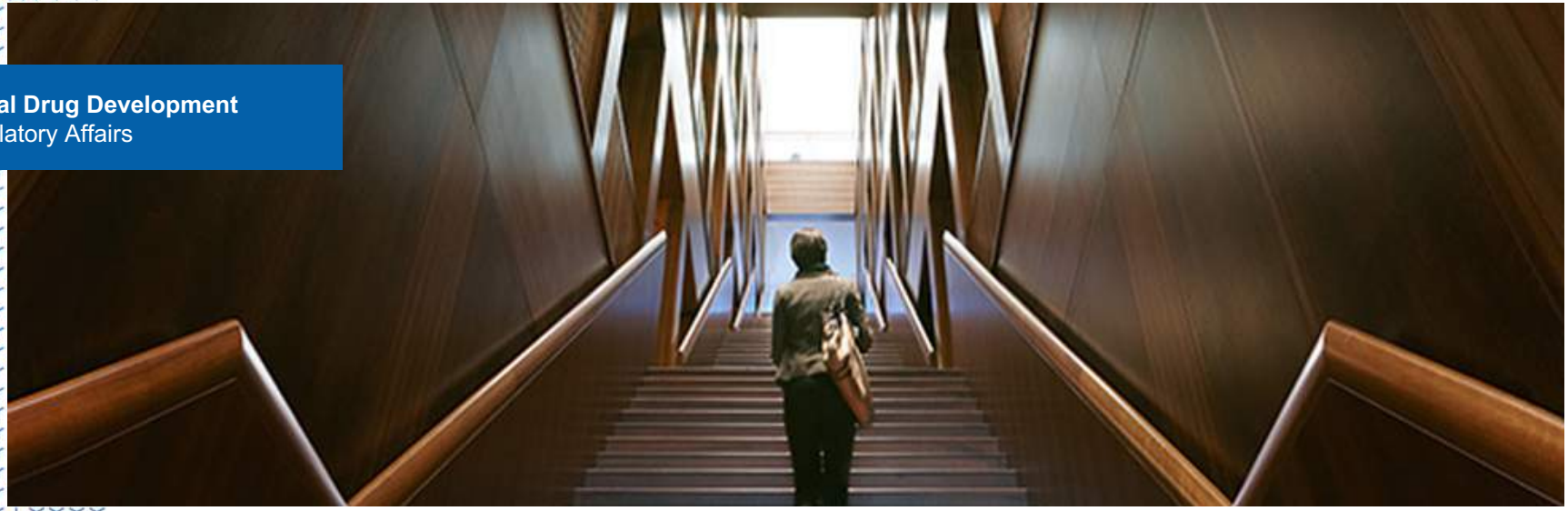
Global Drug Development
Regulatory Affairs



COVID-19: Brazil Regulatory Experience

Patricia Pigola
Brazil Regulatory Affairs Director
May 28, 2020

NOVARTIS | Reimagining Medicine

ANVISA Scope

Food

Cosmetics

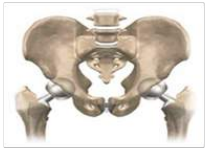
Sanitizing Products

Tobacco

Toxicology (Pesticides)

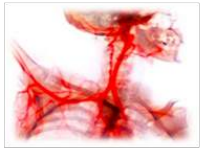
Health Services

Drugs



Medical Devices

Laboratories

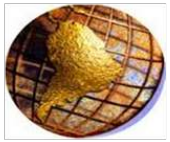


Blood, tissues and organs

Post-market surveillance

Publicity control

Ports, airports and borders



International affairs

Market regulation

Regulatory Panorama

- ANVISA has published more than 50 guidance documents at different areas (e.g. cosmetics; sanitizing products; medicines; medical devices; ports, airports and borders, etc) in response to the coronavirus pandemic.
  - The guidance documents and additional measures can be found at http://portal.anvisa.gov.br/coronavirus/regulamentos.
- Discussions started around January 20th, mainly related to ports, airports and borders actions. At end February, ANVISA published the 1st call for supply information on products for coronavirus.
- ANVISA is prioritizing all COVID-19 actions while trying to progress other activities as much as possible.
  A contingency plan was issued on April 06th to:
  - guide organizational units in maintaining processes and activities;
  - contribute to the definition of preventive, contingency and corrective measures to manage risks related to the discontinuity essential processes and activities.
- ANVISA has been open, flexible, proactive and effective.
  - Frequently meetings with trade associations to identify challenges and discuss solutions.
- Additional information on actions taken by ANVISA can be found at http://portal.anvisa.gov.br/coronavirus.

