimal use of resources across Europe, to address new areas of development where scientific knowledge was potentially scarce in individual countries. The EMA became a joint venture for the protection and promotion of public health, with national medicinal regulatory agencies as well as European institutions collaborating.

As the EU grew over the years, a number of key instruments were used to manage the accession process for new EU Member States: pre-accession strategies; bilateral agreements between the EU and each accession country; political criteria, economic dialogue, and convergence criteria; and accession partnerships for each applicant country, including defining its principles and priority areas, both

short- and medium-term, and describing how it will strive to strengthen its institutions and infrastructure and/or legislation. Each accession country was given the opportunity to participate in EU programs, agencies, and committees prior to formally joining the EU. Through its Pan European Regulatory Forum (PERF) program (funded by the European Commission's program to aid Central and Eastern Europe; 5), the EMA played a key role in harmonizing the European medicines registration system across Europe, particularly by providing regulatory-capacity training content, resources, and systems.

Over time, the training programs prepared new accession countries to be part of the EU network, integrating them into the operation of the European regulatory system and EMA procedures, while maintaining the rhythm of work with no significant slowdown in the centralized procedure. To allow the phasing-in of accession countries, it was expected that they would engage in most EMA activities, such as:

- EMA scientific committees and working parties to prepare for full participation in regulatory procedures;
- Coordination and support of linguistics for all product information produced in new languages, so that timely, relevant decisions can be issued in all the languages of an enlarged EU;
- Coordination and support of information technology (IT) exchange applications and IT services for new Members States, with priority given to those applications/programs that are imperative to full participation in European regulatory procedures.

Another element fundamental to facilitating pre-accession cooperation is an over-arching confidentiality agreement with the EMA, signed by the head of the national medicines authority of each acceding country. In addition, each country's individual experts were required to submit a confidentiality agreement and to declare any conflict of interests before attending any EMA meeting or participating in any EMA activity.

EMA workshops and scientific training sessions are made available to all acceding countries during the preparatory period. Open communication with each acceding country is important to discussing and monitoring the effectiveness and progress of pre-accession preparations,

and capturing or rectifying any potential gaps or re-aligning with the specific requirements.

Priority action areas addressed by the pre-accession program included the *acquis communautaire*, i.e., the existing body of pharmaceutical legislation and requirements; dossier assessment, i.e., quality, safety, and efficacy standards and requirements; pharmacovigilance; good manufacturing practice; telematics; quality management; and where appropriate, veterinary matters.

The PERF programs provided training in a wider scope, from basic legislation through practical application in the European regulatory network. PERF programs also created a platform for exchanging perspectives and for building mutual trust to underpin cooperation within the enlarged EU regulatory network. These programs also addressed some practical arrangements, such as phasing-in of already approved products and ongoing procedures in the new Member States, and offered an opportunity for dialogue with a range of stakeholders, including the pharmaceutical industry, health care professionals, veterinarians, patients, and farmers and other animal owners.

THE EUROPEAN REGULATORY SYSTEM TODAY

Today, the European medicines regulatory system is based on a network of medicines regulatory authorities from the 31 European Economic Area countries (28 EU Member States, plus Iceland, Liechtenstein, and Norway), the European Commission, and the European Medicine Agency. This network is what makes the EU regulatory system unique. Experts from each of the European Economic Area countries participate in the work of the EMA as members of its scientific committees, working parties, scientific advisory groups, *ad hoc* advisory groups, and as expert members of assessment teams charged with evaluating medicines.

Member States rely on each other to exchange information on a number of aspects of medicines regulation, for example, the side effects experienced in their territories, the oversight of clinical trials, and any inspections of medicines manufacturers, including compliance with good clinical practice, good manufacturing practice, good distribution practice, and good pharmacovigilance practice. This works because EU legislation

requires that each Member State abide by the same rules and requirements regarding medicines authorizations and safety. Increasingly, patients and health care professionals are involved across all aspects of EMA activities.

Through the network, the EMA works with a pool of more than 5 500 European experts. It should be noted that the diversity of experts involved in EU medicines regulation encourages the exchange of ideas and best practices among scientists striving for the highest standards for medicines. Relying on the competence of other Member States also reduces duplication of efforts, shares the workload, and ensures the efficient and effective regulation of medicines.

