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# Assessing intra-regional pharmaceutical policies in UNASUR and the EU based on the WHO universal access to medicines framework

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## Table of Contents

|                                                                                                |    |
|------------------------------------------------------------------------------------------------|----|
| List of acronyms .....                                                                         | 3  |
| Summary .....                                                                                  | 4  |
| Introduction .....                                                                             | 5  |
| Union of South American Nations (UNASUR).....                                                  | 11 |
| Introduction on UNASUR .....                                                                   | 11 |
| <b>Dimension 1:</b> Rational Selection and use of medications .....                            | 12 |
| <b>Dimension 2:</b> Affordability of medicines .....                                           | 12 |
| <b>Dimension 3:</b> Sustainable financing.....                                                 | 14 |
| <b>Dimension 4:</b> Reliable healthcare and supply systems for the provision of medicines..... | 15 |
| The European Union (EU) .....                                                                  | 16 |
| Introduction to the EU .....                                                                   | 16 |
| <b>Dimension 1:</b> Rational Selection and use of medications .....                            | 17 |
| <b>Dimension 2:</b> Affordability of medicines .....                                           | 18 |
| <b>Dimension 3:</b> Sustainable financing.....                                                 | 19 |
| <b>Dimension 4:</b> Reliable healthcare and supply systems for the provision of medicines..... | 20 |
| Conclusion.....                                                                                | 21 |
| Policy recommendations.....                                                                    | 23 |
| Annex.....                                                                                     | 25 |
| Table 1. Summary of effectiveness of pharmaceutical policies in UNASUR .....                   | 25 |
| Table 2. Summary of effectiveness of pharmaceutical policies in the EU .....                   | 26 |
| References .....                                                                               | 27 |

## List of acronyms

|         |                                                                                                              |
|---------|--------------------------------------------------------------------------------------------------------------|
| ALBA    | Alianza Bolivariana para los Pueblos de Nuestra América (Bolivarian Alliance for the Peoples of Our America) |
| AMR     | Anti-Microbial Resistance                                                                                    |
| BPMU    | Banco de Precios de Medicamentos de UNASUR (UNASUR Drug Price Bank)                                          |
| E-CRIV  | Electronic Combined Requisition and Issue Voucher                                                            |
| EAHC    | Executive Agency for Health and Consumers                                                                    |
| EC      | European Commission                                                                                          |
| EML     | Essential Medicines List                                                                                     |
| EMA     | European Medicines Agency                                                                                    |
| EP      | European Parliament                                                                                          |
| EPR     | External Price Referencing                                                                                   |
| EU      | European Union                                                                                               |
| FIC     | Fondo de Iniciativas Comunes (Common Initiatives Fund)                                                       |
| Fiocruz | Oswaldo Cruz Foundation                                                                                      |
| GNI     | Gross National Incomes                                                                                       |
| HTA     | Health Technology Assessment                                                                                 |
| ICH     | The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use      |
| ICMRA   | International Coalition of Medicines Regulatory Authorities                                                  |
| INN     | International Non-Proprietary Name                                                                           |
| ISAGS   | Instituto Suramericano de Gobierno en Salud (South American Institute of Government in Health)               |
| ISO     | International Organization for Standardization                                                               |
| LMIC    | Low and Middle-Income Countries                                                                              |
| MSF     | Médecins Sans Frontières                                                                                     |
| NGO     | Non-Governmental Organisation                                                                                |
| PAHO    | Pan American Health Organization                                                                             |
| PIC/S   | Pharmaceutical Inspections Co-operation Scheme                                                               |
| RCTs    | Randomised Clinical Trials                                                                                   |
| RO      | Regional Organisation                                                                                        |
| R&D     | Research and Development                                                                                     |
| SCMS    | Supply Chain Management System                                                                               |
| SDGs    | Sustainable Development Goals                                                                                |
| SUS     | Sistema Único de Salud (Unified Health System)                                                               |
| TRIPS   | Trade-Related Intellectual Property Rights                                                                   |
| UN      | United Nations                                                                                               |
| UNASUR  | Unión de Naciones Suramericanas (Union of South American Nations)                                            |
| USA     | United States of America                                                                                     |
| VPR     | Value Based Pricing                                                                                          |
| WHO     | World Health Organization                                                                                    |
| WHO CC  | World Health Organization Collaborating Centre                                                               |

## Summary

Medicines are a basic element in the provision of health. However, the high cost of some medications is hindering the stability of healthcare systems regardless the level of income of countries. Governments are addressing this problem by prioritising health in their national and foreign policies.

At the supranational level, regional organisations have been fora for creating action plans, disseminating and sharing information as well as generating capacity building. Consequently, they have quickly become fundamental to the successful promotion of sustainable pharmaceutical policies.

This working paper assesses the effectiveness of the implementation of pharmaceutical policies undertaken by UNASUR and the EU under the universal access to medicines framework generated by the WHO, by looking at the conditions of willingness, acceptance and capacity of these regional organisations.

Results show that engagement in international forums is encouraging positive outcomes in the formulation of regional pharmaceutical policies for improving access to medicines based on the globally-accepted frameworks. Moreover, regional organisations have turned out to be the most effective space for the promotion and implementation of such national pharmaceutical policies, as these are prone to be accepted with less opposition in each nation when a regional organisation backs them up.

## Introduction

In 2015 world leaders adopted the UN Sustainable Development Goals (SDGs), which benchmark health in a holistic way. This was a game changer, as they accelerated the linkage of health with other topics like economics, international trade law, international affairs, science, intellectual property and human rights (WHO 2017). The SDGs also nested health in a pragmatic context of multilayer factors, i.e. the conditions in which people are born, grow, live, work and age (WHO 2017) as defined by the World Health Organisation (WHO). These factors are termed determinants of health and they show the complexity of the health policy domain, which is why it is important to incorporate it into social and economic policies too.

One of the main elements in the provision of health are medicines or pharmaceutical products, as they contribute significantly to the control, treatment and cure of diseases. Given their importance, the SDGs seek to address health inequalities with transnational proposals such as securing reasonable drug pricing, providing access to palliative care, treating neglected diseases, facing drug shortages, combating antimicrobial resistance (AMR), using medicines rationally, expanding the globalisation of randomised clinical trials (RCTS), and so on.

The recognition of the SDGs intends to make them available at all times to all segments of society via a functioning healthcare system. However, availability does not only refer to the amount of medication, but also to the assortment and appropriateness of dosage forms, their quality and affordable prices (MSH 2012, WHO 2017).

The WHO calls explicitly for support, research and development in accordance with the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, to increase health financing and enhance the capacity of global healthcare systems. Despite the efforts, access to affordable and available medications has become a global problem that is not only a concern for low and middle-income countries (LMIC). Even in Europe, a region at the forefront of pharmaceutical innovation, there are concerns about future debilitating threats to its health systems.

Pharmaceutical policies are therefore embedded within health policy, since the latter provide the norms for the pharmaceutical market. The WHO determines that a national drug policy "... provides a framework within which the activities on the pharmaceutical sector can be coordinated. It covers both the public and private sectors, and involves all the main actors in the pharmaceutical field" (WHO 2001). Pharmaceutical policies represent a basic element of healthcare planning as they mitigate against the market's negative effect on the provision of essential medicines. They are designed to intervene to ensure a flawless supply and demand of the medicines on the market, thus it is imperative that they are genuinely linked to the country's socioeconomics, reflecting their priorities and conditions (Holloway and Henry 2014, Morrow 2015, Maniadakis, Kourlaba et al. 2017).

Pharmaceutical policy for access to medicines engages a varied range of actors and mechanisms. On the one side there are the non-state actors like pharmaceutical producers, health practitioners, patients, and non-governmental organisations (NGOs); on the other side politicians, national governments, regional and international organisations. The tensions that emerge in the complex relationships between all these actors are often related to the tensions between business models/objectives and social models/objectives (Gagnon 2012). Policy-making in this area depends on the ability of the actors to come up with novel business models and promote consumption/behavioral patterns to counterbalance a system that favors the producers who – as is often argued – have abused the IPR regime.

