

# Digital health policies in LAC: Where do we stand and what can governments do?

Governance Primer & LACNIC

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## Summary

This pilot study raised a set of health-related questions for which Internet-related solutions can be developed or improved upon, with the LAC region as its focus, targeting the following countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Honduras, Mexico, Peru, Venezuela. Emphasis was given to data collection around two axes: “access and quality of medicines” and “digital health information”. Our questions were connected with medicine quality, purchase of medicines over the Internet, personal medicine importation, legality of telemedicine, ccTLD positions during the COVID-19 pandemic. Our findings were summarized in a comparison matrix to presents the findings in a visual way for an at-a-glance evaluation of the data. It was found that the significant presence of substandard drugs in LAC is a cause for concern, constraining the possibility of a more fluid interregional medicines market. High detection of substandard drugs in certain countries may point towards effective policing efforts. It was also found that the purchase of non-prescription medicines over the Internet is mostly legal in LAC, but there needs to be more emphasis on the formalization of laws and official recommendations on the subject. In addition, personal medicine importation appears to be mostly allowed in LAC within the constraints of each country’s laws, and opportunities to increase access to medicines in this manner should be explored in the future. Also, the legalization of telemedicine has been steadily advancing in LAC, particularly in recent times, which is a positive development for the region. Finally, the data pertaining to ccTLD activities was inconclusive.

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## Introduction

Throughout the COVID-19 pandemic, a question that has come up frequently is what society as a whole could have done better, or to be more forward-looking, how structures can be better organized for when an event such as this one takes place again in the future. There is widespread evidence of our collective unpreparedness to deal with the situation, and without all stakeholders assuming a share of the responsibility of generating improvements, it will be difficult for the proper mechanisms to be put into place.

In what Meyer and Kunreuther (2017)<sup>1</sup> call the “ostrich paradox”, policy decisions that follow disasters are often affected by a series of biases, such as excessive optimism about the future and the lack of establishment of longer term plans. This makes it so that once the most significant part of a problem is overcome, subsequent actions lose importance and end up being deprioritized. If longer term policy research is not carried out, the challenges brought about by pandemics might end up forgotten in face of ever evolving global issues.

The Internet Governance community has not been traditionally very involved in matters related to health, but in face of challenges brought about by the pandemic, it becomes necessary to reevaluate how this group can be a contributing factor to the generation of positive change in this area. The variety of stakeholders involved in the community and their innate acceptance of the need to discuss issues taking into account a variety of perspectives and finding mutually acceptable solutions is a strength that cannot be overlooked.

The objective of this pilot study is to raise a non-exhaustive set of health-related questions for which Internet-related solutions can be developed or improved upon, with the LAC region being the focus of the investigation. The themes under consideration are diverse, given that the objective is that of mapping potential areas for further investigation. In this sense, the present research is more focused on understanding the viability of advancing future projects within the LAC region and potentially other regions of the world, rather than providing definitive answers.

Our emphasis is on two axes: “access and quality of medicines” and “digital health information”. In relation to medicines, our concern is both in relation to the quality of the medications being sold in the region and in how they can be purchased by individuals over the Internet; these ideas interconnect in achieving safe and reliable distribution of medicines over the Internet. On the subject of digital health information, we attempt to understand what the telemedicine regulations are at the time of the research and, given our partnership with LACNIC, understand what actions ccTLD operators have taken in reaction to the pandemic.

The themes being studied are of particular interest to governments and Internet Governance bodies, but in reality, there are opportunities for all involved stakeholders to generate meaningful change. This is an idea previously explored in the “Every Internet Governance

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<sup>1</sup> Meyer, Robert; Kunreuther, Howard Chicago: Wharton School Press, Feb 7, 2017.

Stakeholder Has a Role to Play in the Online Health Debate”<sup>2</sup> article, which should be seen as a companion piece to this study, and is included here as Appendix A.

Apart from an in-depth study of each country’s situation in relation to the questions raised by the research, a matrix has been compiled to summarize and contrast the different datapoints, so that the bigger picture of the situation can be understood at a glance. This matrix will be presented in the next section alongside the executive summary of the project’s findings.

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<sup>2</sup> <http://www.circleid.com/posts/20201026-internet-governance-stakeholders-role-in-the-online-health-debate/>

## Executive summary and comparison matrix

After evaluating 5 health-related questions for which there are Internet-related solutions in 10 LAC countries, we are able to point towards some general conclusions that may inform future policymaking and research efforts into the intersection between Internet Governance and health. These are:

- The significant presence of substandard drugs in LAC is a cause for concern, being one of the factors that constrain the possibility of a more fluid interregional medicines market. However, the high number of incidents in some countries is potentially a sign of strong ongoing policing efforts, which may point towards a positive direction.
- The purchase of non-prescription medicines over the Internet is mostly legal in LAC, but there needs to be more emphasis on the formalization of laws and official recommendations on the subject, as those have been found to often be incomplete or unclear, leaving room for interpretation where there should not be any. ccTLDs can definitely play a part in the articulation of such measures.
- Personal medicine importation appears to be mostly allowed in LAC within the constraints of each country's laws. From a practical perspective, this signals the possibility of further studies being carried out in order to find strategies for patients to benefit from this, in improving overall access to medicines.
- The legalization of telemedicine has been steadily advancing in LAC, particularly in recent times, which is a positive development for the region. Even in countries where it was found to be a grey area, the practice still seems to be allowed to a large extent, within the context of the pandemic.
- This study's attempts to gather data from ccTLD operators regarding DNS Abuse during the COVID-19 pandemic, as well as to gauge their level of engagement with local National Regulatory Authorities (NRAs), were not successful to an extent that would enable meaningful analysis. Therefore, these questions were left out of the final document. Circumstantial evidence suggests that there were relatively few active domain names exclusively dedicated to spreading misinformation on the pandemic, which may indicate proactive action against such domains from operators. We suggest that operators publicize this data for future study so that the policymaking community can have a better understanding of the dynamics of bad actors in unprecedented events such as this one.

The following comparison matrix summarizes the findings in a visual way for an at-a-glance evaluation of the data. The substantiation of the data found in it can be studied on the "Research data" section of this document.

### Select LAC countries health-related questions comparison matrix

Country	Substandard drugs presence	Medicine purchase over the Internet	Personal medicine importation	Telemedicine
<b>Brazil</b>	170 incidents	Legal; no prescription drugs; local ccTLD domain required	Legal; NRA approval needed	Legal (2020)
<b>Argentina</b>	38 incidents	Grey area, mostly disallowed	Legal; NRA approval needed	Legal (2020)
<b>Colombia</b>	59 incidents	Grey area, mostly allowed	Grey area	Legal (2010)
<b>Mexico</b>	17 incidents	Legal; no prescription drugs	Legal; NRA approval mostly needed	Legal (2019)
<b>Chile</b>	59 incidents	Legal; almost all drugs, except narcotics	Legal; NRA approval needed	Grey area, mostly allowed
<b>Ecuador</b>	16 incidents	Grey area, prescription drugs implicitly allowed	Legal, with high barrier; NRA approval needed	Grey area, mostly allowed
<b>Venezuela</b>	26 incidents	Grey area, mostly allowed	Apparently allowed	Grey area, mostly allowed
<b>Peru</b>	184 incidents	Grey area	Legal; NRA approval needed	Legal (2019)
<b>Honduras</b>	1 incident	Grey area; prescription drugs allowed	Legal; NRA approval needed	Grey area, mostly allowed
<b>Costa Rica</b>	13 incidents	Legal; prescription drugs allowed	Legal; NRA approval needed	Grey area, mostly allowed

## Methodology

### Objective

This project was designed as a pilot study and carried out within a short research cycle. While academic in nature, it is not aimed at publication in a journal in its current form. This choice allowed for a degree of methodological freedom that would otherwise be difficult to achieve, and permitted ideas to be researched outside of the constraints of a strict framework. Focus was not placed on theory, but rather on cataloguing and performing some light analysis on the available data with the objective of enabling the future design of more structured studies based on these findings.