Today, this European system for medicines is a network of all the national regulatory authorities for both human and veterinary medicines from Member States of the EU and European Economic Area united in the Heads of Medicines Agencies (HMA), and the EMA working closely together in an integrated fashion. The network serves a population of more than 500 million people, the world's third largest population, after China and India. Together, this closely integrated network ensures that patients and animal owners in Europe have access to medicines that are safe, effective, and of good quality. It also ensures that patients, health care professionals and citizens are offered adequate information on approved medicines.

By working closely together, the network can draw on the resources and expertise of the whole EU. The network has access to thousands of experts across Europe provided by Member States and brings together this expertise and knowledge to ensure that medicines are regulated to the highest scientific standards. National competent authorities rely on each other's work to avoid duplication and share workloads and scientific competence. For example, Member States do not conduct inspections in each other's territories, avoid duplication of assessments, and work together on post-marketing safety issues.

The work of the network is coordinated by the EMA and the HMA. Among its tasks, the EMA is responsible for coordinating scientific evaluation of medicines authorized by the centralized procedure (most new active substances) and referrals; supporting innovative products, including the provision of scientific advice and qualification of biomarkers; designating

orphan status or classification as "Minor Use Minor Species"/ limited market; agreeing to pediatric investigational plans; coordinating EU-wide work on safety monitoring of medicines (4).

National competent authorities work closely with the EMA and provide the scientific expertise for assessing centralized products, supporting innovation (including centralized scientific advice), working on orphan and pediatric medicines, and conducting EU-wide safety procedures through the various scientific committees, working parties, and experts groups of the EMA.

Medicines-related EU legislation

In the EU, medicines are governed by a large body of EU legislation that aims to guarantee high standards of quality, safety, and efficacy of medicinal products, as well as appropriate information, and to promote the functioning of the internal market (4). The EU legislation today covers the whole lifecycle of a medicinal product, from the research phase (clinical trials) to approval, manufacturing, distribution, and post-marketing obligations, including specific legislation on orphan and pediatric medicines, advanced therapy medicinal products, and maximum residue limits for food safety. There are some exemptions, notably pricing and reimbursement for human medicines, that remain a national competence. The European legislation governing medicines has been strengthened significantly in recent years in the areas of pharmacovigilance, falsified medicines, and clinical trials. Drafting of new legislation on veterinary medicines is ongoing. Full and harmonized implementation of recent legislation will be a priority for the network in the coming years.

In the near future, the network will have to work even more harmoniously to overcome new scientific, economic, and/or political challenges, but the robustness of its background and the partnerships built over the years are strong elements for adapting and evolving to meet forthcoming needs.

COOPERATION FOR MEDICINES REGULATION IN THE REGION OF THE AMERICAS

The Region of the Americas comprises 55 countries or territories in three

sub-regions, with around 980 million inhabitants. The presence of solid and organized economic and political blocs indicates a decision by countries to establish cooperation mechanisms that promote economic and political convergence (6). In the Region of the Americas, there are a number of blocs with capacity to promote high-level cooperation among regulatory authorities. These include: the Union of South American Nations (UNASUR), an inter-governmental body incorporating the members of two trade unions (Mercosur and the Andean Community of Nations); the Caribbean Community (CARICOM), which has 15 members and five associate members; the North American Free Trade Agreement (NAFTA) among Canada, Mexico, and the United States; and the Central American Common Market (CACM), an economic trade organization established in 1960 by six nations of Central America (Costa Rica, Guatemala, El Salvador, Honduras, Nicaragua, and, in part, Panama; 7). The EU is considered a reference point in the creation process of political-economic blocs and has been the inspiration for decision-making process by some blocs in the Region (8).

The health systems in the Region of the Americas are sustained by sub-systems, including the regulation of health products, particularly, of medicines. The responsiveness of the national health systems is impacted by the capacity of its regulatory systems for health products. Medicines constitute three of the top 10 sources of waste of health system resources. Common reasons for inefficiency are related to regulatory issues, such as inadequate supply-chain agents control, regulatory structures for pharmaceuticals, and regulatory frameworks (9). Monitoring the quality of medicines should be considered essential to ensuring the availability of good quality generic and innovative products (10).

Dedicated structures for regulation of medicines exist in practically all the countries of the Region. In most, such structures are directly linked to the Ministry of Health, while in others there are agencies with deep knowledge and experience that can be used to stimulate and facilitate capacity-building (11). Within the national authorities of the Region, there is a fairly wide range of regulatory and scientific capacity for performing initial authorization reviews of new medicines and for ensuring

appropriate post-authorization and pharmacovigilance follow-up. One consequence of this is that, aside from approval of generic medicines, some authorities are reliant upon approval decisions made elsewhere when it comes to innovative medicines.