Examples of Best Practices

Communication mechanism

- From March 13th, ANVISA meetings with the regulated sector were moved to virtual meetings.
- ANVISA equipped their meeting rooms with videoconference equipments.
- The meeting minutes and recording are being done as it used to be with the face-to-face interactions.
- The meetings' request and schedule were already done through an online system and it was maintained.

➢ The virtual meetings have worked pretty well and have been very effective.

http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/covid-19-parlatorio-pronto-para-reunioes-virtuais/219201?p_p_auth=0WfdDOcy&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp_p_auth%3D0WfdDOcy%26p_p_id%3D101_INSTANCE_FXrpx9qY7FbU%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-4%26p_p_col_count%3D2

Examples of Best Practices

Good Manufacturing Practices (GMP)

- On March 13th, ANVISA published the RDC 346/2020.
- This resolution sets extraordinary and temporary procedures for the certification of GMP for registration and post-registration changes of APIs, medicines and medical devices due to the coronavirus health emergency:
  - possibility to use information from other regulators for GMP certification (reliance on Programme to Rationalize International GMP Inspections of APIs/active substance Manufacturers, PIC/S or MDSAP);
  - flexibility to replace in loco inspections by remote inspections;
  - provides the option on issuing a temporary certification which will be valid only during the effectiveness of this Resolution.
- The RDC is in principle valid for 180 days.

➢ At least 35 GMP certificates have been issued based on reliance procedures.

http://www.in.gov.br/en/web/dou/-/resolucao-de-diretoria-colegiada-rdc-n-346-de-12-de-marco-de-2020-247801951

Examples of Best Practices

Regulatory processes

- On March 18th, ANVISA published the RDC 348/2020.
- This resolution defines extraordinary and temporary procedures to speed up the registration of medicines and products for in vitro diagnosis, as well as post-registration changes of medicines due to the coronavirus health emergency:
  - defines shorter ANVISA timelines;
  - allows submission with reduced requirements based on benefit-risk assessment and commitment agreement.
- Applicable to:
  - medicines for preventing or treating COVID-19 or in vitro diagnosis of SARS-CoV-2;
  - lifesaving products at supply risk.
- The RDC is in principle valid for 180 days.
- There was no official document to formalize but ANVISA is accepting e-CPPs.

http://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-348-de-17-de-marco-de-2020-248564332

Examples of Best Practices

Digitalization

- ANVISA took another simplification measure to allow clinical trials continuity during the coronavirus crisis.
- They implemented a process to allow electronic submission of Clinical Research Development Dossier for Medicinal Products (DDCM) that used to be done in hard copy.
- Digital signatures has been accepted in replace to ink signatures.

http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/alterado-procedimento-de-peticionamento-de-ddcm/219201?p_p_auth=7c3Ig6S8&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp_p_auth%3D7c3Ig6S8%26p_p_id%3D101_INSTANCE_FXrpx9qY7FbU%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3D_118_INSTANCE_KzfwbqagUNdE__column-2%26p_p_col_count%3D2

Examples of Best Practices

Medicines prescription

- On March 24th, ANVISA published the RDC 357/2020.
- This resolution temporarily extended the maximum quantities allowed in prescription of drugs that contain controlled substances (such as narcotics and psychotropic), allowing remote delivery and home delivery of these products.
- This measures came on top of the exceptional approval on the use of telemedicine by the Federal Council of Medicine.

http://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-357-de-24-de-marco-de-2020-249501721

Topics under discussion

- Waiver of local retesting of imported products
- Alternative routes for importing biological medicines (impact to transport validation)
- Free sample distribution

Acknowledges

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Thank you

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Q&A