

Editorial

Open data for society: a history of the National Health Surveillance Agency - Anvisa Plan

Dados abertos para a Sociedade: um histórico do Plano da Agência Nacional de Vigilância Sanitária – Anvisa

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In global terms, there is a trend to use technological resources and adopt policies to facilitate the dynamics of an “information society”. In this direction, as part of the technology’s evolution and the *Internet* expansion, the so-called “Electronic Government” has emerged. In its narrowest definition, Electronic Government refers to the instrumentalization of governmental practices through technologies.¹ It intends to simplify and reduce bureaucracy, streamline and universalize access to services, and increase the transparency of governmental actions. More broadly, it is a form of knowledge organization that aims at the disappearance of merely bureaucratic acts and structures.²

Time has evidenced that the simple use of technology, if not accompanied by true dialog with the citizens, is insufficient to produce effective results in this interrelationship. And it was then that the Open Government movement emerged.¹

In the wake of this movement and based on the concept adopted by the Organization for Economic Cooperation and Development (OECD), which defines Open Government as a governance culture that promotes the principles of transparency, social participation, accountability and integrity in support of democracy and inclusive growth, there is a clear need for governmental actions to become increasingly transparent, participatory and focused on meeting social demands.³

Conceptually, in one of its pillars (transparency), Open Government addresses a more transparent management, with data and information easily available to any interested party, using a friendly and intuitive interface. It can also be said that the population is effectively empowered with knowledge in the decision-making process. It is a movement towards a connected, networked and interactive public administration, enhancing the action of the State and its relationship with society.

Therefore, the difference between Electronic Government and Open Government is not a detail. It is expected that the Open Government will change the *status quo* and the functioning of the administrative machine, empowering citizens, questioning the limits of representative democracy and creating channels of participation and support for decision-making, always seeking to improve public management. Thus, unlike the Electronic Government, which focuses on automating processes and increasing the efficiency of the public machine, the adoption of Open Government practices seeks to increase the transparency of government acts, promote access to public information, encourage social participation and fight corruption and, finally, stimulate economic growth.⁴

In the scope of Open Government, innovation in data and services can originate from the interaction between government and society, as the citizen is treated as much more than a mere receiver of information, starting to be seen as an actor, effectively active in the process of formulating and executing public policies.

In 2011, the creation of the Open Government Partnership (OGP) was launched at the UN General Assembly, which was adhered to by the countries through the signing of the high-level declaration for Open Government, with Brazil having a prominent role in terms of pioneering in this movement. The Brazilian government, as part of the Open Government

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initiatives, created the Brazilian Open Data Portal- dados.gov.br,⁵ which is part of the National Open Data Infrastructure (*Infraestrutura Nacional de Dados Abertos*, INDA).

The normative instruction that instituted the INDA (IN No. 04 of April 12th, 2012) anchors the Brazilian policy for open data and includes a set of standards, technologies, procedures and control mechanisms necessary to meet the conditions for dissemination and sharing of data and public information in this template.

In order to strengthen open data initiatives in the country, the National Open Data Policy (*Política Nacional de Dados Abertos*, PDNA), of the Federal Executive Branch, was instituted by Decree No. 8,777/2016. As of the publication of Decree No. 9,903/2019, the management of this policy became the responsibility of the Union's Accountability Office (*Controladoria-Geral da União*, CGU). Thus, the instruments, tools and coordination of the actions of the Management Committee of the National Open Data Infrastructure (*Comitê Gestor da Infraestrutura Nacional de Dados Abertos*, CGINDA) that make up the government's performance in the area of open data are now managed by the CGU.⁶

The document that guides an organization's actions to implement and promote open data, including geospatial data, is the Open Data Plan (*Plano de Dados Abertos*, PDA). This document is part of the PNDA and aims at organizing and standardizing the State's open data publication processes, resulting in greater transparency, availability, access, quality and wide reuse of open data both by society and by the public administration. Its preparation complies with the Access to Information Law (*Lei de Acesso à Informação*, LAI), Law 12,527/2011.

In short, for a dataset to be able to integrate an organization's PDA and, consequently, to be inserted in the context of the PNDA, the person responsible for the data repository of that agency must ensure that this dataset complies with the following general conditions.⁷

1. The data must be in its rawest possible format, i.e., before any crossing or aggregation. Even if the agency or entity finds it important and has already published some aggregation view of this data, there is great value in disaggregated data.
2. The data must be in an open, non-proprietary, stable, and widely used format.
3. There must be no legal instrument that prevents its reuse and redistribution by any part of society.
4. For data that is structured or in spreadsheets at its source, the original structure must be preserved as much as possible. For example, spreadsheets must not be published in PDF files; in this case, CSV or ODS must be used.
5. It is recommended to make the data available in different formats.
6. Each dataset must have a unique and persistent identifier, following a URL standardization. This requirement is indispensable for this dataset to be referenceable and eventually automatically consumed by an application.