In 2010, the 50th PAHO Directing Council adopted Resolution DC50.R9, which indicated a strong intention on behalf of the countries of the Region of the Americas to create a system that uses the existing regulatory capacity of some countries to build local regulatory capacities in others (2). The PAHO System for the Evaluation of National Regulatory Authorities for Medicines and the work of the Pan American Network for Drug Regulatory Harmonization (PANDRH) support the processes of pharmaceutical regulatory harmonization, while recognizing pre-existing asymmetries in the Americas. These are concrete steps towards a regulatory environment more consistent with the different needs of the health systems in countries of the Americas.

The process of evaluation and assessment of national regulatory agencies is based on verification of the indicators under an instrument recommended by PAHO/WHO for strengthening regulatory bodies. This process allows PAHO to designate an authority as a Regional Reference Authority. One concrete outcome of this mechanism is the mutual recognition of inspection reports among the designated authorities.

In addition to the various ongoing bilateral and multilateral cooperation initiatives between regulators in the Region of the Americas and Europe, there are a number of international forums that offer opportunities to share experiences and best practices. The International Coalition of Medicines Regulatory Authorities, created in 2014, which includes Brazil, Canada, Mexico, and the United States, offers a broader strategic engagement between regulators in the Americas, Europe, and other regions. The increasing closeness among European regulators and counterpart authorities in the Americas may help amplify the outcomes so far with the Regional experiences.

DISCUSSION

As mentioned, the European model has already been identified as an

example of intra-regional cooperation for the various initiatives undertaken in the Region of the Americas. While there is significant political will for intra-regional cooperation in both the Americas and Europe, the most important difference is the legal framework that supports and enforces that cooperation. That robust legal framework is one of the reasons why the European Medicines Agency, working together with the Member States' competent authorities and the European Commission, has put in place programs to assist new Member States as they prepare to join the European Union.

These capacity-building programs have been used a number of times, with success, to help countries adjust their regulatory systems ahead of full and equal participation in the European medicines regulatory network. The programs—run since 1999, ahead of the accession of 10 new Member States in 2004—aim to prepare the national competent authorities of candidate and potential candidate countries for their future participation in the European network. More specifically, these programs open a dialogue and build working mechanisms to help facilitate the adoption of common technical requirements, identify areas where action might be needed to ensure the smooth transposition of EU pharmaceutical law into national legislation, and prepare candidates for participation in EMA committees.

The methodology of these programs are of potential interest to PAHO and the Region given the recent political declaration on cooperation among medicines authorities made at the 24th Ibero-American Summit in Veracruz, Mexico, in December 2014 (12). Even in the absence of a binding legal framework, there are key aspects related to harmonization of regulatory and technical requirements, cooperation mechanisms, and building of mutual trust that are essential ingredients for building a working network. To be effective, these programs require significant investment of resources, primarily in terms of scientific and regulatory expertise and time. They require long-term political will and administrative commitment, clear and achievable ambitions, and practical mechanisms to facilitate communication and exchange among participants on a sustainable basis for the duration of the program and perhaps beyond.

As previously noted, there are a number of initiatives within the Region of the Americas that seek to achieve this level of integration and cooperation. While they are clearly to be welcomed, experience in the EU suggests that it can take a number of years to achieve. With this in mind, what are the different opportunities that the European system could potentially offer in the short-, mid- and long-term to regulatory authorities in the Americas as they move towards cooperation?

There are various European scientific research programs that focus on neglected diseases that particularly affect low- and middle-income countries (e.g., Horizon 2020), and public-private collaborative initiatives to strengthen product development, such as the European & Developing Countries Clinical Trial Partnership (13).

One key short-term activity that would help develop and reinforce capacity is to involve experts from authorities in the Region of the Americas the Region of the Americas with authorities on the EMA's Article 58 procedure. Article 58 is designed to allow the EMA to give scientific opinions on use of medicines in countries outside of the EU. Although the scientific opinion is given by EMA, WHO is closely involved and brings in experts from the countries uniquely affected by the disease or condition. While to date, only a limited number of products have gone through the process, its value has been demonstrated in a number of ways. First, it gives a target country part-ownership of the outcome, which is particularly important when pharmaceutical companies come to apply for marketing authorization in that country. Second, being included in the decision-making process helps ensure that the opinions, and by inference the products, are not seen as inferior or "second class." Third, it allows for any local issues to be taken into account, which

can be particularly important for compliance, distribution, and more.

