Consolidated purchase of medicines and healing material from the Federal Government and Federal Entities

Guide for the registration of medicine

APRIL 2019

GOBIERNO DE MÉXICO

Objective

One of the most important tasks of the Mexican government is to make procurement procedures transparent, as well as establishing competitive mechanisms that open the door to a **greater number of suppliers** to obtain the best conditions for the State in terms of price, quality and opportunity.

In this sense, Mexico will carry out an international bid for the purchase of medicines and healing material and several regulatory changes have been made to accelerate the administrative procedures and sanitary regulation to expand international participation.

Mexican government wants to have the participation of companies of the pharmaceutical industry from different countries in the bid, to expand the supply of the public health sector, which represents nearly 100 billion pesos annually in the purchase of medicines and healing material.

Obtaining sanitary registration

- ✓ The sanitary registration is the authorization that guarantees that the purchased health supplies have safety, quality and efficacy.
- ✓ A normative update was approved to obtain the sanitary registration of the medicines under the modality of Equivalence Agreements:
- ✓ https://dof.gob.mx/nota_detalle.php?codigo=5555923&fecha=29/03/2019

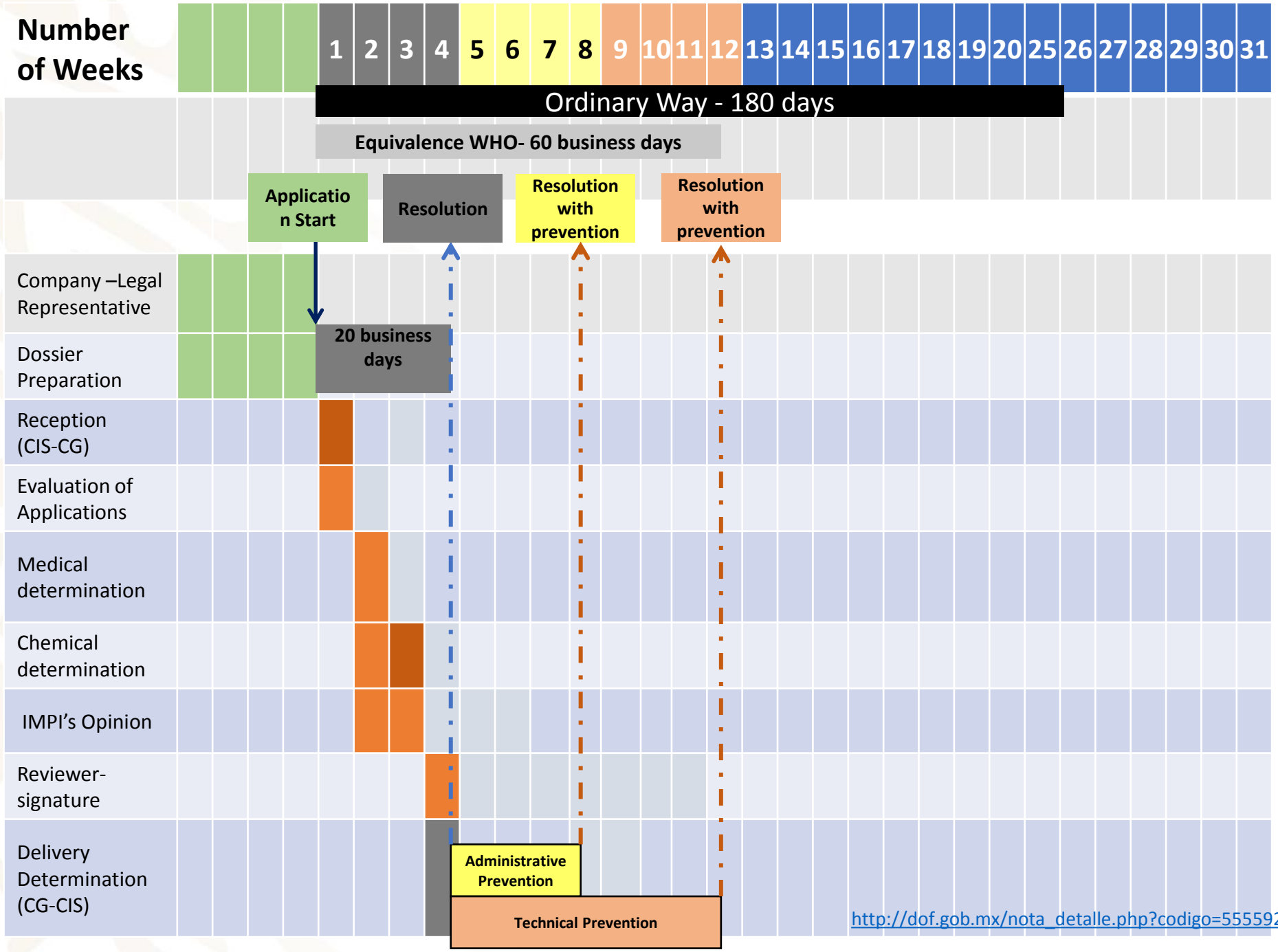
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Schedule of Bidding Process