### Subject selection

With the smaller scope of the project in mind, 10 LAC countries were selected for studying. Given that LACNIC is the organization promoting it, the arbitrary criterion for their choice was the number of LACNIC associates in a given country. This also determined the way the countries are listed in the study, in descending order. This criterion has the potential to reflect, at least in part, the local engagement in Internet-related matters, which in turn is helpful in selecting countries that might be interested in partnering up to create solutions.

Part of the study		Priorities for future studies	
Territory	Associates	Territory	Associates
BR: Brazil	8400	PY: Paraguay	82
AR: Argentina	1048	PA: Panama	73
CO: Colombia	377	DO: Dominicana	68
MX: Mexico	372	GT: Guatemala	50
CL: Chile	306	BO: Bolivia	48
EC: Ecuador	181	SV: El Salvador	45
VE: Venezuela	115	BZ: Belize	28
PE: Peru	112	NI: Nicaragua	28
HN: Honduras	107	UY: Uruguay	22
CR: Costa Rica	90	CW: Curaçao	20

### Actor identification

In our research, we purposefully identified two actors from each of the studied countries: the National Regulatory Authorities (NRAs)<sup>3</sup> and the ccTLD operators. It is our view that these actors

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<sup>3</sup> According to Twesigye, Hafner and Guzman (2021): “Well-functioning national regulatory authorities (NRAs) ensure access to safe, effective, quality-assured, and affordable medical products. However, the benefits of their

are the ones with the most immediate capability to provide the connections between stakeholders that would be necessary to advance the themes presented in this study. It is important to note that, at times, the roles of the NRAs might overlap very significantly with that of National Control Laboratories (NCLs), depending on a given country's structure.

It is also worth noting that among NRAs there are those which are deemed by the WHO to be Regional Reference Authorities (NRARs). These organizations "were assessed against WHO Regional Office for the Americas (AMRO)/Pan American Health Organization (PAHO) standardized evaluation procedure and AMRO/PAHO data collection tool"<sup>4</sup>, being essentially the leading authorities in health within a given region. In our "Research data" section we point out whenever a country's NRA is a NRAR, but, for completeness, in the Americas these are:

- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Cuba
- Mexico
- United States of America

## Questions

From the diverse health-related questions for which there are Internet-related solutions, the issues chosen for exploration fall within two categories/axes: "access and quality of medicines" and "digital health information". These choices speak directly to a set of problems exacerbated by the COVID-19 pandemic: the lack of optimal mechanisms to preserve people's health with nimbleness and at scale, coupled with a demonstrated fragility in the production and supply chain of medicines and health products (such as hand sanitizers and masks).

The questions are:

### Axis 1: Access and quality of medicines

- 1) Does the country have problems with substandard drugs and how severe is it?
- 2) Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

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work are often unseen and difficult to attribute, thereby making NRAs undervalued and under-resourced, particularly in low- and middle-income countries."

<sup>4</sup> [https://www.who.int/medicines/regulation/regional\\_reference\\_authorities/en/](https://www.who.int/medicines/regulation/regional_reference_authorities/en/)

- 3) Does the country allow personal medicine importation, and if it does, under what conditions?

## **Axis 2: Digital health information**

- 4) What is the country's legal situation in relation to telemedicine?
- 5) What has been the local ccTLD's posture on regulation of pandemic-related domains, if any?
- 6) Does the local ccTLD maintain an active line of communication with the country's National Regulatory Authority (NRA)?

In relation to **Axis 1**, several factors are involved in citizens being able to access medicines in a socially distant context, which also extends to (eventual) medicines proven effective against COVID-19 and other future threats. To begin with, an evaluation of whether it is already possible to purchase medicines over the Internet in LAC is necessary. On top of that, there is a distinct lack of regulation in terms of fair access to medicines, which can allow for practices such as hoarding and price gouging, on top of straightforward shortages of stock in home markets. The Internet enables people to legally import almost anything that they require, but medicines and health products are often restricted even if they come from trusted foreign suppliers.

It is widely observable that in the lack of legal financially reasonable alternatives, black markets form and put populations at risk. Rojas-Cortés (2020)<sup>5</sup>, reviewing the reported issues with medicines in Latin American between 2017-2018, found that “substandard, falsified and unregistered medicines persist as a highly prevalent problem,” detailing that “A total of 596 incidents in 13 countries were included (236 substandard, 239 falsified, 116 unregistered and 5 stolen). The therapeutic categories with the highest incidents were: anti-infectives, medicines for pain/palliative care, hormones/contraceptives, medicines for the respiratory tract, and medicines for mental/behavioural disorders.”

It is worth noting that a higher or lower number of incidents does not necessarily correlate with how prevalent the problem is in each country, given that more extensive policing results in more cases, and vice-versa. In fact, five out of the six NRAs (Argentina, Brazil, Chile, Colombia and Mexico) considerably detect and communicate the highest proportion of incidents in the region, hinting at how regulatory maturity creates an environment which fosters the combat of substandard drugs<sup>6</sup>.

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<sup>5</sup> Rojas-Cortés R. Substandard, falsified and unregistered medicines in Latin America, 2017-2018. *Rev Panam Salud Publica*. 2020;44:e125 <https://doi.org/10.26633/RPSP.2020.125>

<sup>6</sup> *Ibidem*

In relation to **Axis 2**, the effort to contain the spread of misinformation needs to be advanced on multiple fronts to be effective. This relates in part to the broader discussion of regulation and accountability in social media platforms, but also involves the establishment of channels for citizens to remotely consult with health professionals who can provide them with accurate information, as well as the regulation of the Web and domain name space to ensure that intentionally fraudulent websites are not kept online.

Roozenbeek et al. (2020) found in their empirical study (which includes Mexico within its sample set) that “while belief in misinformation about COVID-19 is not held by a majority of people in any country that we examined, specific misinformation claims are consistently deemed reliable by a substantial segment of the public and pose a potential risk to public health,” complementing that “although previous research has debated the societal consequences of fake news, we clearly show that susceptibility to misinformation can be a significant factor in influencing people’s behaviour during the COVID-19 outbreak in three important ways: it may make people less likely to report willingness to get vaccinated against COVID-19, it may make them less likely to recommend vaccination to vulnerable people in their social circle, and it may decrease people’s willingness to comply with public health guidance measures.”<sup>7</sup>

The study attempted to gather data from ccTLD operators regarding DNS Abuse during the COVID-19 pandemic, as well as to gauge their level of engagement with local National Regulatory Authorities (NRAs), represented here by Questions 5 and 6. These inquiries were not successful to an extent that would enable meaningful analysis. Therefore, these questions were left out of the final document. Circumstantial evidence suggests that there were relatively few active domain names exclusively dedicated to spreading misinformation on the pandemic, which may indicate proactive action against such domains from operators.