The Anvisa PDA is the document that guides the actions to implement and promote data opening within the scope of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, Anvisa), thus allowing for greater transparency of information and the reuse of public data by the civil society. This document materializes the Agency's commitment to society in opening its public databases within a period of up to two years from the date of its publication, observing the mandatory requirements set forth by INDA.

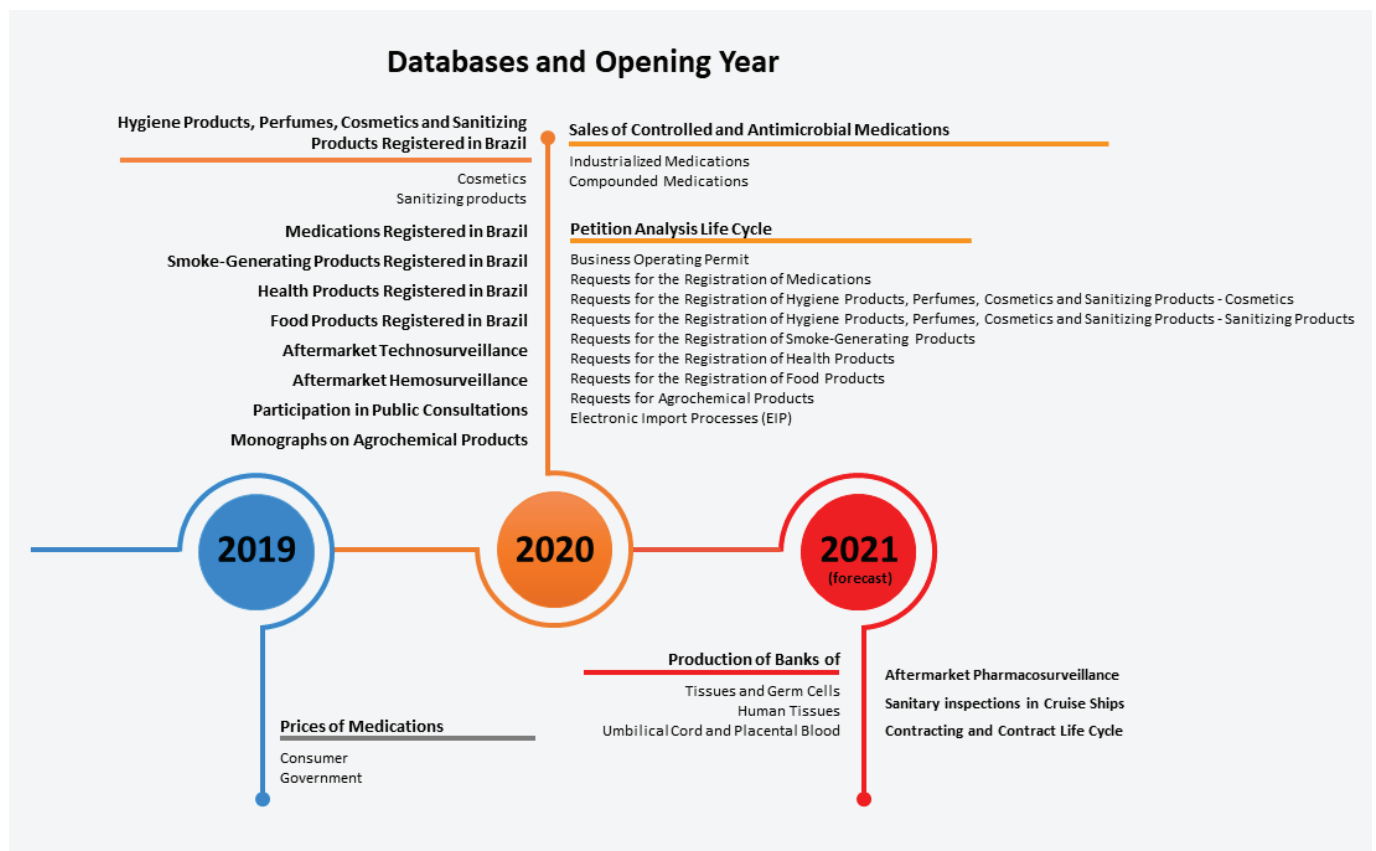
With this initiative, Anvisa proposes to inventory the databases under its custody, provide public knowledge about the databases maintained by the Agency, know the databases that are of greater public interest, identify priorities and make data available in open formats and, whenever possible, georeferenced, encouraging the interoperability of health data through publication in a machine-processable format and promoting the continuous improvement of the quality of the data made available, and also stimulating the visualization of information on the Agency's actions.