Process	Date
Publication of Convocation Project	3 to 16 May
Attention to comments	May 17th
Publication of Convocation	May 23rd
Clarification meeting	May 30th
Presentation and opening proposals	June 12th
Veredict	June 21st

*** Tentative dates 2019**

GENERICS



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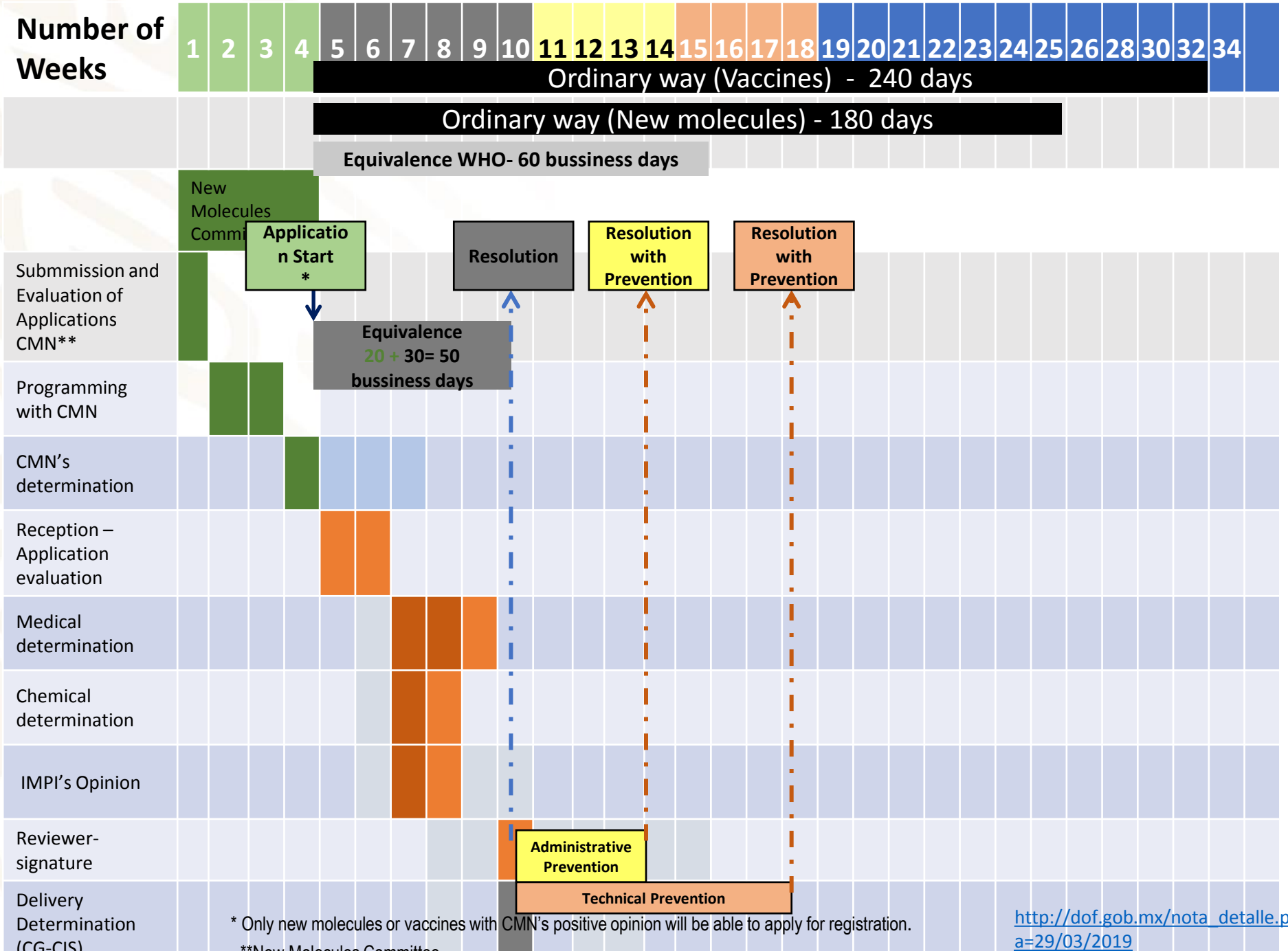
NEW MOLECULES AND VACCINES



* Only new molecules or vaccines with CMN's positive opinion will be able to apply for registration.

