



# Brazilian Pharmacopoeia: vision and expectations for cooperation and convergence

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The views expressed herein are those of the presenter; they do not necessarily reflect the views of the ANVISA



## **Brazilian Pharmacopeia: vision and expectation for cooperation and convergence**

- ✓ ANVISA and Brazilian Pharmacopeia
- ✓ Brazilian Pharmacopeia
- ✓ International cooperation
- ✓ Expectations



## ANVISA and Brazilian Pharmacopeia (FB)

- ✓ Linked to the Ministry of Health
- ✓ Board of 5 directors (Collegiate Directorate Anvisa Resolution)

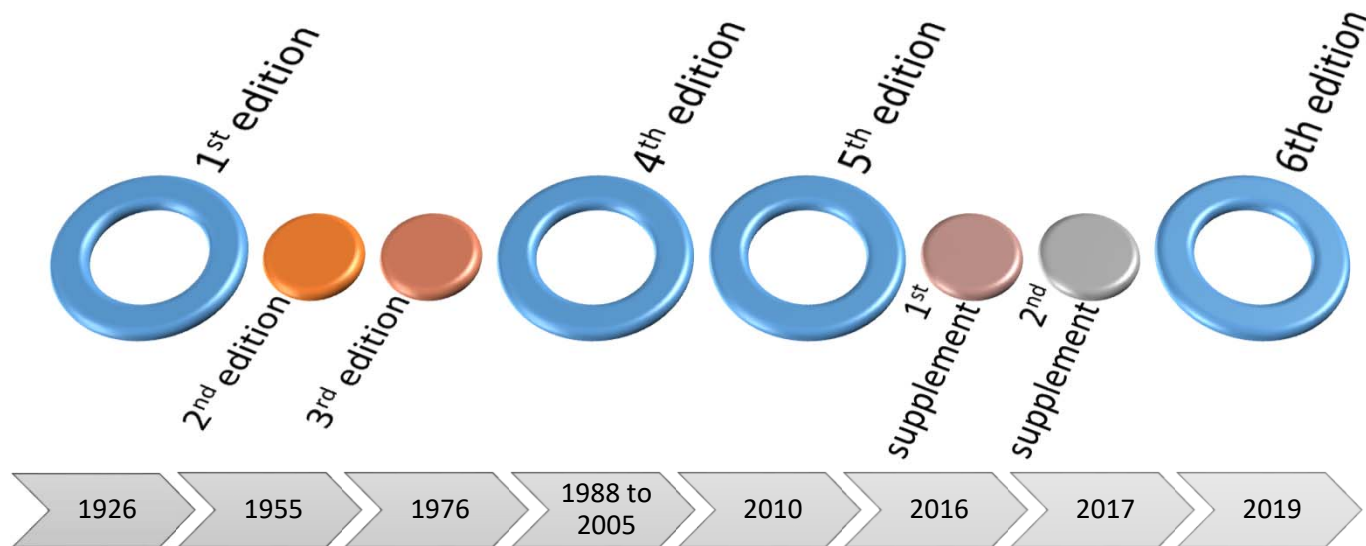


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- ✓ By Law: to promote the periodic review and updating of the pharmacopoeia (Federal Law n. 9782/1999)