The main purpose of this paper is to analyse how effective regional organisations are in influencing intra-regional pharmaceutical policies to: reshape the way different actors and mechanisms interact in the provision of medicines within national health systems; reduce tensions among them; and ultimately attain better access to medicines for the population.

This paper builds on empirical cases of cooperation between countries and regions to achieve access to medicines, where coordination has been driven by national security and economic motives. However, the integration of coherent pharmaceutical policies to improve access to medicines is a very contested issue that competes with trade policy, and which is therefore often framed within the trade argument.

Hence, the specific objective of this research is to understand the role and mechanisms of regional organisations (RO) in the shaping of pharmaceutical policies.

The main question is formulated as ***“How effective are UNASUR and the EU in influencing intra-regional pharmaceutical policies that help achieve better access to medicines?”*** The supporting sub-question is: ***“To what extent does the structure of each regional organisation enable more or less impact on national pharmaceutical policy making?”***

The analytical framework used to answer the main question was originally developed by Luk Van Langenhove and Stephen Kingah and sums up conditions for effective regional health policies (willingness, acceptance and capacity) (Van Langenhove and Kingah 2014). This framework has been adapted to pharmaceutical policies rather than health policies for the purposes of this paper. ***Willingness*** refers to the readiness of regions to articulate and execute policies to achieve social transformation (Van Langenhove and Kingah 2014). ***Acceptance*** is the process of legitimisation of the policies internally (within the region) and internationally. ***Capacity*** concerns the means available to operate effectively in achieving the purposes and goals of the formulated policies (Van Langenhove and Kingah 2014).

Hence, the above conditions serve to evaluate the corresponding four dimensions of the WHO framework for access to medicines: 1) rational selection and use, 2) affordable prices, 3) sustainable financing and 4) reliable health and supply systems for provision (WHO 2004).

Linking health and foreign policy

During the past three decades, health has become a central topic in global politics and an integral element of foreign policy. This is a turning point in the efforts to address and regulate health-related issues, given the fact that previous to that time, health was a mere competence of states concerned with population-based prevention such as the containment of infectious diseases, immunisation, the improvement of sanitation and safer workplaces as well as cooperation between neighboring states that principally watched over the health of immigrant workers (Johnson, Johnson III et al. 2014).

The framing of health within national policies has undergone a gradual evolution shaped by historical events like the HIV/AIDS pandemic outbreak, the changes in the global economy, the prioritisation of world trade, the emergence of more democratic countries on the global stage that demand better accountability and fairer policies, the undesirable side effects of policies in other areas, such as those on migration, that directly or indirectly affect health and the adoption of the UN Millennium Development Goals (MDGs) in 2000. All of these factors have contributed to the ascension of health from the realms of low politics to a matter of high politics, leading governments to prioritise policies related to health and to allocate considerable funds to its realisation. Therefore, the level of decision-making has shifted from the national to the regional and global levels (Cooper and Farooq 2015). By consequence, health ceased to be just a domestic and bilateral issue, and has become a political affair that calls for global collaboration.

The participation of multiple actors and their interests have been instrumental to position global health as an issue of high politics. Policymakers and politicians prioritise issues that are vital to the survival of the state. The positioning of these issues to a higher attracts attention, resources and action for the problem to be addressed (Fidler 2009). As a result, Labonte and Gagnon put forward six arguments to explain the predominance of health in foreign policy, which are: health and security, health and development, health and trade, health and human rights, health and global public goods,

health and moral/ethical reasoning (Gagnon 2012). Due to its strong affiliation to the international trade setting and the power of global economic non-state actors, health equity has been predominantly linked to the security, development and trade concerns of states as the three principal arguments upon which health policies have been constructed by governments and multilateral organisations.

The framing of global public health as national and economic security dominates the governance of public health and directs large amounts of state funding to combat the security risks. The security argument bears three dimensions. The first one is **democracy promotion**, which follows the logic that poor health poses a threat to the stability and spread of democracy in fragile developing countries. An outbreak of epidemics can severely affect the globalisation of the western lifestyle and consequently, reliable access to sufficient and affordable food (Labonte 2008, Labonte and Gagnon 2010). Conflict prevention, the second dimension, deals with intertwined cost-saving interests. For instance, conflicts rooted in epidemic outbreaks and poor health are less expensive to contain than to manage through costly peace-keeping. Additionally, conflicts dent economic growth by suppressing markets for the exchange of goods and services. In view of this, intervention in foreign states to mitigate epidemics prevents the distortion of the world trade by stopping national conflicts becoming regional. Conflict prevention is thus a security concern. (Labonte and Gagnon 2010).

The third dimension is directly linked to the assertion of power through **international humanitarian law** as this sets the rules for the conduct of hostilities and obligations to protect civil society and non-combatants during conflict. Purposely or not, it gave the UN healthcare interventions and human rights observers a role in promoting conditions for peace (Chen 2004, Labonte 2008, Fidler 2009, Labonte and Gagnon 2010, Gagnon 2012). A further security argument is subtly associated with economic interests; for example, epidemic fears like the avian flu in 2007 have generated massive profits for drug manufacturers. Moreover, the terrorist-security discourse sustains a security industry and gigantic domestic expenditures. (Chen 2004, Labonte 2008, Labonte and Gagnon 2010). Consequently, foreign policy assures the momentum and durability of health as a security discourse, and its place in high politics (Labonte 2008).

Another strong argument for the incorporation of health in foreign policy is **Development**. According to this argument, health is a driver for economic growth as it contributes to the national economic productivity cycle. In this way, health-related expenditures are turned into investment for economic return. Health is one of the fields that receives large amounts of aid due to its priority in foreign policy. Therefore, aid is provided for strategic purposes. Aid, together with investment, has become a very controversial feature of foreign policy in the area of health as it may do little to serve well-being, instead contributing to the donor's self-interest. This is mainly the case when foreign aid bears a hidden agenda, such as when aid is given to a recipient to benefit foreign-owned corporations or when the donor country puts economic and political pressure on the receiving entity in return for a favour. There are instances where foreign financial support simply does not reach the most needy but instead feeds corruption and dependency (Labonte 2008, McCoy, Chand et al. 2009, Labonte and Gagnon 2010, The future of working 2016).

Lastly, the **Trade argument** upholds that liberalising health services and privatising the provision of healthcare remove pressure on public systems and attain better health outcomes. This theory has proved inequitable and has reduced health to cross-border exchange of goods and services that responds to profit maximisation.

The logic behind the trade argument is in essence contrary to the reasoning behind the development argument: trade liberalisation brings wealth and growth, which then leads to the improvement of health. According to the development argument, the inclusion of social safety provisions and flexibilities to offset the different development levels and capacities of each country exponentiates improvement to both economic growth and social wellbeing (Kimball 2006, Labonte 2008, Labonte and Gagnon 2010).

## Assessing access to medicines

Unlike other aspects of health, access to medicines has remained in the realm of middle politics. Because of this, governments have retained more flexibility when choosing to include non-state actors in the formulation of pharmaceutical policies. These policies should be designed to “intervene for a flawless supply and demand of the medicines in the market” (Maniadakis, Kourlaba et al. 2017). However, pharmaceutical policy formulation often falls short of incorporating scientific evidence, leaving it vulnerable to political interests. In view of this situation, science diplomacy is vital to tackle this issue as well as to develop transnational cooperation aimed at negotiating treaties and trade agreements that improve health besides providing leadership.

Access to medicines too is considered to be an indicator of the performance of a health system. It is related to two principles: availability and affordability. The WHO has developed a framework as a guide to categorise the policies that includes four factors determining access to medicines in a country (Kar, Pradhan et al. 2010, Kheirandish, Rashidian et al. 2015, Moyer Holz, Van Dijk et al. 2017). This framework is assessed to respond the main research question.