## Limitations

The question that stands out as the greatest limitation to the research that was carried out relates to how the primary healthcare system of each country works in reality, and whether they can be compared with each other. At a glance, the answer might seem as straightforward as individually listing what resources are available as a public service or only as a private one, but the complexity and nuance of these systems are deep and make it difficult to accurately interpret the laws and rules, which led to the collection and analysis of this data falling outside of the scope of the study.

General trends were identified, such as the existence of some form of free public health system to tend to the poor or destitute, but the services provided to the general economically active population vary significantly, as does the way they are taxed and made available. Speaking

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<sup>7</sup> Roozenbeek J, Schneider CR, Dryhurst S, Kerr J, Freeman ALJ, Recchia G, van der Bles AM, van der Linden S. 2020 Susceptibility to misinformation about COVID-19 around the world. *R. Soc. Open Sci.* 7: 201199. <http://dx.doi.org/10.1098/rsos.201199>

broadly, some form of public health system is consistently present, but private options exist and are considered to be preferable.

Future studies should definitely take these aspects into consideration as a priority.

## Research data

Brazil (Brasil)

**NRA – NRAR:** Agencia Nacional da Vigilância Sanitária (Anvisa)

**ccTLD operator:** NIC Brasil/Comitê Gestor da Internet no Brasil

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
110	9	50	1	170

Anvisa (2017-2018), see Rojas-Cortés (2020)

Brazil is the only country in the region implementing the prohibition of advertising of medicines. Substandard drugs are referred to as “irregular”, being those not approved and regulated by Anvisa. Anvisa establishes the criteria for which drugs are substandard, and the rules are the same for national or imported medicines. Brazil was the country with the highest number of regulatory measures taken against substandard drugs, consistently making use of at least eight of the ten main types of measures available<sup>8</sup>.

Further information:

<https://www.ictq.com.br/industria-farmaceutica/990-controle-da-qualidade-de-insumos-farmaceuticos-e-fundamental-para-eficacia-do-medicamento>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7537817/>

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

The remote dispensing of pharmaceutical products was regulated by ANVISA (National Health Surveillance Agency), between articles 52 and 59 of RDC 44 of 2009, establishing rigid rules that must be fully complied with by pharmaceutical establishments:

- All websites must be under the “.br” ccTLD.

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<sup>8</sup> Rojas-Cortés R. Substandard, falsified and unregistered medicines in Latin America, 2017-2018. Rev Panam Salud Publica. 2020;44:e125 <https://doi.org/10.26633/RPSP.2020.125>

- The website must contain all compliance information and authorizations needed for selling drugs online.
- All medicines must be bought with a prescription that can be sent remotely.
- Medicines subject to special control cannot be sold remotely or exposed on the website.
- The pharmaceutical establishment must guarantee the user the right to information and guidance by a pharmacist on the use of medicines ordered by remote means.
- The use of images, advertising, publicity and promotion of prescription medicines is prohibited anywhere on the website.
- The warning phrases required for non-prescription drugs should be highlighted, according to specific legislation.

Several pharmacy chains currently operate in partnership with app delivery services to maintain social distancing.

Further information:

[http://portal.crfsp.org.br/images/stories/2016/06\\_16/anfarmag.pdf](http://portal.crfsp.org.br/images/stories/2016/06_16/anfarmag.pdf)

### **Does the country allow personal medicine importation, and if it does, under what conditions?**

Regulated by “*Resolução DC/ANVISA nº 81*” de 05/11/2008”.

To import a medicine that is registered in Brazil, it is necessary to have Anvisa’s approval and, in order to be entitled to a zero-import tax rate, there is need to present the medical prescription and other documents that demonstrate the need for the order. Initially, the cap for how much can be imported is set at USD 10,000.

If a drug is not registered in Brazil, import is possible through an exceptional import order for personal use. Orders must be filed with Anvisa, where they will be analyzed by the agency’s technicians. For approval, aspects such as efficacy and safety of the product are taken into account, with the agency not necessarily needing to agree with claims by third parties.

Further information:

<https://www.abracomex.org/importacao-de-medicamentos-o-que-preciso-saber-sobre-isso>

### **What is the country’s legal situation in relation to telemedicine?**

On December 13th, 2018, the *Conselho Federal de Medicina* (CFM) regulated telemedicine in Brazil, by “*Resolução nº 2.227/2018*”, establishing rules for its practice. On March 19th, 2020, the federal government and the CFM exceptionally authorized the broad use of telemedicine by

means of “*Ofício CFM nº 1756/2020-Cojur*”, recognizing the possibility and ethics of using telemedicine during the fight against COVID-19.

On March 23rd, 2020, “*Portaria nº 467*” was published, where it was formalized that “doctors may, within the scope of telemedicine care, issue medical certificates or prescriptions electronically” and “the issuing of prescriptions and medical certificates at a distance will be valid electronically”, considering that some criteria are met. On April 16th, 2020, Law “*Nº 13.989*” formally authorized telemedicine during the COVID-19 crisis. The regulation of telemedicine will be decided by CFM in a more permanent manner after the pandemic ends.

The public health system (SUS) developed new ways for people to access remote health care. Since March 2020, there has been pre-clinical care by phone, online chat and WhatsApp communication, follow-up services and remote monitoring of suspected cases of COVID-19. There have also been virtual consultations to some extent.

Further information:

<https://www.in.gov.br/web/dou/-/portaria-n-467-de-20-de-marco-de-2020-249312996>

<https://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=16/04/2020&jornal=515>

<https://agenciabrasil.ebc.com.br/politica/noticia/2020-08/bolsonaro-promulga-liberacao-de-receita-medica-digital>

<https://portal.cfm.org.br/images/PDF/notacfmhonorarioscovid19.pdf>

<https://www.brhommed.com.br/cfm-regulamenta-atendimentos-online-no-brasil/>

<https://aps.saude.gov.br/noticia/8136>

<https://aps.saude.gov.br/noticia/8577>

<https://www.conasems.org.br/ministerio-da-saude-lanca-telesus-para-auxiliar-populacao-sem-sair-de-casa/>

## Argentina

**NRA – NRAr:** Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)

**ccTLD operator:** NIC Argentina/Secretaría Legal y Técnica de la Presidencia de la Nación

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
22	15	1	0	38

ANMAT (2017-2018), see Rojas-Cortés (2020)

According to “*Ley Nº 16.463, Medicamentos*”, medicines must follow the conditions imposed by *Farmacopea Argentina*<sup>9</sup>, a guidebook maintained by ANMAT, which “specifies that which concerns origin, preparation, identification, purity, assessment and other conditions that ensure the uniformity and quality of the properties [of the medications]”. If not contained in the book, the conditions might be decided by ANMAT and can be ones established by other NRAs or backed by trusted scientific research.

Further information:

[https://www.fefara.org.ar/files/LEY1463\\_decreto\\_reglamentario.pdf](https://www.fefara.org.ar/files/LEY1463_decreto_reglamentario.pdf)

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

There doesn't seem to be a law that condemns or allows the purchase of drugs using the Internet in Argentina. We have verified the following national laws, at least as far as “*Ley Nº 16463, Medicamentos*” and “*Ley Nº 17565, Farmacias*” are concerned.

