IMDRF International Medical Device Regulators Forum

REGULATORY UPDATES

IMDRF Stakeholders Meeting
Ottawa, Canada, September 2017

ANVISA

Brazil

Minamata Convention

- **Resolution RDC 147/17** – Establishes a phase out date for clinical thermometers and sphygmomanometers containing mercury.

- Date after which the use, manufacture or import of the product must not be allowed (Phase-out date): jan/2019.

Minamata Convention

- **Public Consultation n° 324/2017** – Restrics the use of dental amalgam to its encapsulated form.

- Date after which the use, manufacture or import of non encapsulated dental amalgam shall not be allowed (Phase-out date): jan/2019.

Regulatory Updates

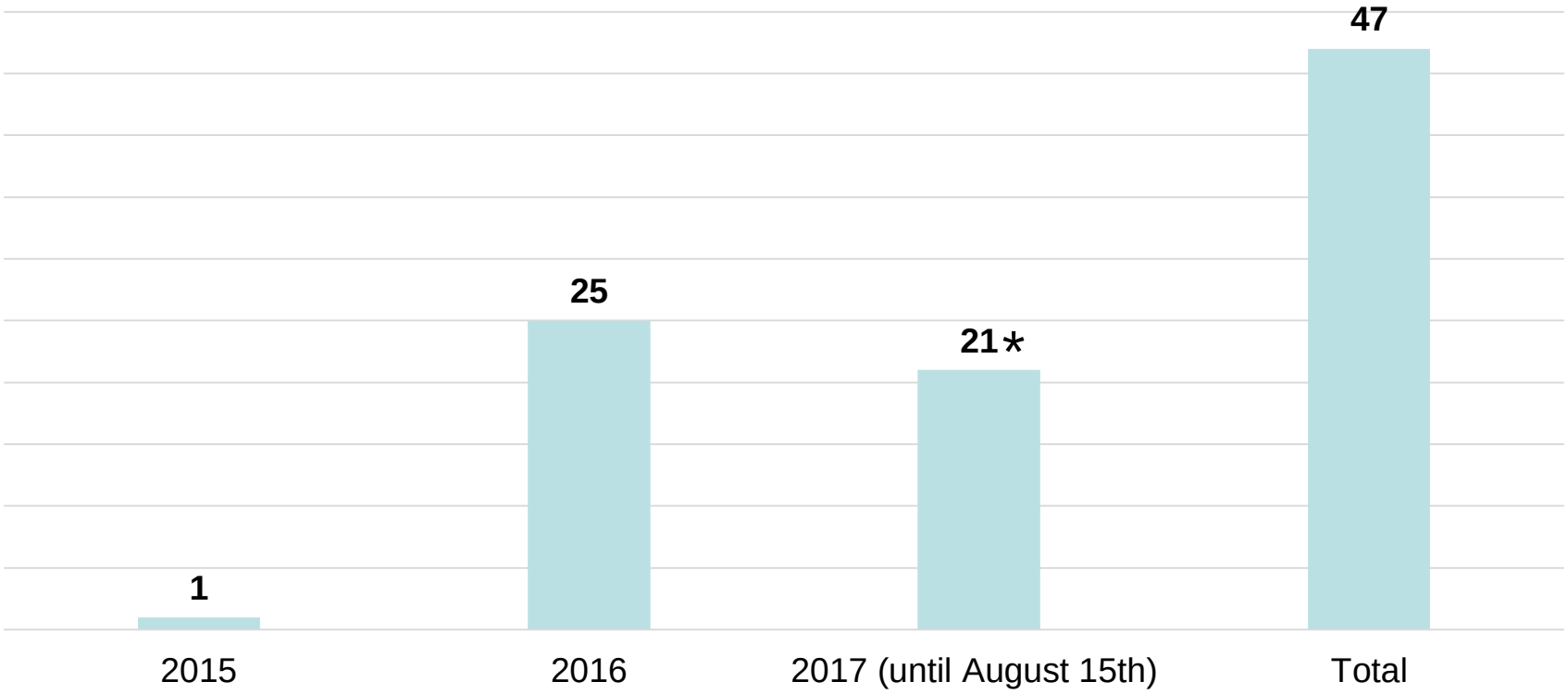
- **Public Consultation n° 371/2017-** Changes the expiration date of medical device registration from 5 to 10 years.

Regulatory Updates

- ✓ Auditing Organizations Recognized by ANVISA (Allows ANVISA to use MDSAP regulatory audit outcomes to issue the GMP certificate)

Auditing Organization	Resolution	Date	Published on	Expiry date
Laboratoire National de Métrologie et d'Essais (GMED Certification Division)	31	05/01/2017	09/01/2017	30/06/2018
DQS Medizinprodukte GmbH	194	24/01/2017	25/01/2017	31/12/2018
DEKRA Certification B.V.	193	24/01/2017	25/01/2017	31/12/2018
TUV SUD America Inc.	324	07/02/2017	08/02/2017	31/12/2020
Intertek Testing Services NA Inc.	323	07/02/2017	08/02/2017	31/12/2020
BSI Group America Inc.	651	13/03/2017	14/03/2017	27/02/2021
National Standards Authority of Ireland (NSAI)	1.783	06/07/2017	07/07/2017	15/06/2019
Lloyd's Register Quality Assurance Inc.	2.057	28/07/2017	31/07/2017	16/07/2019

ANVISA´s GMP Certification using MDSAP audit reports



* 3,8% of the international GMP Certificates issued by ANVISA in 2017

THANK YOU!

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