


Accelerating CMC Review in PAC: **ANVISA's Online Optimized Assessment Project**



CASSS for CMC Latin America 2023

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Brazil
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Office of Biological Products


Assessment of applications (marketing authorization and PAC*) of Biological Products[#]

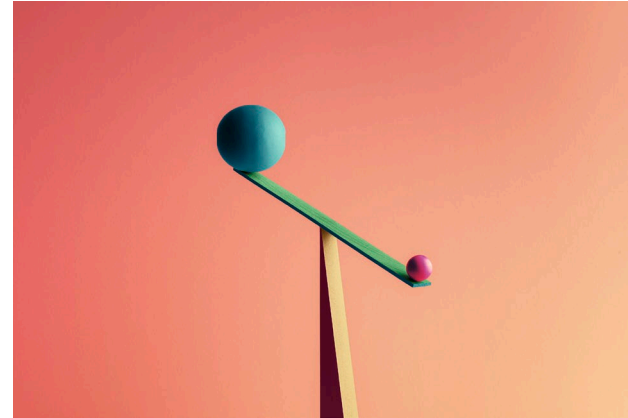
[#]Biotechnological products, vaccines, blood products, hyperimmune serum, medicines obtained from biological fluids or animal-originated tissue, medicines containing live, attenuated or dead microorganisms.

PAC*: post-approval changes



Ensuring timely access to biological products with quality, safety and efficacy is part of our mission and a constant pursuit in the work process.





The number of new applications

VS

Imbalance

Human resources

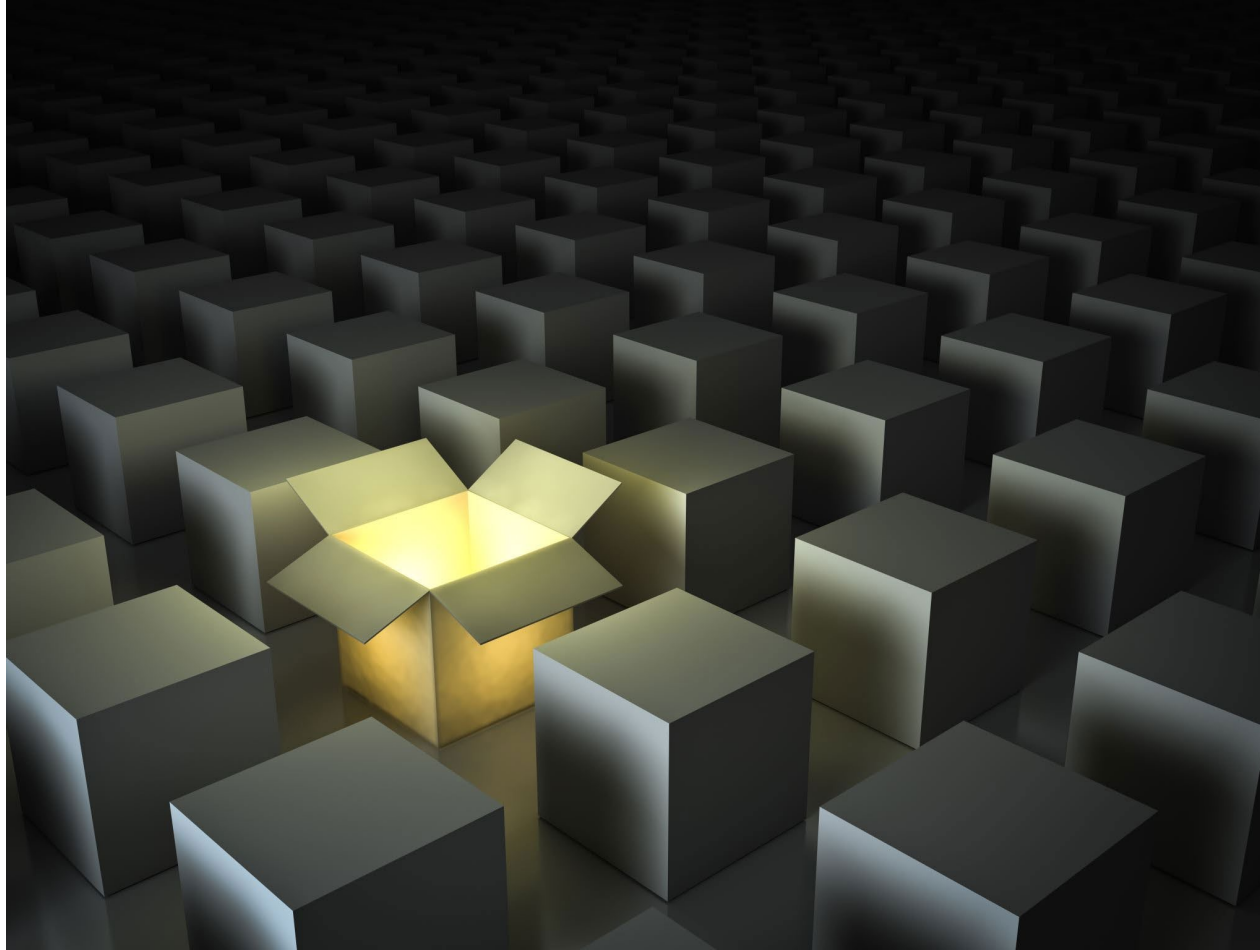
Establish procedures that encourage analysis optimization of the marketing authorization / post approval changes applications