The WHO framework for access to medicines (figure 1) is an approach to guide the identification and categorisation of pharmaceutical policies. It acknowledges the importance of the pharmaceutical industry for economic development as a job generator, its crucial role in research and development (R&D) and as a driver for cutting-edge and competitive science. It also incorporates the social right to ensure the highest possible standards of health for all. The framework serves as a guideline to assist states in formulating their national drug policies. In addition, it is intended to provide norms to coordinate the activities of public and private sectors. (WHO 2004)



**Figure 1. (WHO 2004) framework for access to medicines**

The WHO access to medicines framework is composed of four dimensions: a) rational selection and use, b) affordable prices, c) sustainable financing, and d) reliable health and supply systems for provision. Each of these four dimensions are directly or indirectly impacted by the local, national and international contexts (Bigdeli, Javadi et al. 2013, Kheirandish, Rashidian et al. 2015).

### a) Rational selection and use of medicines

Rational selection and use of medicines refers to the receipt of the appropriate medications in suitable amounts, at a suitable dosage and at a suitable cost by patients (WHO 2017). Irrational use of medicines occurs when patients take more medicines than necessary (also known as poly-pharmacy), use them ineffectively, consume inappropriate dosages or self-medicate. They raise healthcare costs, cause adverse reactions, reduce the productivity of the active substance and decrease the accessibility of essential medicines (Holloway 2006, Kar, Pradhan et al. 2010, MSH 2012, Holloway



and Henry 2014). This malpractice arises at all levels of the medicine-use cycle, from the health system, the prescriber, the dispenser and the user (MSH 2012).

The policies and strategies to improve medicines' use are grouped into four categories. The first one is educational actions: e.g. training of prescribers, educational out-reach, promotion and use of generic medicines. The second category comprises managerial strategies, such as development of clinical guidelines and setting of healthcare priorities, monitoring, supervising and feedback. The third category covers economic strategies, including price setting and the provider-pay-for-performance model (P4P), in which incentives are given to healthcare providers for meeting performance measures. Lastly, the regulatory strategies include actions such as drug registration and the use of medicines list (MSH 2012, Holloway and Henry 2014, Kheirandish, Rashidian et al. 2015).

#### b) Affordability of medicines

Medications are the major source of health spending, they account for 20-60% of total health expenditure (Bigdeli, Javadi et al. 2013). It is therefore no surprise that this issue remains a key priority on health and foreign policy agendas. The normative context of affordability comes down to the question of who pays for health expenditure and how it should be covered. For instance, out-of-pocket-expenses imply that people pay for the cost of medicines through a scheme of co-payments in which the burden is shared between the population and the government or completely through public financing (tax revenues) (WHO and HAI 2008, Niens and Brouwer 2013).

Price-setting by public authorities is constrained by the prices charged by the manufacturers and the additional costs incurred along the supply chain. The costlier the drugs, the higher the barrier to obtaining the medications. This condition paves the way for conflicts of interest and discussion in the international fora.

Some approaches implemented to mitigate against this issue at the national level are to reduce the prices of medicines by enforcing mandatory use (and reduced prices) of generic medicines; to minimise profit margins either for medicines, pharmacies and wholesalers; and, finally, to negotiate with pharmaceutical companies to persuade them to lower the prices of their medicines. Another method undertaken is to increase user financial protection by increasing reimbursement of generics. This entails building targeted social safety nets via health insurances or other mechanisms (Bigdeli, Javadi et al. 2013, Kheirandish, Rashidian et al. 2015).

#### c) Sustainable financing

The third component of the framework deals with attaining a balance of costs within the whole healthcare system provided and heavily funded by the government. If governments are purchasing expensive medications or the demand for medicines becomes excessive, then the system is fed with less resources. This economic reality is defying the public governance of health (MSH 2012).

Actions taken to mitigate against these big issues encompass, among other measures, improving technical and allocative efficiency. The allocation of pharmaceutical resources is directed towards favouring the use of domestically produced medicines or importing generics instead of brand medicines. (MSH 2012, Bigdeli, Javadi et al. 2013, Kheirandish, Rashidian et al. 2015).

#### d) Ensuring reliable healthcare and supply systems for provision of medicines

The elements of an effective healthcare and supply system that supports access to medicines are vulnerable to political pressures and abuse. Sustainable supply relies on effective management systems, which are poor in many countries characterised by little transparency and accountability procedures as well as a lack of human resources and expertise (MSH 2012).

The WHO outlines the foundations of an effective management system as follows: i) a health sector development (direct obligation of governments), ii) a constructive public-private and NGO intervention for procurement, storage and distribution of medications and services, iii) adequate regulatory controls, iv) procurement cooperatives and v) traditional and complementary medicines (WHO 2004).

Regional organisations and NGOs focus most on this rubric because they have the ability to identify more rapidly and accurately the market needs and the medicines shortages in each country as well as to contribute to the improvement of the medicines procurement cycle. A regional approach also increases interactions with the manufacturing companies and facilitates negotiations (Kheirandish, Rashidian et al. 2015).

#### Conditions for an effective regional health policy

There are three conditions that determine the effectiveness of regional health policies under the framework selected. In this work, the conditions have been extended to pharmaceutical policies to determine the role of UNASUR and the EU in the promotion of a regional pharmaceutical policy with regards to medicines access.

**Willingness** is the first of these conditions. Regional formations offer advantages when addressing global challenges because they are composed of a group of countries that are, in theory at least, convergent in values and objectives. Agreement by politicians to collaborate makes strategies to progress more quickly (Deacon, Ortiz et al. 2007). However, this assertion only holds true as long as there is willingness of the leaders of all member states to meet the common goals agreed upon and to efficiently implement them. In short, regions should be willing to articulate and execute policies to achieve social transformation.

**Acceptance**, the second condition, refers to the process of legitimisation of the policies. The importance of acceptance results from the imperative of internalising the desired norms at the regional level. As noted by Dupuy and Van Ingelgom, in order to attain legitimatisation “the design of the standards must be distinct, need to be supported by the public and lastly, they need to perform well” (Dupuy and Van Ingelgom 2013). The other dimension in which the social policies gain acceptance is at the international level. The promoting region should seek to obtain a ‘buy-in’ from other regional and international organisations, like the WHO in the case of health-related matters.

Thirdly comes the **capacity** of the regional organisations to effectively act in the domain of medications. The successful development, promotion and implementation of the pharmaceutical policies is realised through the presence of robust institutions and strong funding means. If regions are to implement new pharmaceutical policies they will not only require significant financial resources, but skilled manpower. Each region is responsible for building its own capacity. . Important in the determination of capacity is to achieve integration of the regional pharmaceutical policies into the national regulations of the member states (Van Langenhove and Kingah 2014).

#### Comparative cases

Regional organisations play a key role in collecting and disseminating knowledge among member countries for a more homogeneous negotiating position between government officials vis-à-vis private pharmaceutical manufacturers and suppliers as well as with regard to policy-making, harmonisation of pharmaceutical legislation, and so forth (Amaya, Kingah et al., Deacon, Ortiz et al. 2007). Moreover, regional organisations have become more present in international dialogues, giving greater recognition to effective health governance (Bianculli and Ribeiro Hoffmann 2015, Cooper and Farooq 2015). Ribeiro and Tabak observe that “regional organisations have become key actors in the UN system in addition to the original five official UN regional groups” (Ribeiro Hoffmann and Tabak 2017).

## Union of South American Nations (UNASUR)

### Introduction to UNASUR

The Union of South American Nations is a relatively new regional organisation. Its constitutive treaty was signed in 2008 and it has its headquarters in Quito, Ecuador. Its 12 member countries are: Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Suriname, Uruguay and Venezuela (UNASUR 2017).

The creation of UNASUR resulted from the necessity to build South American identity and citizen participation after the changing global political-economic scenario in the 2000s. It serves as a space for multilateral cooperation among South American countries as well as a model of regionalism founded on social, cultural, ideological and political grounds, outlining cooperation and the collective developing of harmonised right-based social policies (Ribeiro Hoffmann and Tabak 2017, UNASUR 2017).