**New Molecules Committee

http://dof.gob.mx/nota_detalle.php?codigo=5555923&fecha=29/03/2019

General requirements for sanitary registration

Generics: Chemical Synthesis	
Generics 404B National 404D **Foreigner**	**Module I.** Legal Administrative Information. **Module II.** Quality Information. **Module III.** Bioavailability and/or Bioequivalence. (Safety and efficacy)

Module I.
Contracts, GMP certificates, **FSCs,** Licenses, Patents, D.D., QR code, IPs, Distributors, **Legal Representatives**, etc.

Module II.
Information of raw materials (drugs and additives), evaluation of the final product, manufacturing orders, controls in process, conditioning, stability studies, etc.

Module III.
Bioavailability and/or Bioequivalence Analysis (Type tests A, B, C) according to current NOM 177 SSA1

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https://www.gob.mx/cms/uploads/attachment/file/419394/COFEPRIS-04-004-B.pdf

General requirements for sanitary registration

New Molecules: Chemical and Biological Synthesis	
New Molecules/Reference 404A National 404C **Foreigner**	**Module I.** Legal Administrative Information **Module II.** Quality information **Module III.** Preclinical studies **Module IV.** Clinical studies **Module V**. CMN Determination

Module I.
Contracts, GMP certificates, **FSCs**, Licenses, Patents, D.D., QR code, IPs, Distributors, **Legal Representatives**, CMN's technical opinion, etc.

Module II.
Information of raw materials (drugs and additives), evaluation of the final product, manufacturing orders, controls in process, conditioning, stability studies, etc.

Module III, IV y V.
Preclinical and clinical Studies Reports, monitoring and CMN determination

FSC: Free Sale Certificate
D.D.: Distinctive denomination
IP: Information to Prescribe

https://www.gob.mx/cms/uploads/attachment/file/419396/COFEPRIS-04-004-C.pdf

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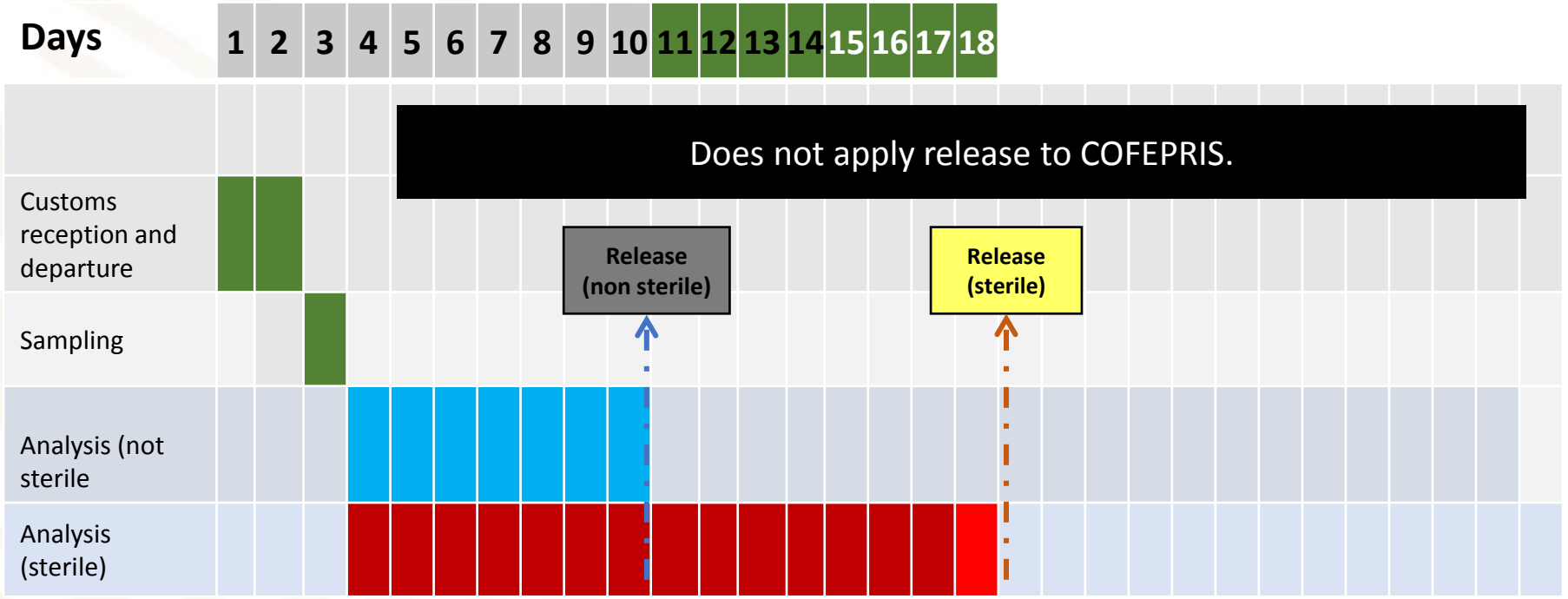
GENERICS – Batch Release