Nevertheless, a pronouncement by Miguel A. Lombardo, president of the Federación Argentina de Cámara de Farmacias (FACAF), states that selling drugs over the internet “*vulnera la legislación vigente, constituye una práctica desleal y atenta contra la salud pública*<sup>10</sup>”. FACAF also takes the position of demanding that local authorities prohibit the sale of medicine using the Internet or

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<sup>9</sup> [http://www.anmat.gov.ar/webanmat/fna/pfds/farmacopea\\_argentina\\_2013\\_ed.7.pdf](http://www.anmat.gov.ar/webanmat/fna/pfds/farmacopea_argentina_2013_ed.7.pdf)

<sup>10</sup> Trans.: “Violates current legislation and constitutes a disloyal practice that threatens public health.”

any digital platform. The Cámara Argentina de Especialidades Medicinales (CAEME), takes an opposing view of that presented by FACAFA.

According to our observations, most drugstore websites focus on selling beauty products and cosmetics. However, Farmacity, possibly the most commanding drugstore chains in Argentina<sup>11</sup>, started offering a delivery service during COVID 19 crisis in a limited number of cities and making use of a rather bureaucratic process.

Further information:

<https://www.farmacity.com/comunicacion/medicamentos>

<http://www.facaf.org.ar/informacion-util/leyes-decretos-y-resoluciones/>

<https://www.telam.com.ar/notas/202006/481569-advienten-que-la-venta-de-medicamentos-por-internet-es-riesgoso-para-la-salud.html>

### **Does the country allow personal medicine importation, and if it does, under what conditions?**

The “*Régimen de Acceso de Excepción a Medicamentos no Registrados*” (RAEM-NR) allows for the importation of medicines not commercialized in Argentina. A patient must initiate the procedure, which is done through the Sistema Trámites a Distancia (TAD), over the website. The request is authorized by ANMAT. The patient then has to submit many documents, online and also on paper, such as the doctor’s prescription, declaration and curriculum and the patient’s clinical history. It’s also needed a “clave fiscal”, given by AFIP (Administración Federal de Ingresos Públicos) which is the “organismo que tiene a su cargo la ejecución de la política tributaria, aduanera y de recaudación de los recursos de la seguridad social de la Nación”. If the medication is still in trial, there must be also a document that explains why it is indicated; then, it will be analyzed by ANMAT. It is all regulated by “*Disposición 10874-E/2017*”.

Further information:

[www.tramitesadistancia.gob.ar](http://www.tramitesadistancia.gob.ar)

<https://www.afip.gob.ar/informacionVisual/documentos/importacion-medicamentos/Infografia-Medicamentos.pdf>

<https://www.afip.gob.ar/importacion-medicamentos/procedimiento/como-se-hace.asp>

<https://www.afip.gob.ar/importacion-medicamentos/procedimiento/quien-inicia-tramite.asp>

<https://www.afip.gob.ar/institucional/default.asp>

### **What is the country’s legal situation in relation to telemedicine?**

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<sup>11</sup> <https://www.statista.com/statistics/1116989/argentina-pharmaceuticals-digital-advertising/>

On August 11th, “Ley N° 27553” was published, pertaining to electronic or digital prescriptions. It establishes that the prescription and dispensing of medicines can be performed by means of handwritten, electronic, or digital signatures of qualified doctors. It also established that telecare platforms can be deployed in the country as long as the law on the protection of personal data and the law on patient rights are followed.

Corroborating the data that the sale of medicines over the Internet is a complex subject in the country, the law establishes that medicines prescribed through electronic or digital means must be dispensed in a commercial pharmacy, health center pharmacies, and other health establishments.

On October 28th, 2020, the Senate approved a bill to allow the provision of telemedicine services in a formal manner. The senators recalled that telemedicine or telehealth does not replace traditional health services, reinforcing that contact with the patient is essential. However, they highlighted that in a pandemic scenario it was necessary to rethink health care, and technology can function as a complementary tool in the provision of health services.

Further information:

<https://saluddigital.com/comunidades-conectadas/senado-y-camara-de-diputados-en-argentina-aprueba-la-ley-de-recetas-electronicas-o-digitales/>

<https://saluddigital.com/comunidades-conectadas/aprueban-proyecto-de-ley-en-argentina-para-la-regulacion-de-la-telemedicina/>

[https://www.argentina.gob.ar/sites/default/files/anexo\\_1\\_recomendacion\\_uso\\_de\\_telemedicina\\_-\\_grupo\\_asesor\\_1.pdf](https://www.argentina.gob.ar/sites/default/files/anexo_1_recomendacion_uso_de_telemedicina_-_grupo_asesor_1.pdf)

## Colombia

**NRA – NRAR:** Invima (Instituto Nacional de Vigilancia de Medicamentos y Alimentos)

**ccTLD operator:** .CO Internet S.A.S/Neustar/Ministerio de Tecnologías de la Información y las Comunicaciones de Colombia

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
28	3	28	0	59

Invima (2017-2018), see Rojas-Cortés (2020)

“Decreto Numero 667 de 1995”<sup>12</sup> “partially regulates the matter. According to articles 19 and 20, the requirements for the issuance of the sanitary registration of drugs are: a) Pharmaceutical evaluation; b) Legal evaluation. The purpose of the pharmaceutical evaluation is to assess the technical capacity of the manufacturer concerning the manufacturing process and the quality of the product. The legal evaluation includes the legal study of the documentation that is provided by the interested party for the registration and its compliance with local norms.

Further information:

<https://app.invima.gov.co/alertas/>

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

This study did not find any specific law concerning the sale of drugs over the internet. However, the local pharmacy Farmalisto sells medicines that do not require prescription online<sup>13</sup>. Another pharmacy, Cruz Verde, sells a range of generic medicines online as well<sup>14</sup>. We can therefore surmise that it is considered a licit practice.

### Does the country allow personal medicine importation, and if it does, under what conditions?

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<sup>12</sup> [https://www.invima.gov.co/documents/20143/453029/decreto\\_677\\_1995.pdf](https://www.invima.gov.co/documents/20143/453029/decreto_677_1995.pdf)

<sup>13</sup> <https://www.farmalisto.com.co/2103-no-formulados>

<sup>14</sup> <https://www.cruzverde.com.co/promocion-medicamentos-genericos/>

Invima's "Guía de Diligenciamiento de Intenciones de Importación Ante La Ventanilla Única de Comercio Exterior (VUCE)" contains rules for importation and resale of medicines. If a patient, or a group of patients, needs a vital medication that is not registered in Colombia, or one necessary to alleviate grave symptoms (as per "Decreto No. 481 – 2004"), it is possible to make a request for its importation. The body that handles medicine registration is the Dirección de Operaciones Sanitarias del Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

Further information:

<https://www.invima.gov.co/documents/20143/349821/pautasdiligenciamientodevistosbuenosdeimportacionfinal.pdf/f9f8e05b-0a43-2aed-13e3-120fe09a23ef>

<https://www.invima.gov.co/medicamentos-vitales-no-disponibles>

### **What is the country's legal situation in relation to telemedicine?**

On the relatively early date of December 13, 2010, the Colombian Congress approved "Ley 1419" with the aim of developing telemedicine in Colombia, with the intention of providing access to this resource to the general population. On October 3, 2019, "Resolución 2654" was passed with the aim of "regulating and modernizing the current regulations regarding telemedicine and telehealth, promoting greater and better access to health services in the most remote populations in the country".