The principle of universality, interdependence and indivisibility of human rights imprinted in the Strategic Commission of Reflection for a New Model of South American Integration formed in 2005 is the precursor of UNASUR foundational ideological purposes. Two of its main goals areas are to promote and strengthen political dialogue between the member states and reinforce South American participation in the international arena (UNASUR 2017).

One of the priorities for the region is raising health standards. UNASUR's strategy to achieve universal health is through the consolidation and integration of social health policies, area in which South America possesses considerable expertise thanks also to UNASUR regional cooperation in the field (Amaya, Kingah et al., Riggirozzi and Grugel 2015).

In 2010 UNASUR launched the Quinquennial Working Plan, also known as the Five Year Plan (2010-2015), which contains five priority actions in health. Universal access to medicines stands out as the third priority to address. In order to achieve these goals it was agreed to establish a health institute that could serve as a regional health think-tank, the South American Institute of Government in Health (Instituto Suramericano de Gobierno en Salud) known as ISAGS. This institute provides policy-oriented research, promotes innovation, helps to build capacity and disseminates best practices (ISAGS 2012).

A hierarchical structure promotes intra-regional cooperation and enables transversal diplomacy for health negotiations in the international setting. Owing to this organisational arrangement, UNASUR does not delegate its governance to supra-national bodies, but is instead characterised by a horizontal configuration that relies on intergovernmentalism, with relatively compact councils and loosely cohesive secretariats. When it comes to judicial power, UNASUR does not have a dispute settlement mechanism in place to enforce rules, which makes the organisation less predictable (Bianculli and Ribeiro Hoffmann 2015).

UNASUR has no binding regulations, meaning that each member country adopts comprehensive national policies and/or strategies, accompanied by legal and regulatory frameworks taking into account their context and national priorities (PAHO 2016).

The case of UNASUR focuses on how this organisation is designing and implementing pharmaceutical policies based on the WHO access to medicines framework given its socially-oriented goals, its capacity, its horizontal structure and significant difference in economy sizes of its member states. The conditions of effectiveness of pharmaceutical policies is done for each dimension of the WHO framework. For instance, the conditions of willingness, acceptance and capacity analyse the ways in which UNASUR's pharmaceutical policies are tackling the issue of rational selection and use of medications, how these are contributing to attaining more affordable medications, more reliable

healthcare and supply systems and lastly, what the approaches aimed at obtaining sustainable financing are.

*Dimension 1: Rational Selection and use of medications*

### **Willingness**

UNASUR's policy related to this rubric on access to medications is outlined in section 6 of the Five Year Plan. This Five Year Plan sets programmes and actions plans to be developed based on five work areas, including health (SELA 2015). According to item 11, UNASUR's policy aims "to promote the rational use of medications, particularly in the promotion, advertising, prescription sales and use" (UNASUR 2010).

All countries of the Union, except Venezuela, have incorporated in their national laws or national pharmaceutical policies a clause to promote the rational selection and use of medicines and technology. The Ecuadorian Regulation for Control of Drugs, Advertising and Promotion goes beyond this by regulating the marketing of medicines. The Argentinian provision allows authorities to implement actions such as the modification of package inserts, dosage adjustments, sales conditions, restriction of use and drug recalls (ISAGS 2012).

### **Acceptance**

ISAGS provides advocacy to systematically disseminate policies and research information. It also conducts trainings and capacity-building for member states and at a global scale, mainly within the UN system. In addition, member countries promote rational use of drugs through health professionals and pharmacists. Traditional media has been used to reach the general population. Training is performed through workshops covering a broad range of health-related topics, such as health governance; health surveillance; health, environment and sustainable development; and global health and health diplomacy (ISAGS 2012, Bianculli and Ribeiro Hoffmann 2015, Giovanella and Faria 2015).

### **Capacity**

UNASUR has developed human capacity by conducting regular meetings with Ministries and Councils. When it comes to training, UNASUR has a highly educated human capacity in health-related issues. Considerable resources go to public investments in pharmaceutical education (Amaya, Cabral et al. 2015).

UNASUR has strongly advocated for actions and policies that enable the rational selection and use of medications. In the same fashion, the member states have incorporated them into their national regulations and have promoted them with the support of the Union, which also provides highly skilled human resources and solid training programs.

*Dimension 2: Affordability of medicines*

### **Willingness**

One of the priorities to UNASUR is to gradually accomplish affordable medications. This goal has been emphatically outlined in UNASUR's normative constitution. Notably delineated in various directives within the Five Year Plan, for example, directive 3 calls for the implementation of an essential medicines list and other mechanisms for negotiating drug prices in each member country. Moreover, directive 5 urges measures to effectuate and/or extend the capacity of national production of medications as well as of the network of pharmaceutical laboratories. Likewise, subsequent directives make a call to strengthen technology transfer in the production of medications among member countries and to intensify research of pharmaceutical and biotech products. Equally important are directives 14 to 16, which incentivise for the application of TRIPS flexibilities and the

use of generic versions of medications (UNASUR 2010). All UNASUR's member countries are also members of the WTO and signatories to the TRIPS agreement. Only Brazil has successfully applied the flexibilities of parallel licencing and compulsory licences (WIPO).

The implementation of these policies is instrumental in improving the availability and affordability of medication consistent with the clinical needs of the region and of particular population groups in each country.

All UNASUR members have at least basic drug information systems, pricing regulations and laws guarantying access to medications and an implemented Essential Medicines List (EML) (Herrero and Tussie 2015). Brazil and Argentina's regulations are the most robust, going as far as designing norms that support state production of medications and granting mandatory licences. Bolivia and Venezuela are the most ambiguous and unregulated (ISAGS 2012).

### ***Acceptance***

Openness to embrace and learn the relevant norms set by the regional organisation is manifested in the creation of the Health Committee. This committee establishes local focal points in the figure of each country's Health Ministries, which are directly or indirectly involved in the promotion and formulation of pharmaceutical policies generated in the Union. However, they are hindered by the fragmented and heterogeneous healthcare systems, entrenched in local, national and international interests and capacities. Nevertheless, most of the countries have programmes in place to support the promotion and implementation of health policies that not only align with the regional strategy but also seek to create awareness among citizens (Hakonsen 2017). In spite of the legitimacy efforts, compliance varies from nation to nation, with the countries with the most robust policies operating better monitoring systems.

A possible cause for non-compliance of the regionally agreed norms is that national legislators are most likely to embrace the policies crafted at the Union level when they bring political revenues to them or to their political party. This fact debilitates the leading role that the National Health Regulatory Authorities can bear, not to mention the little involvement of civil society organisations and the fragmented and isolated local communities.

### ***Capacity***

Brazil is the powerhouse of the Union. It disseminates its mechanisms by systematic training and capacity building. Brazil's national strategy is to prioritise procurement of national pharmaceutical products and increase national production by investing heavily in large-scale manufacturing plants and research centres. Despite this fact, disparities within the Union persist. Chile, for instance, has little capacity for national production of medicines, and Ecuador relies on imports of finished products, raw materials and supplies. None of them have prospects of improvement in the near future. Bolivia and Venezuela, also part of the Alianza Bolivariana para los Pueblos de Nuestra America (ALBA - Bolivarian Alliance for the Peoples of Our America), have bilateral treaties with other countries from which they import most of their essential medications from (Herrero and Tussie 2015).

The Union has urged the member countries for health reforms and coherent policies to promote national production capacity of at least basic medications to decrease dependence on imports. However, not all countries have the internal political strength and/or financial means to promote the pharmaceutical industry. Peru and Ecuador are the nations that depend most on foreign drug supplies. Venezuela safeguards its medicines supply through binational agreements (Herrero and Tussie 2015, UNASUR 2017).

Nevertheless, it is to be observed that all states run a Drug Price Information System and have national pharmaceutical regulations to guarantee medicines access, such as tax exemptions, regulations on parallel imports, and compulsory licencing, or a combination of all of them (ISAGS 2012).

There is strong willingness from UNASUR to achieve affordability of medications, which translates into various directives. In spite of the mechanisms, support and expertise provided by Brazil, the acceptance and capacity from the other Union member countries varies depending on their own institutional capabilities and treaties.