# Brazilian Pharmacopoeia



✓ 6<sup>th</sup> edition  
2019

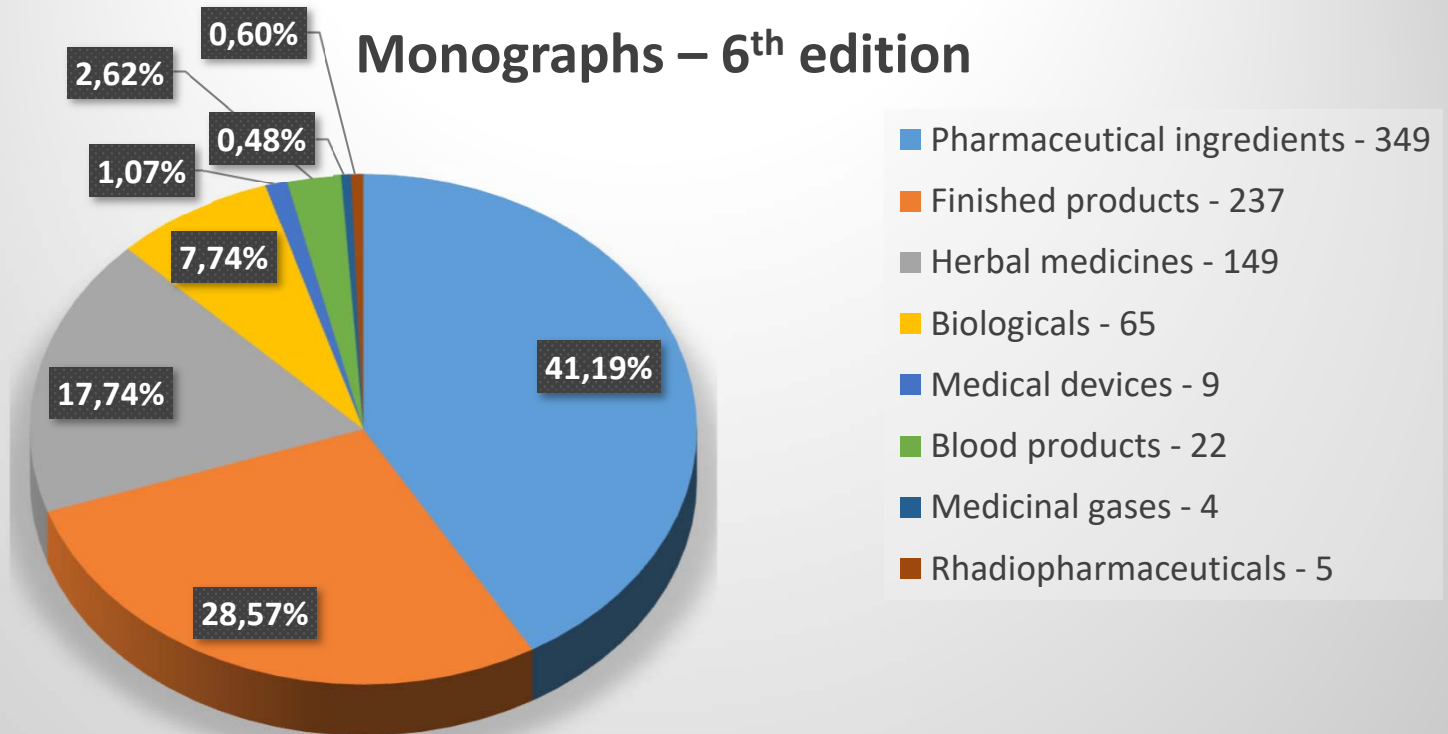




# Brazilian Pharmacopoeia



## Monographs – 6<sup>th</sup> edition

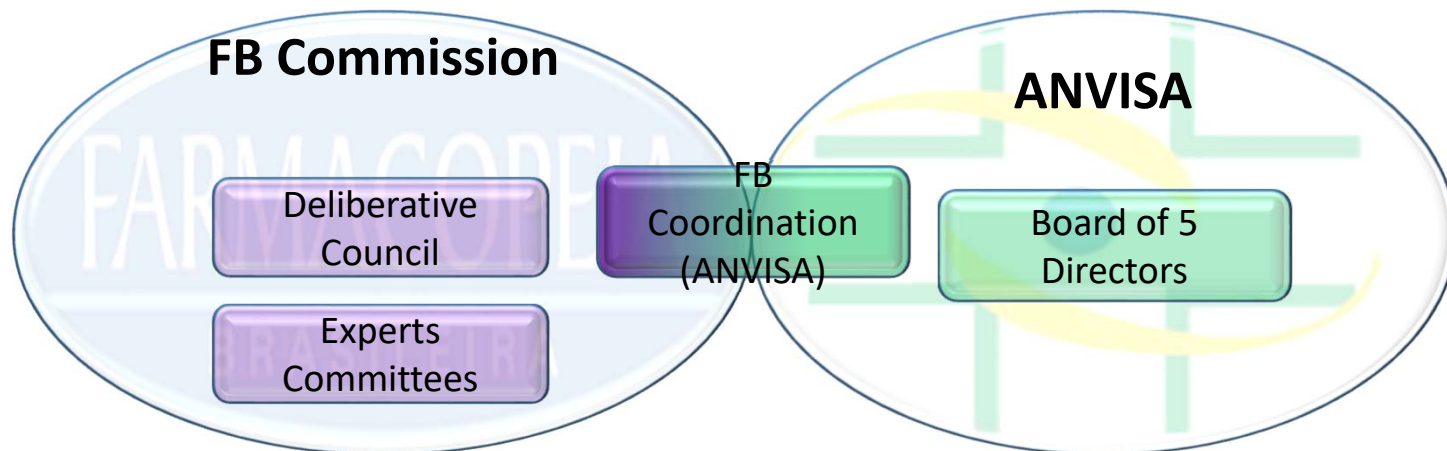




## FB Structure



Previous structure:

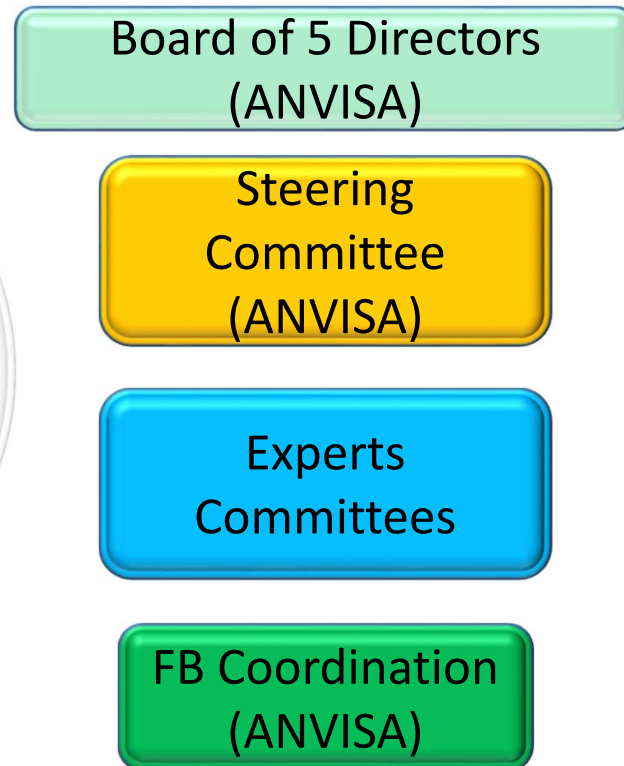




## FB Structure



- ✓ Reviewing the approach: new structure for The Brazilian Pharmacopoeia



- ✓ Change in our Internal Rules
- ✓ Number of Experts Committees
- ✓ Number of experts in each committee



## Brazilian Pharmacopoeia - Products



- ✓ Brazilian Pharmacopoeia;
- ✓ Brazilian Homeopathic Pharmacopoeia, 3<sup>rd</sup> ed. (2011)  
– 85 monographs
- ✓ National Formulary, 2<sup>nd</sup> ed. (2013) – 133 monographs
- ✓ Herbal Medicines Formulary, 1<sup>st</sup> ed. (2011) – 83 monographs;
  - 1<sup>st</sup> Supplement (2018) – 68 monographs;
  - 2<sup>nd</sup> ed. – Public consultation – 89 monographs.