Further information:

[https://www.funcionpublica.gov.co/eva/gestornormativo/norma\\_pdf.php?i=40937](https://www.funcionpublica.gov.co/eva/gestornormativo/norma_pdf.php?i=40937)

[https://www.minsalud.gov.co/Normatividad\\_Nuevo/Resoluci%C3%B3n%20No.%202654%20del%202019.pdf](https://www.minsalud.gov.co/Normatividad_Nuevo/Resoluci%C3%B3n%20No.%202654%20del%202019.pdf)

<https://www.elhospital.com/temas/Expiden-resolucion-que-reglamenta-mejores-practicas-de-telemedicina-en-Colombia+132152>

Mexico

**NRA – NRAr:** COFEPRIS (Comisión Federal para la Protección Contra Riesgos Sanitarios)

**ccTLD operator:** NIC Mexico/Instituto Tecnológico y de Estudios Superiores de Monterrey

**Does the country have problems with substandard drugs and how severe is it?**

Substandard	Falsified	Unregistered	Stolen	Total
1	7	9	0	17

COFEPRIS (2017-2018), see Rojas-Cortés (2020)

The “*Farmacopea de los Estados Unidos Mexicanos*” is the document issued by the Secretaría de Salud that sets the general methods of analysis and the requirements on identity, purity and quality of drugs, additives, medicines, biological and biotechnological products.

Further information:

<https://www.farmacopea.org.mx/>

**Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?**

Medicines that do not require prescription and antibiotics can be bought online. Pharmacy chains San Pablo Farmacias and Farmacia Vitau seem to operate digitally throughout the extension of the country. Controlled medications have to be bought in person.

In the wake of the COVID-19 pandemic, medicine ecommerce grew significantly in Mexico. Many drugstores created apps for online sale, while a lesser number partnered with delivery apps, such as Rappi, which has over a thousand affiliated drugstores.

Further information:

<https://vitau.mx/>

<https://www.farmaciasanpablo.com.mx/preguntas-frecuentes>

<https://marketing4ecommerce.mx/la-venta-de-medicamentos-online-en-mexico-crecio-19-en-los-ultimos-6-meses-sin-embargo-las-apps-de-delivery-aun-no-logran-convencer-a-las-farmacias/>

## Does the country allow personal medicine importation, and if it does, under what conditions?

Yes. There is need of a valid prescription and to fill an authorization form Copefris. This procedure is loosened in the case of medicines that don't require a prescription, which appear to be unregulated to some degree. This research could not assert whether those medicines without prescription face problems in customs upon arrival, however.

Further information:

<https://www.gob.mx/tramites/ficha/permiso-sanitario-de-importacion-de-medicamentos-destinados-a-uso-personal/COFEPRIS693>

## What is the country's legal situation in relation to telemedicine?

According to the "*Cédula de Instrumentos Jurídicos aplicables a la práctica de la Telesalud en México*", published by the Secretaría de Salud in April, 2019, Mexico considers telemedicine as a support tool, and should be seen as an activity integrated into clinical practice, and therefore should not be regulated separately from the general practice of medicine. The document considers it is up to the health professionals to adapt to new technologies and provide medical services for all.

This position dates back to 2015, when the project "*NOM-036-SSA3-2015*" was presented with the intention of regulating telemedicine. 3 years later, it was shelved due to the consideration that the only difference between telemedicine and the one performed face-to-face was technological assistance, as the same protocols were applied for diagnosis and evaluation. It was also positioned that, with the fast advance of technology, a regulation might be detrimental for the furthering of innovation.

Regarding prescriptions, "*Lei General de Salud*", published in March 8, 2017, offers in Article 64 that "*la expedición de la receta médica debe contener la firma autógrafa o, en caso de contar con medios tecnológicos, firma digital o electrónica de quien la expide*"<sup>15</sup>, thus recognizing digital certificates as a valid means to authenticate a prescription.

Further information:

[https://www.gob.mx/cms/uploads/attachment/file/500965/Cedula\\_Instrumentos\\_Juridicos\\_Telesalud\\_Mexico\\_2019\\_WEB\\_LIGHT.pdf](https://www.gob.mx/cms/uploads/attachment/file/500965/Cedula_Instrumentos_Juridicos_Telesalud_Mexico_2019_WEB_LIGHT.pdf)

<https://www.eluniversal.com.mx/techbit/telemedicina-una-opcion-contra-el-covid-19>

[http://www.diputados.gob.mx/LeyesBiblio/pdf\\_mov/Ley\\_General\\_de\\_Salud.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf)

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<sup>15</sup> Trans.: "The prescription should contain the signature or, in case of making use of digital mediums, a digital or electronic signature of the person writing it."

## Chile

**NRA – NRAr:** Instituto de Salud Pública de Chile (ISP Chile)

**ccTLD operator:** NIC Chile/Universidad de Chile

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
53	4	1	1	59

ISP Chile (2017-2018), see Rojas-Cortés (2020)

Key figures in the regulation of these matters are: Agencia Nacional de Medicamentos (ANAMED), Laboratorio Nacional de Control, Instituto de Salud Pública. The Laboratorio Oficial de Control de Medicamentos de ANAMED (LOCM) carries out laboratory analysis and provides technical advice, also acting as an authority in relation to the release of batches of vaccines, blood products, and other biological products.

Further information:

<https://www.ispch.cl/anamed/>

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

As of May 8, 2020, a person is able to buy medicines using the Internet, be it those that require a simple or withheld prescription. This was reported by the Minister of Health, Jaime Mañalich, after announcing a decree that authorizes the general electronic commerce of medicines<sup>16</sup>.

For the electronic sale of medicines, pharmacies or pharmaceutical warehouses must have installation and operation authorization, both for the website and the dispatch service, which may be their own or that of third parties. There is also a prohibition on using expressions that induce the use of a certain product over another or that prevent their comparison.

In the case of withheld prescriptions, the patient must present the prescription at the time of delivery of the product. The only drugs that are exempt from electronic sale are those that require a check prescription, such as narcotics.

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<sup>16</sup> <https://www.minsal.cl/ministerio-de-salud-autoriza-venta-de-medicamentos-por-internet/>

Further information:

<https://www.minsal.cl/ministerio-de-salud-autoriza-venta-de-medicamentos-por-internet/>

### **Does the country allow personal medicine importation, and if it does, under what conditions?**

ISP, by agreement with Subsecretaría de Salud Pública representing the Seremis de Salud, is in charge of granting the Certificado de Destinación Aduanera (CDA) to products subject to sanitary control throughout the national territory, in compliance with the provisions of “Ley 18.164/82”. The Servicio Nacional de Aduanas manages the Declaración de Ingreso of goods to the country (DIN). Considering this framework, the ISP is the technical body in charge of evaluating and authorizing the use, consumption, distribution, transfer or disposal of goods subject to sanitary regulation that enter the country, by issuing a Resolución de Autorización de Uso y Disposición.

Further information:

<https://www.ispch.cl/anamed/importacion-y-exportacion/>

<https://www.ispch.cl/anamed/importacion-y-exportacion/importacion-uso-personal/>

### **What is the country’s legal situation in relation to telemedicine?**

“Ley No 20.724 (2014)” made it possible for medical prescriptions to be issued electronically. The “Decreto Exento No. 530 del Ministerio de Salud (2015)” is the first regulation that explicitly deals with telemedicine, differentiating from traditional medicine, and categorizing it as a service rather than equaling it to medical practice. During the COVID-19 pandemic, some stimulus is being provided for the practice of telemedicine, but the future of the matter is unknown.

In the absence of specific laws, pre-existing laws are extrapolated to the virtual world. Some of the most important ones are the “Código Sanitario (1968)”, “Ley No. 19.628 (1999)”, and “DFL No. 1 del Ministerio de Salud (2006)”.