### *Dimension 3: Sustainable financing*

#### ***Willingness***

UNASUR's efforts for securing sustainable financing has led to two strategies, as indicated in the Five Year Plan. The first strategy is the Voluntary National Funds in which the member countries designate voluntary annual amounts. The major state donors are Brazil, Argentina and Venezuela. The second strategy is foreign financing and/or donor contributions (UNASUR 2010). Initiatives like the Network for Drug Monitoring, Drug Policies Mapping, Drug Price Bank (BPMU) and the Mapping for Regional Drug Production Capacities and Health Supplies are financed by the Common Initiatives Fund (FIC as per its name in Spanish) with the participation of other organisations such as Fundación Oswaldo Cruz (Fiocruz), Médecins Sans Frontières (MSF) International, World Health Organisation (UNASUR 2017).

The rules and guidelines for the common initiatives fund are outlined in the Regulation for the execution of the UNASUR Common Initiatives Fund (UNASUR 2017).

#### ***Acceptance***

Part of the financing burden for acquisition of medications is relieved by two Pan American Health Organisation's (PAHO) Funds: the Strategic Fund and the Revolving Fund. The former is a mechanism for pool procurement of essential medicines and the latter for vaccines and related products at the lowest available price (PAHO 2016). A strong feature of the Strategic Fund is the financial support all signatories are entitled to through the Strategic Fund Capital Account, which provides interest-free loans for countries that require credit. All UNASUR members have signed the agreement with PAHO to use the fund (PAHO 2016). Despite not being UNASUR-exclusive, there is openness in the region to collaborate and engage with international and regional relevant institutions.

At country level, members have implemented specific mechanisms according to their needs and capacity for ensuring access to a number of high-cost medicines and other health technologies. The Sistema Único de Salud (SUS - Unified Health System), already up and running in Brazil and in incubation in Venezuela, Bolivia and Ecuador, illustrates the influence UNASUR exerts on health policy-making at the federal, departmental and municipal level.

Funding for health provision in South America relies on fiscal resources at large, mainly income and consumption taxes. An important issue to overcome by UNASUR is the level of inefficiency in the management of each country's resources and the inadequacy of tax collection (ISAGS 2012).

#### ***Capacity***

The financial capacity of the Union countries to provide universal access to medicines is politically challenging. The ministries of health and other relevant political authorities are involved to different degrees. Health reforms to provide universal coverage carried out from 1990 to 2000 led to a range of diverse insurance-based schemes supported by tax resources. The reality is that the purchase of medicines for the population represents the highest private out-of-pocket spending for health-related payments in all twelve countries (ISAGS 2012, Hakonsen 2017).

In most countries of the Union, the purchase of medications depends largely in the income and capacity of households. According to PAHO, "two thirds of drug financing comes from household

spending". The countries with the most drug expenditure within the Union are Chile and Brazil. In Chile 30% of medications circulating in the country are provided by the public system while Brazil provides 25% of them (Pan American Health Organization 2012).

Despite the efforts and investments done so far to achieve universal access of these products, a report from PAHO reveals that UNASUR member states have been sued by patients for lack of medicines (PAHO 2016). Sustainable financing is perhaps the dimension that is the most challenging for the organisation because it is a highly politicised topic. Financing represents the biggest limitation to advance UNASUR programs; this is not to say that the FIC is useless, but rather insufficient. Member states have resorted to international funding and credit schemes. Capacity is still poor and has led to a reduced number of medications provided free of cost to the population.

*Dimension 4: Reliable healthcare and supply systems for the provision of medicines*

### ***Willingness***

The EML generated and updated by each member country of the union is intended, among other objectives, to secure medicines for the treatment of a nation's prevalent diseases and to encourage proper country-wide supply (ISAGS 2012). UNASUR had all its member countries adopt EMLs in their National Drugs Policy and regulate for generic drugs and a reliable supply system. The latter follows the logic that a timely and proper supply of medicines is crucial in the provision of healthcare (ISAGS 2012, UNASUR 2017).

The supply management of pharmaceutical and medical products is generally done through joint private-public entities, a collaboration and coordination of territorial networks of organisations and public networks (Giovanella and Faria 2015).

Governments and Health Ministries are faced with a gridlock when it comes to the supply and distribution of medicines in their healthcare systems. They have responded by integrating policies within their National Laws that enable the creation of programmes, such as Argentina's Remediación + Redes in which drug dispensing is systematised for the first level of care. Guyana, on the other hand, has developed a creative supply chain model in conjunction with the private sector. It is called the Supply Chain Management System (SCMS) and it has introduced a new storage system that strengthens the purchase and distribution network. The SCMS led the Ministry of Health to expand the resources for providing free drugs within the health units under its jurisdiction. The system is an electronic version of the combined requisition and issue voucher (E-CRIV) that aims to improve the process of drug requests by integrating all levels of the supply system and monitoring through network of small laboratories. (ISAGS 2012).

Unlike the other countries of UNASUR, Venezuela considers the concept of first level of provision of healthcare oversimplified and has thus departed from it. Instead, the country has implemented the Barrio Adentro Model. This scheme is based on a social territorial approach that addresses the needs and problems of a whole family group, including provision universal and free essential medicines for all. The model also strengthens the medicine supply and distribution network country-wide (ISAGS 2012).

For novel treatments and drugs that are too expensive and protected by patents, South American countries have to resort on PAHO's strategic and revolving fund (PAHO 2016).

### ***Acceptance***

Given that health provision lies within the national and local spheres in most states of the Union, public sub-systems grow fragmented as a result of different funding sources and schemes, latent patient pools and different provision modalities with little coordination among them. The largest

budget allocation goes to health facilities for the delivery of complex care located in the countries' capital cities, leading to unequitable supply and infrastructure with basic healthcare clinics located in the less densely populated peripheries (Giovanella and Faria 2015).

To address this problem, UNASUR promotes the use of generic drugs and the use of communication and information technologies to improve the supply and distribution of medications in remote areas. The government of Peru, for instance, operates an Integrated Drug Supply System with private pharmacies to distribute generic drugs using their chain network across the country. Through the system the Ministry of Health is able to optimise the technical and administrative processes of the supply chain developed to select, program, purchase, store, distribute and administer the drugs and surgical-medical supplies in a decentralised fashion (ISAGS 2012, Giovanella and Faria 2015).

### **Capacity**

In order to achieve universal health provision, the factors leading to unequal accessibility of healthcare services (including availability of medicines) are to be addressed by allocating budgets to improve their supply chain and infrastructure. The use of communication and information technology systems improve the processes for optimal drug and healthcare provision (ISAGS 2012).

Throughout the Union, capacity building activities, demanded by increasingly complex technologies employed in health management, are carried out through presentations, seminars, and discussion forums, where knowledge and skills are disseminated to develop central capacity for the realisation of better health provision (UNASUR 2017).

Health institutions and authorities, supported by ISAGS, are also separating the purchase functions from those of the service provision to optimise the supply chain's technical and administrative processes and cooperation with diverse private partners (ISAGS 2012).

Nevertheless, it is still necessary to establish follow-up systems to ensure compliance and of more robust analytical frameworks. There has been a strong push from UNASUR to integrate policies that address the drug supply systems into national regulations. Acceptance varies from country to country; some have responded with innovative models and schemes that include the private sector and the use of technology. However, capacity is still limited, as unequal health and medicines provision perseveres between rural and urban areas.

## **The European Union (EU)**

### Introduction to the EU

The European Union is both a political and economic integration model with exclusive legislative competence and the power to issue binding regulations in areas such as monetary policy. In other areas, like social policy, the legislative function is shared between the EU and the member states (Furtak 2015). It is based on the rule of law and promotes economic integration, representation and democracy (European Union 2017).