With the publication of the PDA and the availability of qualified data to society, Anvisa takes an important step towards transparency and social control, in line with the principles of publicity and efficiency for decision-making by public managers.

The datasets produced and held in custody by the agency and that shall be subjected to franchising in a format open to the citizens were identified,⁸ except in cases of legally express prohibition. For the establishment of the data opening goals and prioritization stages, the following criteria were considered:

1. The degree of relevance for the citizens, observing the demands sent via the Call Center and Ombudsman, the most sought-after sectors and services on the Anvisa's websites, as well as the expression of interest in research carried out on the Anvisa portal about the databases of greater interest to the citizens;
2. Legal regulations and commitments formally assumed by Anvisa and the Ministry of Health, including before international organizations;
3. Alignment in relation to the Institutional Strategic Planning, as well as those related to the areas of information technology;
4. The set of information and systems under the management of Anvisa, in particular the structuring systems that are of mandatory transversal use across bodies of the Federal Public Administration; and
5. The maturity level of the organization of the existing information and data that allow its opening, complying with the legal provisions herein mentioned.

In this context, 26 data sets meeting the prioritization criteria were identified, since they already have a level of information organization that facilitates availability in an open format. Due to the complexity of some of these databases, it was necessary to subdivide these datasets, totaling 29 databases intended to be offered to society. Of this, 23 are available, leaving, up to date, 6 databases expected to be available until September 2021. The figure below shows the topics listed for the 2019-2021 Anvisa PDA.⁸



The PDA brings together essential actions to comply with the PNDA and is one of the main drivers to make Anvisa's management more open and participatory, thus seeking to be in tune with the Open Government strategy in Brazil.⁹

Within the scenario of Health Regulation and Surveillance, it is possible to verify, through the Anvisa PDA, greater interest of society in having access to open data on notifications of adverse drug reactions (58.18%).

Later this year, Anvisa will start the development of its next open data plan with a duration of two more years.

Knowledge is a common good, that is, anyone can use it or participate in its construction. Thus, this knowledge can only be considered open when anyone can freely access it, as well as use and share it.

Finally, it is relevant to understand and disseminate, across the board, the importance of making open data available by the various bodies that make up the Brazilian State, as a transparency tool fundamental for the progress of the numerous initiatives that promote knowledge, science and innovation.

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References

- Raminelli, Francieli Puntel. Os Governos Eletrônicos e Aberto na Era da Sustentabilidade Multidimensional: Perspectivas sob a Ótica da Dimensão Jurídico-Política. Available in: www.derechoycambiosocial.com.:file:///tmp/mozilla_monica0/Dialnet-OsGovernosEletronicoEAbertoNaEraDaSustentabilidade-5470253.pdf. Accessed on April 22, 2021.
- Rover, Aires José. Governo eletrônico: quando a tecnologia faz a diferença. In: Seminário Virtual: temas atuais do direito e internet, Âmbito Jurídico e DCDireito da Fundação Universidade Federal do Rio Grande, 2004. Available in: <http://www.infojur.ufsc.br/aires/arquivos/governo%20eletronico%202005.pdf>. Accessed on April 22, 2021.

3. OECD iLibrary. OECD Legal Instruments <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0438>. Accessed on April 22, 2021.
4. Berberian, Cynthia de Freitas. Governo Aberto: a tecnologia contribuindo para maior aproximação entre o Estado e a Sociedade. *Revista TCU.* 2014: 131.
5. Anvisa. Plano de Dados Abertos Anvisa 2019-2021. Available in: <https://dados.gov.br/dataset/plano-de-dados-abertos-anvisa>. Accessed on April 27, 2021.
6. Controladoria-Geral da União. Infraestrutura Nacional de Dados Abertos – INDA, Plano de ação 2021-2022, publicado em março de 2021). publicado em março de 2021). <https://dados.gov.br/wp/wp-content/uploads/2021/03/Plano-de-A%c3%a7%c3%a3o-INDA-vf.pdf> Accessed on April 22, 2021.
7. Secretaria de Logística e Tecnologia da Informação Cartilha Técnica para publicação de Dados Abertos no Brasil V0.1. Available in: <https://dados.gov.br/pagina/cartilha-publicacao-dados-abertos>. Accessed on April 22, 2021.
8. Anvisa. PDA 2019/2021 da Anvisa (dados.gov.br). PDA 2019-2020 Anvisa. Available in <https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos>. Accessed on April 22, 2021.
9. Anvisa. Plano de dados abertos da Anvisa (<https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2019/conheca-o-plano-de-dados-abertos-da-anvisa>). Accessed on May 5, 2021.

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