While these efforts may be helpful in the short-term, they do not necessarily offer solutions to help fulfill the long-term aims of Resolution WHO67.20 (1), and in particular the strengthening—and in some instances building—of regulatory capacity in the national authorities of the Americas. Meeting the objectives of this resolution is clearly a different matter, for which longer-term action should be about building regulatory and scientific capacity, both pre-authorization and post-authorization.

The European experience suggests that such ambitions can be successfully achieved in a sustainable manner through intra-regional cooperation. While the benefits of intra-regional cooperation are significant, the challenges and pitfalls should not be underestimated. In addition to the clear and agreed ambition level mentioned above, partners will need a realistic step-wise timeframe to achieve clear objectives, and the human and financial resource commitment to support the process.

Often overlooked in the process is the importance of putting in place robust technology platforms to underpin and support the network and the exchange of information upon which so much of modern regulatory work is dependent. In the same way as organizations seek to future-proof their information technology systems, it is also important to ensure that the cooperation model is flexible enough to adapt to future challenges, including advances in medical and pharmaceutical technology, political developments, and the needs of international cooperation. However, that experience has also shown that the whole burden of responsibility cannot be borne only by the regulators. There are a variety of stakeholders in the public health arena, not

just in the Region of the Americas, but in all parts of the world, that include politicians and policymakers, non-governmental organizations, donor and philanthropic organizations, civil society, and of course, the pharmaceutical industry.

CONCLUSIONS

If the countries of the Region of the Americas are to move towards a regional approach for pooling regulatory capacities, then all stakeholders should play their role in accepting and supporting the creation of independent and expert regulatory authorities. There is a need for a debate with stakeholder groups to ensure the right environment for constructive dialogue and trust-building among the institutions. This requires proactive stakeholder communication and a level of transparency to promote credibility on all sides.

This year sees Europe celebrating 50 years of harmonized pharmaceutical legislation and the 20th anniversary of the creation of the EMA and the European network. Even so, it remains a work in progress, constantly changing and adapting to new challenges. Intra-regional cooperation is, therefore, not a single action at a given point in time, but rather a long-term engagement with partners sharing a common aim—to work together to improve public health for all citizens. There can be no better enterprise or journey for regulators in any region of the world.

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RESUMEN

Cincuenta años de la red europea de reglamentación farmacéutica: reflexiones en torno al fortalecimiento de la cooperación intrarregional en la Región de las Américas

En el presente informe se examina la forma en que podría aprovecharse la experiencia del sistema reglamentario europeo para ayudar a fortalecer los sistemas de reglamentación farmacéutica de la Región de las Américas. Las agencias europeas de medicamentos (EMA) llevan a cabo su labor por conducto de sus comités científicos, que están integrados por miembros de los países del Espacio Económico Europeo. Un marco jurídico sólido les permite a estos organismos coordinar los recursos de las autoridades competentes en los Estados Miembros para fines como, por ejemplo, ayudar a países candidatos a prepararse para ingresar en la Unión Europea (UE). Los programas de fortalecimiento de la capacidad ayudan a los países a ajustar sus sistemas de reglamentación antes de empezar a participar de lleno en la red europea de reglamentación farmacéutica. Estos programas facilitan la adopción de requisitos técnicos comunes, determinan las áreas en que podrían hacer falta medidas para lograr la transposición eficaz de las leyes farmacéuticas de la UE en leyes nacionales, y preparan a los países candidatos para su participación en los comités de las agencias europeas de medicamentos y en la red de reglamentación europea.

Los métodos aplicados en estos programas podrían ser de interés para la Organización Panamericana de la Salud (OPS), que es la Oficina Regional de la Organización Mundial de la Salud (OMS) para las Américas. Dadas las resoluciones adoptadas por la Asamblea Mundial de la Salud y el Consejo Directivo de la OPS, hay claros indicios de que los países de la Región de las Américas aspiran a crear un sistema en el que se utilice la actual capacidad reglamentaria de determinados países para fortalecer la capacidad reglamentaria local en otros.

Palabras clave

Legislación de medicamentos; aprobación de drogas; regulación y fiscalización en salud; control de medicamentos y narcóticos; vigilancia sanitaria; Unión Europea; Américas.