The EU recognises that health is affected by social and environmental factors, and it has carried out interventions and crafted evidence-based regulations that promote health based on these drivers. The EU also recognises that health systems represent a large stake of the European economy. There is a large, competitive market of buyers and sellers of healthcare products, given that the EU pharmaceutical products industry is one of the world's largest and most profitable, and a source of jobs for a substantive number of Europeans. Consequently, the EU's health policies are mainly directed towards three areas. The first area relates to the determinants of health, for instance regulations that mobilise resources to meet the daily needs of citizens, such as educational and job opportunities, income and nutritious food, as well as solid social support, to cite some. The second area is directed towards facilitating the integration of the internal market, e.g. as regards professional



mobility. The last area is concerned with health regulation, including pharmaceutical policies (Greer, Fahy et al. 2014).

*Dimension 1: Rational Selection and use of medications*

### **Willingness**

Along with the WHO, the EU has developed instruments to encourage the rational use of medicines. These are: a) prescription of active ingredient name or International Non-Proprietary Name (INN), b) prescription guidelines, c) pharmaceutical budgets for doctors, d) generic substitution and e) active monitoring of prescription. These instruments are implemented in each member state, either in an indicative or obligatory fashion (Zimmermann, Habl et al., Vogler and Schmickl 2010, Vogler, Zimmermann et al. 2016).

All EU member states have implemented measures to promote the rational use of medications. However, implementation and monitoring differ among countries. Some have made the mechanisms obligatory, enabling violations to be sanctioned (Zimmermann, Habl et al., Vogler and Schmickl 2010). In twenty-one member countries for instance, doctors are encouraged to prescribe INN instead of the brand name. And in Estonia, Lithuania, Portugal and Romania the enforcement is mandatory. Comparatively, Cyprus made it obligatory only in the public sector but not in the private one. In the case of prescription guidelines, nine countries of the EU have made them compulsory, while twenty-three have only introduced them. When it comes to pharmaceutical budgets, only Latvia and Czech Republic apply sanctions, while in all of the other countries they are uncommon. In particular for the generic substitution measure, only six countries have implemented it in a mandatory fashion, although this regulation is applicable in nineteen of the member countries. Lastly, in nearly all nations conforming the EU, payers are indeed entitled to monitor the prescription behaviour of the physicians (Vogler and Martikainen 2015).

### **Acceptance**

The EU works in partnership with NGOs, intergovernmental agencies, research centres and health institutes to jointly generate reports and policy briefs aimed to better advocate and promote the rational use of medicines among state members.

As an example, the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHO CC) and the Austrian Health Institute released a report in 2010 on the perspectives on the rational use of medicines in the EU, to identify challenges and policy gaps.

### **Capacity**

Some countries, like Denmark and Italy, have established dedicated departments for the promotion of the use of medicines. In countries like Spain, the mechanisms are not harmonised, and policies can vary depending on the region (Zimmermann, Habl et al.).

Overall, monitoring the adoption of practices aimed to improve rational selection and use of medications is an area that requires more attention, especially in those countries where mechanisms are only introduced as indicative. Considerable achievements have been observed in terms of the higher share of generics in countries where enforcement mechanisms are in place (Vogler and Schmickl 2010).

In the European Parliament Report 2016/2057(INI), Recommendation 87, the European Parliament (EP) calls on the European Commission (EC) to promote the rational use of medicines across the EU through campaigns and educational programs. Moreover, the EU urges that national information activities target general public and not only medical doctors (European Parliament 2017).

The EU recognises rational selection and use of medications as a key dimension to improve access to medicines. Despite the development of instruments and mechanisms, its willingness and acceptance are dented by some member countries that have not enforced such principles in their national regulations. Capacity is still in construction, but is building up solidly.

#### *Dimension 2: Affordability of medicines*

##### **Willingness**

The EU's health policy outlines the specific objective of affordable medicines (Article 168, TEU), in which the Union's policies complement national ones. The Council of Ministers of Health recognises that the price levels of new drugs pose a burden to the sustainability of health systems and the affordability of medicines. Respecting the division of competences, they have called for the examination of the EU pharmaceutical system and legislation to facilitate the availability of generic medicinal products, in addition to emphasising the implementation of a regulatory framework on orphan medicinal products for the treatment of rare diseases (Regulation (EC) No 141/2000) (Van Ginneken and Busse 2010, European Council 2016, Zaprutko, Kopciuch et al. 2017). Moreover, in March 2017, the EP adopted a non-legislative resolution calling for improved traceability of R&D costs, funding and marketing expenditure (Franklin 2017).

While pricing, dispensing, prescribing and reimbursement are national competences (Ministry of Health or Ministry of Social Affairs), the supervision, evaluation and monitoring of medicines is done through regulatory mechanisms set by the European Medicines Agency (EMA), a decentralised agency of the EU responsible for the legislation and procedures of human medicines throughout their life, from R&D, to marketing authorisation, to post-authorisation (EMA 2017).

As all medicines require approval at the national or EU level before being placed on the market, the EMA also has the function of providing support and scientific assistance to national regulators by coordinating the scientific assessment of the quality, safety and efficacy of medicines (EMA 2017).

Finally, the control and information on pharmaceutical patents is a competence of the national patent offices or the European Patent Office for regional level patents.

##### **Acceptance**

With regard to pharmaceutical policies, the working party on pharmaceutical and medical devices handle regulatory issues for market access, clinical trials, authorisations of pharmaceutical products with the aim to achieve patient safety and a functioning internal market. The working party dialogues openly with multiple stakeholders, like patient organisations, the pharmaceutical industry, healthcare professionals and member states. The EMA, on the other end, works closely with several partners and stakeholders, as well as with an important network in and out of Europe (European Commission 2016, EMA 2017).

The EMA partners with over fifty national regulatory authorities, EU member states and the EC to carry out its regulatory responsibilities. Among these responsibilities is to interact with pharmaceutical companies under the principles of accountability, transparency and representation, as the pharmaceutical industry is one of the main stakeholders. Finally, the EMA enters into collaborative partnerships with international organisations like the WHO, the International Coalition of Medicines Regulatory Authorities (ICMRA) and the Pharmaceutical Inspections Co-operation Scheme (PIC/S). The EMA undertakes tasks on standardisation initiatives not only within the International Organisation for Standardisation (ISO) but also within the International Council on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) (EMA 2017).

## **Capacity**

Through Horizon 2020 and the Innovative Medicines Initiative (IMI), the EC considers further investments at national and EU level for the development of novel medicines and treatments of nearly €80 billion of funding over 7 years. Alternatively, along with EMA, the EC seeks to promote open access to research data and equitable licencing. The EMA itself operates with seven committees and a number of working parties and other groups to conduct the scientific work. In the same vein, in cooperation with national competition authorities and the European Competition Network (ECN), the EC monitors cases of market abuse, excessive pricing and other market restrictions from pharmaceutical companies operating in the EU (European Commission 2016, European Council 2016, EMA 2017).

Price cuts were among the most common pharmaceutical interventions in recent years. All competent authorities of EU countries have been involved in the development of the Euripid (European Price) database. Some EU countries like Portugal, Spain and Greece have limited capacity to review and monitor prices on an regular basis, so they have to resort to alternative arrangements (Vogler and Martikainen 2015).

Although this is a dimension that raises controversy, the EU is seeking mechanisms and regulations from which affordability of medicines can be improved. Here there is still work to be done, mainly when it comes to boosting the take-up of generics. The existence of EMA is a sign of positive acceptance however, and the agency is open to working with stakeholders such as pharmaceutical laboratories. Resources assigned to the agency are destined to deliver cutting-edge knowledge and train employees.

*Dimension 3: Sustainable financing*

## **Willingness**

The EU is self-sufficient when it relates to funds and resources feeding the healthcare systems and medicines provision of the member states. Unlike UNASUR, the EU does not rely on international organisations or foreign donors to supply essential medicines to the population. The EU demands strict control and management of domestic finances and sets mechanisms for compliance; it is therefore, for member states to leverage domestic budgets for the acquisition of at least essential medicines. (European Commission 2014, European Parliament 2017).

Regarding healthcare provision, member states offer universal coverage financed out of either public sources, social insurance contributions or a mix of both. As a matter of fact, eligible medicinal products are reimbursed, all essential medicines are 100% covered, whereas non-essential medicines are funded at lower percentage rates.