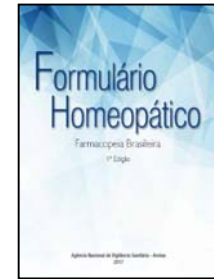




## Brazilian Pharmacopoeia - Products

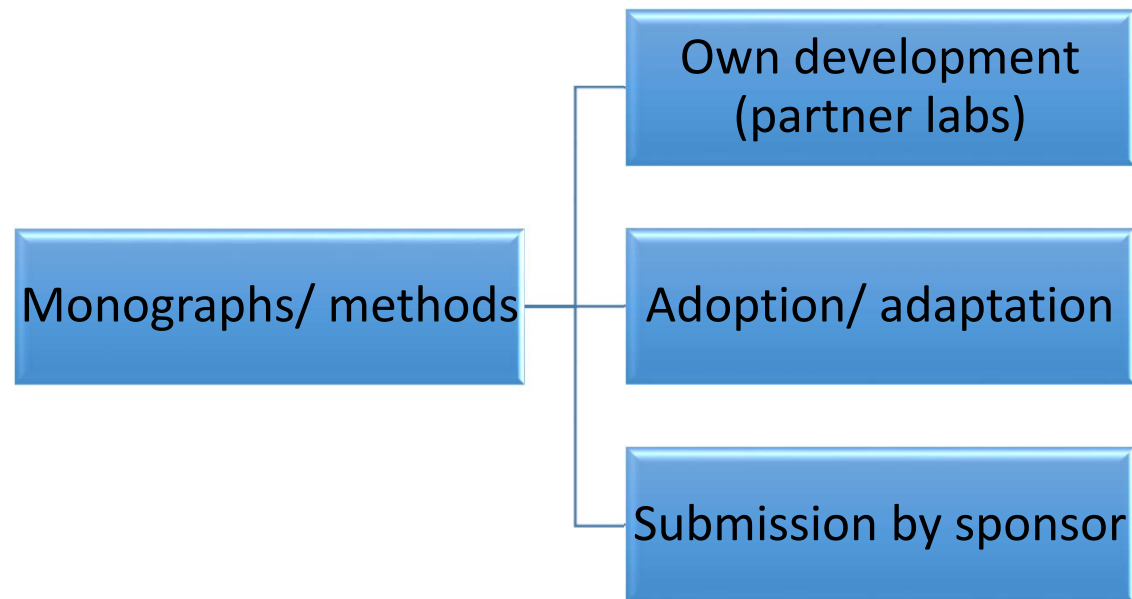


- ✓ Homeopathic Formulary
  - 1<sup>st</sup> ed. (2016) – 84 monographs;
  - 2<sup>nd</sup> ed. (2019) – 106 monographs.
- ✓ Memento of Herbal Medicines, 1<sup>st</sup> ed. (2016) – 28 monographs
- ✓ Brazilian Nonproprietary Names (DCB) ~12.000
- ✓ Chemical Reference Substances (SQR) – 84





## Methods & Tech Transfer



- ✓ Analytical validation: Anvisa Resolution n. 166, July 2017



## Reliance



- In absence of monographs and methods in the Brazilian Pharmacopoeia, the following pharmacopoeias recognized by Anvisa can be used:

❖ Argentine Pharmacopoeia	
❖ British Pharmacopoeia	
❖ European Pharmacopoeia	
❖ French Pharmacopoeia	
❖ German Pharmacopoeia	
❖ International Pharmacopoeia	
❖ Japanese Pharmacopoeia	
❖ Mexican Pharmacopoeia	
❖ Portuguese Pharmacopoeia	
United States Pharmacopoeia	

Application





# International Cooperation



## ✓ Anvisa Strategic Planning

- ✓ Strengthen international operations and compromises with actors and strategic partners (OB 12)
- ✓ Promote a friendly regulatory environment to social and economic development (OB 4)





# International Cooperation

## Memorandum of Understanding - MoU

### ❖ Purpose

- Strengthen relations and promote cooperation on standard setting efforts of the Pharmacopoeias

### ❖ Argentinian Pharmacopoeia (ANMAT)

- Signed on October, 2007
- Remain effective for two years, with automatic renewal

### ❖ United States Pharmacopoeia (USP)

- Signed (renewed) on August, 2018
- Remain effective for 3 years

### ❖ International Pharmacopoeia (WHO)

- Signed on May, 2019
- Remain effective for three years, with automatic renewal

### ❖ European Pharmacopoeia (EDQM)

- Signed on April, 2017

### ❖ Japanese Pharmacopoeia (MHLW)

- Signed on September, 2015
- Remain effective for five years, with automatic renewal



# International Cooperation



ICH



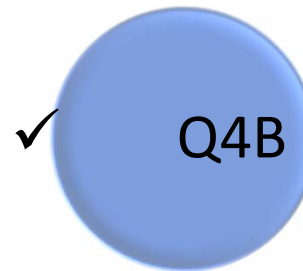
❖ Q3C

Residual Solvents



Q3D

Elemental Impurities



✓ Q4B

Pharmacopoeias



## Expectations



### ✓ Collaboration among pharmacopoeias

- Prospective harmonization

### International reality of Pharmacopoeias

- Improvement of GPhP

### Expansion of cooperation between Pharmacopoeias

- MoU

### Increase the accuracy of decisions

- Sharing information and approaches

### Alert network

- Quick responses to global urgencies



# Thank you!

## Getting in touch

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**ANVISA**  
Agência Nacional de Vigilância Sanitária

MINISTÉRIO DA  
SAÚDE