Further information:

<https://www.minsal.cl/wp-content/uploads/2018/03/Programa-Nacional-de-Telesalud.pdf>

<https://www.camara.cl/verDoc.aspx?prmTIPO=DOCUMENTOCOMUNICACIONCUENTA&prmID=75386>

<https://discourse.forosaluddigital.cl/t/2020-el-ano-de-la-telemedicina-en-chile/734/3>

Ecuador

**NRA:** ARCSA (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria).

**ccTLD operator:** NIC Ecuador/ Ecuadordomain S.A.

**Does the country have problems with substandard drugs and how severe is it?**

Substandard	Falsified	Unregistered	Stolen	Total
4	4	8	0	16

ARCSA (2017-2018), see Rojas-Cortés (2020)

The “*Acuerdo Ministerial 10723*”, from May 1991 and last modified in February 2017, details the pharmacological standards necessary for obtaining legal registration. Any drug that doesn’t fit the established norms is not allowed to be sold<sup>17</sup>.

In August 2016, the “*Normativa Técnica Sanitaria Sustituya for the functioning of the Sistema Nacional de Farmacovigilancia*” was issued, establishing the process for the detection, identification, quantification, evaluation, prevention, understanding, and management of risks associated with the use and consumption of drugs, in order to monitor their efficacy, effectiveness, quality, and safety. The Ministerio de Salud Pública published the current policies on medicines in January 2017 as “*Política Nacional de Medicamentos 2017-2021*”<sup>18</sup>.

Further information:

<https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2020/07/ACUERDO-MINISTERIAL-586-REGLAMENTO-SUSTITUTIVO-DE-REGISTRO-SANITARIO-PARA-MEDICAMENTOS-EN-GENERAL.pdf>

**Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?**

No laws were found regarding the sale of drugs over the Internet. The Farmacia Medicity pharmacy chain does sell medicines online, however. The product pages provide information if a medical prescription is needed for the purchase of a given medicine. In case it’s necessary, a

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<sup>17</sup> <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2019/04/Acuerdo-Ministerial-10723-Normas-farmacol%C3%B3gicas.pdf>

<sup>18</sup> <https://www.salud.gob.ec/wp-content/uploads/2017/03/Politica-Nacional-de-Medicamentos-con-acuerdo.pdf>, p. 21-23

prescription needs to be provided upon delivery. The Rappi app also intermediates the sale of medicines that don't require a prescription.

Further information:

<https://www.farmaciasmedicity.com/>

### **Does the country allow personal medicine importation, and if it does, under what conditions?**

*"Norma Técnica Importación Medicamentos, Tratamientos Especializados, Resolución 11, Registro Oficial 760"* establishes the process to authorize the importation of medicines, biological products, medical devices, biochemical and diagnostic reagents that have not obtained the corresponding sanitary registration for people or corporations. ARCSA asks for the submission of extensive documentation for that purpose, being perhaps the most demanding set of requirements found during this study.

### **What is the country's legal situation in relation to telemedicine?**

In July 24, 2020, in an interview provided by Paúl Franco<sup>19</sup>, from DS Legal Group, a legal office specialized in health law, it was recognized that although Telemedicine is "totally accepted" in Ecuador, there is a legal void around the system, which can generate confusion, doubts and misinterpretations, both for health professionals and patients. He stated that there should be laws regarding telemedicine, establishing the limitations and basic requirements for the service. According to him, various requests had been made for the government to recognize the activity.

Trying to understand this void, lawyer José I. Vallejo poses<sup>20</sup> that since 1992, there is the *"Acuerdo Ministerial No. 14660"*, which in its Article 101, prohibits doctors from giving consultations and indicating treatments through any means of remote communication. On the other hand, several state entities have already taken important steps to incorporate telemedicine, including the Ministerio de Telecomunicaciones y de la Sociedad de la información (MINTEL). ARCSA) has also emphatically stated that health professionals and pharmacies have the authorization to both issue and accept electronic prescriptions.

Villejo concluded that consultations can be made through telemedicine, but the country would benefit from clearer laws.

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<sup>19</sup> <https://www.edicionmedica.ec/secciones/profesionales/la-telemedicina-debe-ser-regula-formalmente-en-ecuador-96207>

<sup>20</sup> <https://www.edicionmedica.ec/opinion/la-telemedicina-y-su-regulacion-en-ecuador-2089>

## Venezuela

**NRA:** Instituto Nacional de Higiene “Rafael Rangel”

**ccTLD operator:** Comisión Nacional de Telecomunicaciones de Venezuela

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
1	19	6	0	26

INHRR (2017-2018), see Rojas-Cortés (2020)

As established by the “*Ley de Medicamentos (August, 2000)*”, any drug, national or imported, needs to be registered by a sponsoring pharmacist in the Ministerio de Salud y Desarrollo Social. Instituto Nacional de Higiene “Rafael Rangel”, the technical organ of Ministerio de Salud, is responsible for analyzing every new medicine, and also keeping control of drugs that are already being commercialized. Once standards are met, an authorization is published in the *Gaceta Oficial de la Republica de Venezuela*.

Further information:

[http://www.inhrr.gob.ve/pdf/pdf\\_ir/ley\\_de\\_medicamentos.pdf](http://www.inhrr.gob.ve/pdf/pdf_ir/ley_de_medicamentos.pdf)

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

No laws were found regarding the sale of drugs over the Internet. The pharmacy chain Farmatodo considers itself an online pharmacy and delivers medicines to several cities, but its position in relation to prescriptions is unclear.

Further information:

<https://www.locatelcolombia.com/descubre-locatel/pedidos-internacionales>

### Does the country allow personal medicine importation, and if it does, under what conditions?

“Ley de Medicamentos, Título 5, Ch 1, Ar. 66 y 67”, the law about drug importation, seems to be concerned basically with large scale importation, leaving a legal void in relation to personal importation.

Locatel, a pharmacy chain from Colombia, delivers medicines to Venezuela, even if a prescription is necessary. In this case, the patient must send an email to Locatel with their ID and a copy of the prescription. However, the service only reaches Caracas.

An article published by the Brazilian news agency G1 in 2019<sup>21</sup>, discussing the medicine crisis in Venezuela, suggests that it is an option for patients to buy medicines from other countries, as they may be cheaper than in Venezuela.

### **What is the country’s legal situation in relation to telemedicine?**

In Venezuela, the adoption of telemedicine has accelerated due to the COVID-19 pandemic, however, it faces challenges such as the lack of Internet connectivity and issues with the electric grid. Regulation is unclear. A governmental publication from 2009 brings up the subject of telemedicine and supports its implementation. It says: “In order to guarantee and ensure the right to health and quality of life with equity for the population, the government will use the ‘Simón Bolívar’ satellite as a means of transportation to provide remote medicine services, which will allow social inclusion in the health sector in rural localities and populations in remote regions that have a deficiency in dissemination services.” We see, then, that the government supports telemedicine in concept, but has not proposed laws to regulate it.