The expenditure on pharmaceuticals in EU member countries ranges from 30% of healthcare budget in Hungary to 6% in Denmark of the total health expenditure of the states (Vogler and Martikainen 2015).

On the other hand, a forecast commissioned by the Executive Agency for Health and Consumers (EAHC) reveals that the drug market in Europe is likely to decrease due to the increased use or preference for generics and biosimilars, which make pharmaceutical products cheaper (CreativCeutical 2012).

## **Acceptance**

The EU's Pharmaceutical Pricing and reimbursement regulations are binding on all EU member states, despite being a national competence. These regulations emphasise value for money and attempt to reduce cost-containment practices. Rather, new practices are disseminated EU-wide. For example,

the prices of reimbursable and prescription-only medicines in the EU are controlled by each government authority, unlike non-reimbursable medicines prices, which are determined by pharmaceutical companies. In some countries like Belgium, the prices of all medications are controlled by the state authority (Thomson, Foubister et al. 2009, Vogler and Martikainen 2015).

Another illustrative tool becoming widely accepted and implemented, despite opposition from manufacturers, is the External Price Referencing (EPR). EPR is the comparison of the price or value of a new medicine in other countries to derive a benchmark price for setting or negotiating a price. For new drugs, a tool called Value Based Pricing (VBP) is increasingly gaining support. The evaluation is done using Health Technology Assessment (HTA) or economic evaluation (Vogler and Martikainen 2015).

As a result, EU member states have achieved similar prices of medicines despite differences in their specific policies.

### **Capacity**

Europe's pharmaceutical regulations are based on cost-effectiveness and evidence criteria. Consequently, they require highly-trained staff. The EU budget in 2017 was largely allocated to research, innovation, capacity building and education programmes (notably Horizon 2020 and Erasmus+) to maintain solution-oriented institutional capacity. The budget also destines money to the enforcement and compliance of tax collection that, ultimately, support the social systems in place. The social systems provide universal access to high-quality medicines, generate jobs and enhance EU competitiveness (European Commission, Thomson, Foubister et al. 2009).

An example of regional funding arrangement is the already mentioned Euripid database. It was funded for a period of four years by the EC until 2013. Now it is a joint effort of 24 European countries. Similarly, the EU funded a five year project denominated ATOME (Access to Opioid Medication in Europe), aimed at providing policy recommendations to 12 European countries based on applied research, to improve accessibility, availability and affordability of controlled opioid medicines to people with medical need (European Commission 2015).

The EU has developed and ensured a sustainable financing model which is followed and unchallenged by its members. Adequate monitoring and accountability measures are undertaken to keep finances in good shape, in addition to maintaining robust institutions, solid infrastructure and human resources.

*Dimension 4: Reliable healthcare and supply systems for the provision of medicines*

### **Willingness**

EU Directive 2001/83/EC sets the rules governing the distribution of medicinal products. It specifically points out that the "rules for trade and distribution of medicines are incumbent of Member States competent authorities". Article 85a outlines that any person acting as a distributor has to hold a distribution authorisation and must comply with the Good Distribution Practice of Medications for Human Use (2015/C 95/01) published by the EC (European Commission 2001, European Commission 2015).

In the EU, pharmaceutical companies, wholesalers and retailers of medicines are private enterprises. State regulations stipulate the maximum margins in pharmaceutical distribution. Pharmaceutical companies and wholesalers usually supply directly to hospitals, which procure via tenders (in some countries central tendering is practiced) or via direct negotiations in compliance with each national system and regulations (Vogler, Habl et al. 2010, Vogler and Martikainen 2015).

## **Acceptance**

The EU is host to five big pharma countries: Germany, France, Spain, UK and Italy (Vogler and Martikainen 2015). The pharmaceutical industry has a great share of market value in Europe and thus investment in R&D is larger than in the United States of America (USA). It is by consequence an important job provider. The research-oriented industry presses for congruent conditions that facilitate the trade of medicinal products and the development of the pharmaceutical industry. Despite the private nature of the pharmaceutical sector, there are increasing shortages across the EU of a wide range of medicines hindered by disparities between national provisions. Information systems monitoring the supply and possible shortages of medicines are used widely in EU countries to automatise the re-supply of medicines. These systems are managed by either stakeholders or the government (Vogler and Schmickl 2010, Vogler and Martikainen 2015).

Austria, The Netherlands, Spain and France use stakeholder-led systems. In the case of Austria, it has two different systems: Datacare – a web-based interface which communicates shortages from wholesale distributors to manufacturers – and the Index of Medicines, an online publication managed by the manufacturer. In the Netherlands, for example, pharmacists submit shortages notifications through a system called Farmanco, which is hosted by the government (Vogler and Martikainen 2015, AESGP, EAEPCC et al. 2017).

Countries that operate government-led systems are Belgium, Italy, Germany and Portugal. Belgium's system, for instance, is compliant with the EU legislation, in which the notifications are managed by the Federal Medicines Agency through the Supply Actors platform called "medicines (un)availability" (Vogler and Martikainen 2015, AESGP, EAEPCC et al. 2017).

The EU's efforts to standardise the information and assessment of shortages and supply systems comes through an EMA initiative. In November 2013, with the participation of stakeholders related to the supply of medicines, the agency established a public catalogue for the supply of medicines aiming to offer stakeholders, healthcare professionals and patients updated information of shortages (EFPIA 2008, AESGP, EAEPCC et al. 2017).

## **Capacity**

Supply of medications is affected by multiple factors, including problems in production, global consolidation of manufacturing, unintended impacts of pricing and tendering policies, and problems within the supply chain. There is a need to streamline harmonised data packages developed in partnership between authorities and Supply Chain Actors (EFPIA 2008, AESGP, EAEPCC et al. 2017).

The private sector, through the industry trade associations, is very active in providing solutions to mitigate the impact of shortages, such as unique medicines coding and identical trigger point for notification. EU authorities support the integration of a technology system at the European level. However, further backing from national authorities is necessary to institute an adequate legal, political and operational framework (EFPIA 2008, AESGP, EAEPCC et al. 2017).

The EU has the willingness to make a positive impact on the national healthcare and supply systems. However, national regulations in some countries are more relaxed than the EU directives, so as to allow for private sector-led initiatives to operate to privilege good market functionality.

## **Conclusion**

The WHO has asserted itself as the authority in charge of global health governance. It has impacted health and pharmaceutical policy formulation in its member countries, despite the fact that these policies are domestic competence for most of them, including UNASUR's and the EU's member states. Regional organisations seem to provide the most fertile environment for actors to advance strategies aimed at collectively managing problems affecting like-minded nations. Not only does regionalism

strengthen cooperation inside and outside the regions, but it disseminates information that leads eventually to the standardisation and alignment of policies and common stances. It encourages understanding and intensive collaboration processes. As a consequence, regional organisations have quickly become fundamental to the successful promotion of sustainable pharmaceutical policies.

One difference between the two regions here compared is how they frame health. UNASUR, on the one hand, has been a strong activist of a social agenda and has therefore incorporated human rights into health policies leading to a universal health access approach. This feature has been possible due to the continuity of UNASUR's health policies, despite a period of political transitions in South America. The EU, in contrast, has opted for a more pragmatic and holistic approach, associating health also with development and trade as drivers of economic growth. This is the root of the universal health coverage approach. It is worth noting that health is an important component of a wider EU agenda, but that, unlike UNASUR, it is not a structural element used to build European identity. It has never constituted an axis for the unification of the EU, and there is no evidence that it has helped strengthen European regionalism.

In spite of the divergent approaches to health at UNASUR and the EU, both organisations foster social protection and place the population as the main focus of their healthcare systems.