✓ **During COVID-19 pandemic**

- Efforts were focused on the assessment of COVID-19 drugs/vaccines applications
- Backlog of non-COVID-19 applications increased significantly
 - 23/03/2022: ~ 460 CMC post-approval changes applications waiting for review
- Team size remained the same

Think outside the box!





Accelerated assessment: Online Optimized Assessment Project

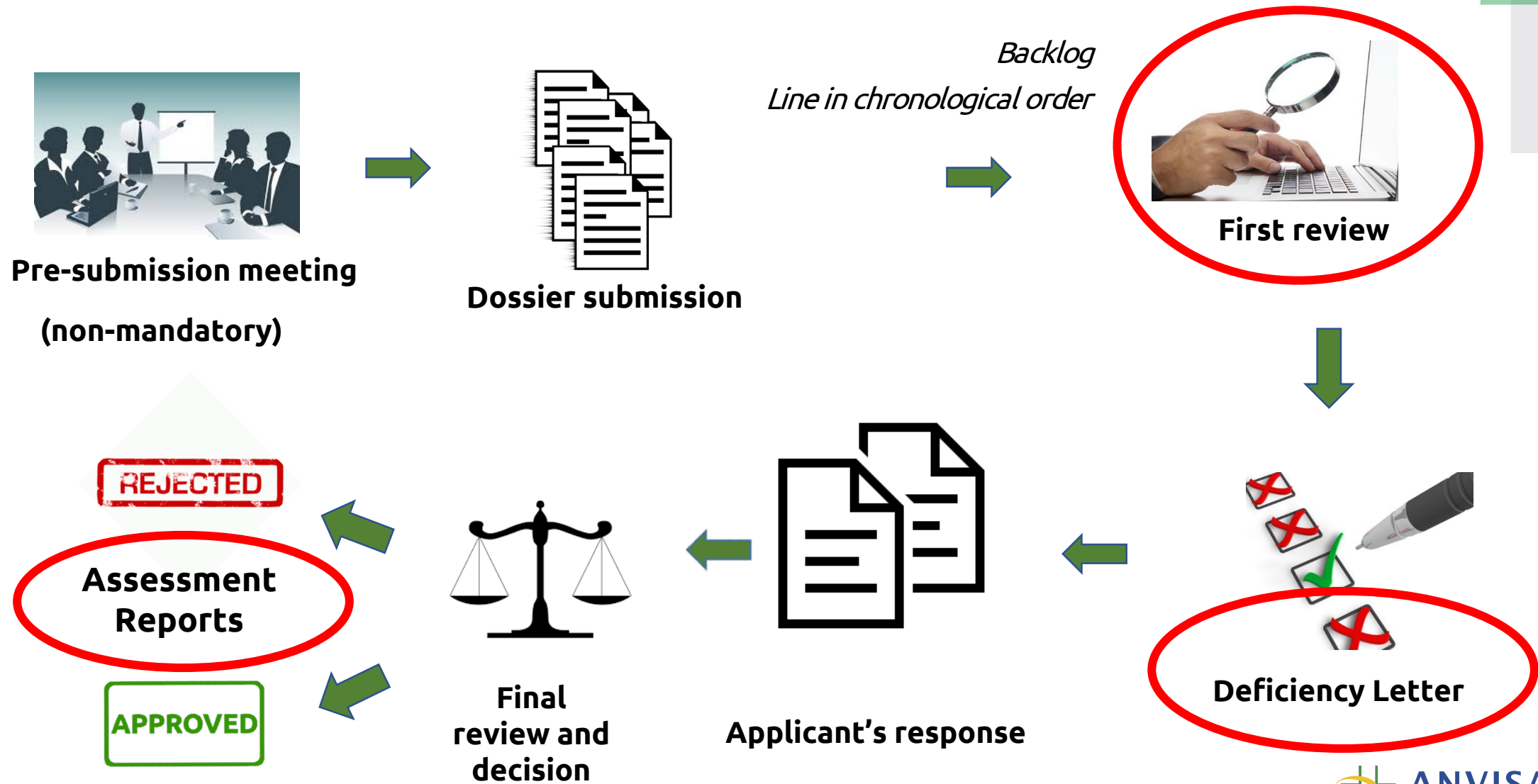


Optimization of the assessments/reviews: Online Optimized Assessment Project

✓ Putting together:

- A previous strategy of accelerated assessment, which grouped different applications of the same products/applicants to speed up the assessments;
- Online tools (virtual meetings and chats);
- Reliance (OS 45/18 or RDC 750/22).