Further information:

<https://saluddigital.com/en/plataformas-digitales/la-telemedicina-como-apoyo-en-el-sistema-de-salud-venezolano/>

<https://www.voanoticias.com/venezuela/telemedicina-alivia-sinsabores-pandemia-venezuela>

[http://ve.scielo.org/scielo.php?script=sci\\_arttext&pid=S0367-47622009000200003](http://ve.scielo.org/scielo.php?script=sci_arttext&pid=S0367-47622009000200003)

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<sup>21</sup> <https://g1.globo.com/mundo/noticia/2019/02/22/escassez-de-remedios-assola-venezuela-enquanto-prosegue-impasse-sobre-ajuda-humanitaria-internacional.ghtml>

Peru

**NRA:** Dirección General de Medicamentos Insumos y Drogas (DIGEMID)

**ccTLD operator:** NIC Peru/Red Científica Peruana

**Does the country have problems with substandard drugs and how severe is it?**

Substandard	Falsified	Unregistered	Stolen	Total
12	171	1	0	184

DIGEMID (2017-2018), see Rojas-Cortés (2020)

“Ley N° 29459, de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios” defines and establishes the principles, standards, criteria and basic requirements on drugs and devices for use in human beings.

It’s worth noting that Peru registered a very significant number of incidents relating to falsified medicines, which considerably differs from other countries in the region. It is the Latin American country present in the study with the largest number of reported incidents in this category by a wide margin<sup>22</sup>.

**Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?**

An official declaration from Digemid dating from 2010 mentions that the Internet sale of drugs is forbidden, as there would be no way to attest the quality of the product<sup>23</sup>. In the statement, Digemid urges pharmacies not to sell medicine over the internet. However, there are now pharmacies such as Farmalisto and Farmacia Universal that sell medicine which doesn’t require a medical prescription. It is unclear if medicines that require a prescription can be purchased.

**Does the country allow personal medicine importation, and if it does, under what conditions?**

According to Article 16 from “Ley N° 29459”, a person can import medicines provided they have a justification. This is further regulated by “Decreto Supremo N°016-2011- SA” and “Decreto

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<sup>22</sup> Rojas-Cortés R. Substandard, falsified and unregistered medicines in Latin America, 2017-2018. Rev Panam Salud Publica. 2020;44:e125 <https://doi.org/10.26633/RPSP.2020.125>

<sup>23</sup> <https://bvcenadim.digemid.minsa.gob.pe/noticias/27-comprar-medicamentos-por-internet-es-peligroso-y-perjudicial-para-la-salud>

*Supremo N°016-2013-SA*". Cosmetic products are largely disallowed. Digemid's main concern appears to be bulk importation masking as individual importation.

Further information:

<http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Ley29459.pdf>

<http://www.digemid.minsa.gob.pe/Main.asp?Seccion=852>

[www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/AutorizacionRecetas.pdf](http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/AutorizacionRecetas.pdf)

### **What is the country's legal situation in relation to telemedicine?**

The Law nº 30421 is the Ley Marco de Telesalud, and it was approved on February 22nd, 2018, through the Resolución Ministerial nº 144-2018/MINSA. It says that the access is to be universal and of good quality. It also establishes that the Ministerio de Salud is the one responsible for planning, directing, coordinating, supervising and evaluating national and sectorial telemedicine policies. Also, CONATEL (Comisión Nacional de Telesalud) was created, and under Ministerio de Salud (Art 6). CONATEL has among its functions (Art 7):

1. Propose the technical mechanisms for the implementation, monitoring and evaluation of the National Telehealth Plan, suggesting priority lines of intervention within the framework of the aforementioned National Plan.
2. Propose rules and procedures on the use, development and implementation of new information and communication technologies.
3. Propose indicators and standards of the National Telehealth Plan at the national level, in coordination with the regional lead levels according to the sector, monitoring their proper implementation.
4. Propose training programs and training of human resources in the use, development and implementation of new information and communication technologies.
5. Issue technical reports and recommendations on the use, development and implementation of new information and communication technologies according to the information and communication technological advances that are presented.

On February 15th, 2019, the Reglamento de Ley N ° 30421 was approved and modified with Decreto Legislativo (DL) No. 1303, DL that optimizes processes related to Telehealth and has as Governing entity the MINSA. Considering the present regulation, the Telehealth services are developed in five axes: 1.- Telemedicine (Provision of health services), 2.- Telemangement (Management of health services), 3.- TeleIEC (Information, education and communication to the population about the health services), 4.- Tele-training (Strengthening the capacities of health

personnel), 5. - Others of a technical nature related to the application of information and communication technologies in Telehealth services (3).

Further information:

[ftp://ftp2.minsa.gob.pe/normaslegales/2018/R.M\\_144-2018-MINSA.pdf](ftp://ftp2.minsa.gob.pe/normaslegales/2018/R.M_144-2018-MINSA.pdf)

<https://busquedas.elperuano.pe/normaslegales/ley-marco-de-telesalud-ley-n-30421-1363168-1/>

<https://busquedas.elperuano.pe/normaslegales/aprueban-el-reglamento-de-la-ley-n-30421-ley-marco-de-tele-decreto-supremo-n-003-2019-sa-1741932-4/>

<https://saluddigital.com/plataformas-digitales/gobierno-de-peru-impulsa-la-adopcion-de-la-telesalud-en-todo-el-pais/>

## Honduras

**NRA:** Agencia de Regulación Sanitaria (ARSA)

**ccTLD operator:** Red de Desarrollo Sostenible Honduras

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
0	0	1	0	1

ARSA (2017-2018), see Rojas-Cortés (2020)

According to the “*Decreto PCM-032-2017*” from the executive branch, issued on April 28th, 2017, ARSA is responsible for “the supervision, review, verification, control, surveillance and oversight of compliance with legal, technical and administrative regulations of establishments, suppliers, products and services of health interest and of those who carry out activities or practice behaviors that impact or may affect the health of the population, and the regulation, granting, renewal, modification, suspension or cancellation of the registries, permits, licenses, certifications and other sanitary authorizations”.

Further information:

<https://arsa.gob.hn/paginas/registroSanitarioDM>

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

No laws were found regarding the sale of drugs over the Internet. Upon searching for pharmacies that offered the service, it was found that the PuntoFarma chains delivers medicines in several localities, even ones that require medical prescription.

### Does the country allow personal medicine importation, and if it does, under what conditions?

According to “*Ley General de Medicamentos*”, from 2013, in “*Sección III, Art. 29, Autorización para importar*”, medicines and pharmacological products may be imported by pharmaceutical laboratories, drugstores, pharmacies or any natural or legal person. ARSA makes a centralized

online form available for requests for importation, be the purpose scientific research, personal importation, or any other<sup>24</sup>.

### **What is the country's legal situation in relation to telemedicine?**

In an article by Roxana Espinal from 2020<sup>25</sup>, concern is expressed for the lack of telemedicine legislation, especially considering the COVID-19 pandemic. In 2018, Secretaria de Salud published on their official website<sup>26</sup> that the Ministry of Health and CONATEL were to launch a telemedicine program. Apparently, the government supports the implementation and use of telemedicine, but hasn't issued compatible legislation.

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<sup>24</sup> [https://docs.google.com/forms/d/e/1FAIpQLSd8rx0GfGcJGHiU\\_mgD9rsHV8ra53rhbfkJOjEn-McGHzdynQ/viewform](https://docs.google.com/forms/d/e/1FAIpQLSd8rx0GfGcJGHiU_mgD9rsHV8ra53rhbfkJOjEn-McGHzdynQ/viewform)

<sup>25</sup> Revista de Ciencia y Tecnología Vol. 09, N° 1, 2020

<sup>26</sup> <http://www.salud.gob.hn/site/index.php/component/k2/item/1070-salud-y-conatel-lanzaran-el-proyecto-telemedicina>

Costa Rica

**NRA:** Ministerio de Salud de Costa Rica

**ccTLD operator:** Academia Nacional de Ciencias Costa Rica

### Does the country have problems with substandard drugs and how severe is it?

Substandard	Falsified	Unregistered	Stolen	Total
0	2	9	2	13

Ministerio de Salud de Costa Rica (2017-2018), see Rojas-Cortés (2020)

The “*Guía Para la Verificación de la Calidad de los Medicamentos*” is the document that serves as the canonical reference for drug quality in the country.