Of equal significance are the intra-regional activities. A structural feature shared by both regions is that social policy legislation is an ultimate competence of national authorities. The regional health body in UNASUR (ISAGS) and supranational institutions in the EU (EC and EP) only support and advise policymakers and health ministers. However, they have developed mechanisms to streamline health policy across the region. Both regions make use of soft law tools consisting of gathering information of member states, generating policy advice and disseminating non-binding guidelines, peer-review, educational campaigns and events. Although this subtle use of health for diplomacy does not bear tangible results, the strategy has led to more harmonised health policies at least in the formulation phase and more prominently in the EU than in UNASUR. However, disparities between countries within each regional organisation make implementation issues something that should be further looked at.

Access to medicines remains a pressing issue for healthcare systems worldwide, and this is not going to change anytime soon. However, initiatives have been established to manage the most detrimental effects, showing the elasticity of policymaking and health governance. The WHO framework of access to medicines is an important step towards the sharing of the burden between civil society and governments. Its incorporation into regional pharmaceutical policies is governed by regional priorities. They are designed as cost-saving measures, as opposed to the general perception of strategies to pursue low drug prices.

The first element, concerning the rational use and selection of medicines, is directed towards creating awareness around the prescribing, delivery and consumption of medications. Hence, it stimulates cost savings. Its status is patent, and is outlined in the UNASUR and the EU regional constitutive treaties as well as in national regulations. Therefore, considerable investments are done for educational campaigns and awareness creation among doctors and pharmacists.

Although there is willingness and acceptance to achieve affordability of medicines, capacity in UNASUR is still somewhat limited. The efforts to nurture and encourage national production of generics have fallen short, regardless of pharmaceutical regulations. Many of the UNASUR member countries are still reliant on imports, be it of raw materials and supplies or of the end product. This dimension poses several political and economic challenges, such as mitigating the impact of the pharmaceutical industry's lobbying activities and finding legal and legitimate avenues within the TRIPS agreements, the creation of a functional internal market, setting up initial investment funds and strengthening human capacity. Member countries may have to surpass (or to confront) the neoliberal model adopted with the reforms in the 1990's and 2000's in order to take control of policymaking and its development.

In the European Union – despite some member countries hosting a consolidated pharmaceutical industry – the affordability of medications remains a hurdle as the treatment of rare diseases still bears high costs. The EU's commitment to affordability is thwarted by its commitment to the optimal functioning of the internal market. For the EU, the challenges are twofold: firstly, to couple social-oriented policies with development and trade policies and, secondly, to improve the compliance with the guidelines created by the EC in all member states.

So far, the financing models have worked in both regions. The EU model is far less dependable on the powerhouses, unlike UNASUR, which is more heterogeneous because contributions are voluntary and largely flow from the wealthiest countries. With regard to access to medicines, the PAHO fund has proved to be adequate for the reality and needs of South American countries, but in the long run, they will need to move away to a more sustainable scheme and create their own robust financing institutions/model.

Important initiatives have been undertaken by UNASUR member states to consolidate reliable healthcare and supply systems for the provision of medicines. Countries have shown willingness by adopting National Drug Policies and by integrating communication and information technologies. However, commitment is latent, dominated by private-public partnerships. There is no empirical evidence of UNASUR's budget allocation to the development of new, or upgrading of existing, infrastructure. This remains primarily the competence of health institutions and authorities, therefore, institutions with greater revenues or budgets invest more than those with less financial resources.

In the realm of effective social health governance, UNASUR has the capacity to influence, but it has limited resources, while the EU lacks willingness to place population over commercial interests when it comes to health policy formulation. In any case, further development of robust monitoring systems and frameworks is necessary. All in all, it has been observed that within UNASUR and the EU compliance with regional guidelines is suppressed by national self-interest.

As a concluding remark, although national authorities retain legislative competence in sensitive topics such as health and access to medications, regional organisations are in a position to imprint significant influence in policy-making among state members and will play an important role in the containment of medicines crisis.

### **Policy recommendations**

Herebelow are suggested some policy recommendations to improve access to medicines in the regions assessed:

UNASUR:

1. Ensure participation and consultation of civil society and healthcare professional groups during the decision-making and policy-formulation phases to achieve more transparent and accountable processes and institutions (de Freitas Campos 2017).
2. Build stronger and larger human capacity to objectively study, improve, increase the efficiency, monitor and evaluate the healthcare model in the region and to promote it at the international arena and among other regional organisations (Van Langenhove and Kingah 2014).
3. Support and incentivise needs-driven production capacity and evidence-based R&D among all member states to boost innovation and biomedical knowledge to meet regional, national and local priority health demands. A percentage of the R&D costs can be removed from the final price of medications if government institutions (either regional and local) contribute to the costs of R&D jointly with the private industry (ISAGS 2012, Health Action International 2017).

The EU:

1. Maximise public funds and use of programmes like Horizon 2020 to encourage the delivery of medicinal products that add real therapeutic value to address non-commercial-driven public health needs (European Commission 2016, Health Action International 2017).
2. Legislate in support of major competition and government acquisition of generic medicines to supply the public healthcare systems (Health Action International 2017).
3. Develop a consistent health policy that incorporates foreign and trade goals. The health policy should encourage the creation of novel business models and a change in consumption/behavioral patterns that set public health and affordable prices of medicines as the main target.

This contribution calls for further research and theoretical analysis to generate knowledge and recommendations to couple trade and health policies. When these two are more harmonised, pharmaceutical policies will be more efficient and, most important of all, medicines will reach a wider population.



## Annex

Table 1. Summary of effectiveness of pharmaceutical policies in UNASUR

| <i>Pharmaceutical policies</i>                                    | UNASUR                                                      |                                |                   |                                      |                          |                              |                                               |
|-------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------|-------------------|--------------------------------------|--------------------------|------------------------------|-----------------------------------------------|
|                                                                   | Willingness                                                 |                                | Acceptance        |                                      |                          | Capacity                     |                                               |
|                                                                   | Rules/Policies                                              | Committed Political Leadership | Openness to learn | Compliance with regional disciplines | International engagement | Robust regional Institutions | Financial, infrastructure and human resources |
| Rational selection and use of medicines                           | Outlined in Quinquennial Working Plan                       | Adequate                       | Adequate          | Deficient                            | Adequate and influential | Adequate                     | Deficient                                     |
| Affordability of medications                                      | Directives 3, 5,6,7,8,9,11                                  | Adequate but fragmented        | Adequate          | Adequate                             | Deficient                | Deficient                    | Deficient                                     |
| Sustainable financing                                             | Five Year Plan and PAHO Strategic Fund                      | Adequate but heterogeneous     | Adequate          | Adequate                             | Adequate                 | Deficient                    | Adequate but fragile and insufficient         |
| Reliable healthcare and supply systems for provision of medicines | Adequate on national regulations. Insufficient in practice. | Deficient                      | Adequate          | Deficient                            | Adequate                 | Deficient                    | Deficient                                     |

Table 2. Summary of effectiveness of pharmaceutical policies in the EU

| <i>Pharmaceutical policies</i>                                    | <i>EU</i>                                                                                       |                                |                   |                                      |                          |                              |                                               |
|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------|-------------------|--------------------------------------|--------------------------|------------------------------|-----------------------------------------------|
|                                                                   | Willingness                                                                                     |                                | Acceptance        |                                      |                          | Capacity                     |                                               |
|                                                                   | Rules/Policies                                                                                  | Committed political leadership | Openness to learn | Compliance with regional disciplines | International engagement | Robust regional institutions | Financial, infrastructure and human resources |
| Rational selection and use of medicines                           | Outlined in TEU                                                                                 | Deficient                      | Adequate          | Deficient                            | Adequate and influential | Adequate                     | Adequate                                      |
| Affordability of medications                                      | Article 168, TEU                                                                                | Deficient                      | Adequate          | Deficient                            | Adequate                 | Adequate                     | Adequate                                      |
| Sustainable financing                                             | Article 311, TEU                                                                                | Adequate                       | Adequate          | Adequate                             | Adequate                 | Adequate                     | Adequate                                      |
| Reliable healthcare and supply systems for provision of medicines | Directive 2001/83/EC and Good Distribution Practice of medications for Human Use (2015/C 95/01) | Adequate but fragmented        | Adequate          | Deficient                            | Adequate                 | Adequate                     | Adequate                                      |

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