Regular Assessment/Review Process



Online Optimized Assessment Project (first phase)

Strategy

- Scope: CMC PAC applications
- Top 5 applicants in number of PAC applications
 - Initial Perspective: reduction of 50% of the number of PAC applications
- 1 coordinator, ~2 senior reviewers, 2 weeks of online meetings (for each applicant)
- Stimulation of choosing reliance pathway (OS nº 45/18)
- Grouping of common documents of different applications
(for the same product)
- Online discussions -> avoiding deficiency letter
- Grouped Assessment Reports of different applications (for the same product)

Saving time!!!!

Online Optimized Assessment Project (first phase)

Results (October of 2022)

- Approval of 261 post approval changes applications, of 36 different biological products, within 11,5 weeks of online meetings (< 3 months), ~ 2 senior reviewers

Applicant #1	Applicant #2	Applicant #3	Applicant #4	Applicant #5
- 100 approved applications	- 59 approved applications	- 32 approved applications	- 29 approved applications	- 41 approved applications
- Deficiency letter for 4 applications	- No deficiency letter	- No deficiency letter	- No deficiency letter	- No deficiency letter
- 15 products	- 5 applications (partners – tech transfer)	- 3 products	- 2 products	- 1 product
- 11 days	- 15 products	- 10 days	- 12 days	- 13 days
	- 11 days			

Reduction of at least 50% of the time for assessments
Reduction/stabilization of the backlog for CMC applications
(benefit for all applicants - not only for those ones who participated in the project)

Online Optimized Assessment Project

- Exchange of experiences and standardization of understanding between the applicants and Anvisa;
- Increased adherence to the reliance analysis pathways (OS 45/18 and RDC 750/22);
- Awareness of issues related to the quality of the dossiers;
- Avoidance of deficiency letter (in most cases);
- Extremely positive feedbacks from the applicants, national and international, claiming to be an innovative action for the assessment of PAC applications and considered “SMART”, for its efficiency, maintaining the reviews without compromising the assessment quality.

Online Optimized Assessment Project

The project generated excellent results and we intend to have a new round in the future, with other applicants.

However, this way of assessment cannot be permanent or applicable for all applications, since it requires a lot of planning and energy and specific application characteristics. Notwithstanding, can be applied sporadically to reduce/control the backlog.

Online Optimized Assessment Project



March 2023

<https://diapublications.podbean.com/e/project-architect-explains-new-anvisa-online-optimized-assessment/>

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ANVISA Explains Innovative Online Optimized Assessment Project
Tuesday Mar 14, 2023

For regulators in Brazil, the pandemic's aftermath includes a backlog of post-approval changes, delayed by emergency development of COVID-19 vaccines and therapies, related to biologic product quality. ANVISA's new Online Optimized Assessment Project has significantly resolved these pending requests. "The pandemic had already enabled use of online tools for remote assessment of applications and virtual meetings between ANVISA and applicants, and also helped us be closer to other reference regulatory authorities in the process of building trust," explains project architect Elkiane Macedo Rama, an Adviser of ANVISA's Third Directorate. "The Online Optimized Assessment Project was a way to gather all these tools in a strategy to speed up the review process of these applications."

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Elkiane Rama –
one of the project
architects

Online Optimized Assessment Project (second phase)



Strategy

- Scope:
 - Efficacy and safety (e.g., a new or modified indication) PAC applications
 - Only applications using Reliance Pathway (OS 45/18 or RDC 750/22)
- Temporary specific line
- 1 Senior Reviewer



Online Optimized Assessment Project (second phase)

Results (January - May of 2023)

- Approval of 13/20 PAC applications (10 products from 8 applicants)
- Reduction of at least 75% of the time for assessments.

Problems and/or points for improvement

- Lack of Assessment Reports from a Reference Authority;
- Label differences;
- Strengthening of virtual meetings to avoid deficiency letters.

✓ Perspectives

- A new round with other 5 applicants for CMC PAC applications;
- Strengthening of the reliance strategies;
- The Online Optimized Assessment Project is a powerful toll to speed up the analyzes but is not a full substitute of regular assessment.



Optimized actions are more likely to succeed if the team is on board with the project and if companies are willing to adapt their applications.

Project Team



Architects

Carolina Blades

Elkiane Rama

Coordinator

Elkiane Rama

Reviewers

Maria Fernanda Thees

Neemias Silva

Renata Eto

João Tavares Neto

Andrea Andrade



Obrigada!
¡Gracias!
Thank you!

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