Further information:

[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?param1=NRTC&nValor1=1&nValor2=65444&nValor3=76484&strTipM=TC](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=65444&nValor3=76484&strTipM=TC)

### Does the country allow for the purchase of medicines over the Internet, and if it does, under what conditions?

On October 3, 2019, the Ministerio de Salud issued the “*Reglamento para la vigilancia y control del uso de medicamentos y su aplicación con el sistema de receta digital*”, making it so that prescriptions medicines could be prescribed in digital form<sup>27</sup>.

Considering data from the online pharmacy Mi Farmacia en Linea, one can buy almost all medicines online<sup>28</sup>.

### Does the country allow personal medicine importation, and if it does, under what conditions?

To import drugs for personal use, one has to fulfill the requirements presented by the Ministerio de Salud, and present it to Autoridades Sanitarias de la Ventanilla Única de Comercio Exterior de PROCOMER. There can be also a special authorization for non-registered drugs, following the

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<sup>27</sup>

[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?nValor1=1&nValor2=82896](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?nValor1=1&nValor2=82896)

<sup>28</sup> <https://mifarmaciaenlinea.com/>

*“Reglamento para la autorización para la importación y adquisición de medicamentos no registrados, N° 36358-S”, Articles 3 and 4.*

Further information:

<https://www.ministeriodesalud.go.cr/empresas/importacion/requisitos.htm>

<https://www.ministeriodesalud.go.cr/index.php/tramites-ms/autorizaciones-y-certificados?id=1117>

[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?param1=NRTC&nValor1=1&nValor2=69580&nValor3=85538&strTipM=TC](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=69580&nValor3=85538&strTipM=TC)

### **What is the country’s legal situation in relation to telemedicine?**

No laws were found regarding the practice of telemedicine. According to the La Republica news outlet, on an article published in November 6, 2020, there is no law in Costa Rica that regulates telemedicine, but it does do occur at a significant scale<sup>29</sup>.

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<sup>29</sup> <https://www.larepublica.net/noticia/telemedicina-requiere-marco-regulatorio-para-velar-por-su-calidad-sugieren-laboratorios-farmaceuticos>

## Appendix A: “Every Internet Governance Stakeholder Has a Role to Play in the Online Health Debate”

Much has been discussed in relation to the impacts of the COVID-19 pandemic on most aspects of human life, but the dialogue around the long-term repercussions of this event on health online has been rather limited. Telemedicine seems to be the most notable topic to have emerged, [skyrocketing in interest in March, but in steady decline thereafter](#) (Google Trends query performed in English, but similar results can also be found in Romance languages), perhaps because it is assumed that, soon enough, healthcare will simply revert to the way it was before.

However, telemedicine is but one of the aspects involved in the wide set of implications that surround this moment in history. The fundamental health structures of most of the world have proven unreliable in face of the pandemic, and had the effects of the disease been more severe or affected a larger portion of the population, our outcomes could be quite different. Based upon the experience of the novel coronavirus, nothing guarantees that the world will be ready for a future pandemic.

The reason why a subject such as access to medicines did not become the ultimate global trending topic is because there was no proven cure for COVID-19 available, and treatment methods had to be painstakingly developed by the global medical community. Had there been effective medication from the get-go, the rush to buy it would have been unprecedented. But what would guarantee access to it? Which rules would govern sales? Would people be limited to buying from their own home markets with potentially low supply or would they be able to import from trusted foreign manufacturers?

If the price gouging of Personal Protective Equipment (PPE) and even hand sanitizer is anything to go by, it can be assumed that the situation would have looked rather chaotic. The question of the upcoming vaccines is also filled with reticence and uncertainty on what is the best approach to take. Matters of health are by and large kept at the local government level, but new challenges demand concerted global efforts from our part. Understanding where we should be going and what we could do has become that much more important.

Looking into the relation between the Internet and health makes a great deal of sense, particularly in face of the fact that the network has proven as resilient as we hoped it would be. Even though there were initial concerns over how the Internet would perform under significant added stress, through good engineering practices and multistakeholder cooperation, networks around the world mostly thrived with minimal degradation of overall quality. In a health emergency of large scale, we have observed that the Internet allows people to preserve their health in several different ways.

The need to discuss the subject is real, but which is the correct forum to carry out these discussions? What institutions can be the appropriate conveners? Governments are locked in fierce debates inside and outside arenas such as the World Health Organization (WHO), but the

subject of harmonized or at least agreed upon general rules for health online does not seem to register on their radar. Meanwhile, the Internet Governance community is already steeped in discussions over DNS Abuse related to COVID-19, misinformation campaigns, increase in cyberattacks due to more people working from home, and so forth.

A nascent group of experts has been gathering around the subject at RightsCon and the UN Internet Governance Forum over these last few years, and important steps have been taken, such as the establishment of the [Brussels Principles on the Sale of Medicines over the Internet](#), a set of guidelines that orient what fair access to medications within this context should look like. However, there is a need to take the debate further, get more stakeholders to sit at the same virtual table, and understand what we as a community can do.

Here are some ideas of what various stakeholder groups can contribute.

Civil society and NGOs need to look no further than the UN SDGs, in the form of “Goal 3: Ensure healthy lives and promote well-being for all at all ages”. Of particular interest to the theme of access to medicines, we have: “3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”. There is still much to be advanced in the mobilization of actors towards sustainable activism around these matters.

For Academia, there is a wide range of unexplored topics and data-driven research needed to be performed regarding integration of health and digital technologies. In fact, this is an area with a perceivable gap in interdisciplinary research, that could benefit from greater interaction with other scientific fields. There are significant data points emerging from COVID-related research that need to be studied and understood under the light of the existing Internet Governance literature.

When it comes to Businesses, apart from working directly with the sector, there is a significant ancillary market to that of health online, which involves cybersecurity, certification and authentication technologies, software development, solution development, and a number of other opportunities that might be explored further to the benefit of all. As new strategies are developed to engage local and global markets, these opportunities should be taken into consideration.

Entities that are Contracted parties to ICANN should be particularly aware of the critical role they play in this process, seeing as the [DNS Abuse Framework](#) already contains measures targeted at combating the proliferation of illegal opioid sales online. The Framework shows promise in its effort to weed out some of the rogue actors from the network. This is a great first step in generating trust online and ensuring greater safety for consumers, but there are further actions that can be taken.

Indeed, DNS Abuse seems to be the subject in which we have progressed the furthest in terms of dealing with this subject within the Internet Governance ecosystem, having transcended ICANN,

entered national and global IGFs, and starting to coalesce into a reference for future debates. The question moving forward is how to deal with the various actors involved in this space, both good and bad.

As we find ways to punish the bad actors, we should also consider what we could do to create incentives for the good actors, such as is the case of reliable and trusted Internet Pharmacies. How can we shift the equation for it to make objective sense for actors to behave well, and how can we engage as a community to generate positive outcomes? These are among the many questions that will increase in relevance in the upcoming years, and there is still much to be discussed, hopefully under less strained times.