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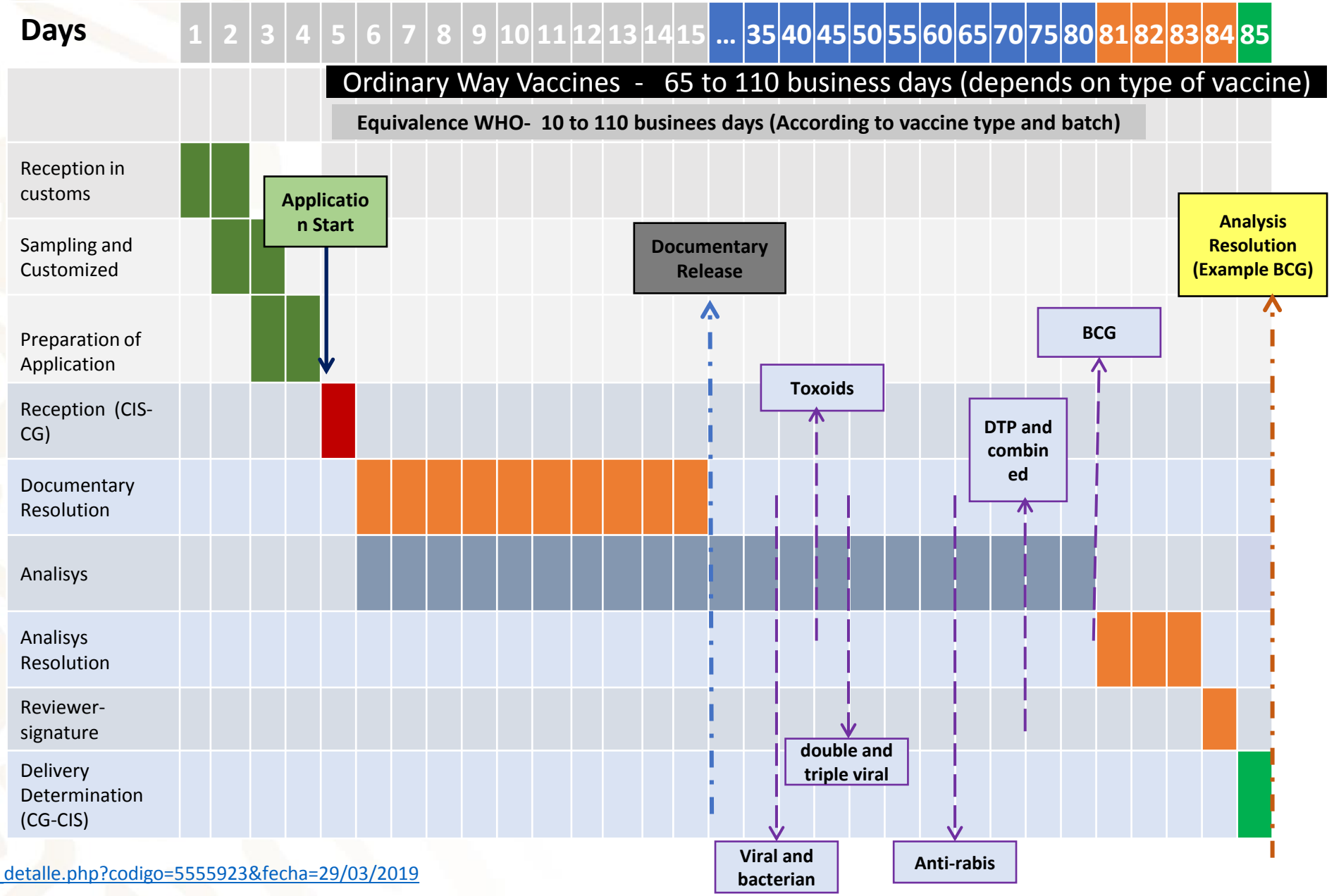
General requirements for generics release

Responsability of the Chief of Sanitary Regulation in Mexico	
Documents	**Manfacturer**: GMP certificate **Batch**: Manufacturer's Certificate of Analysis **Analysis:** In the laboratory of the importer or with an auxiliary laboratory to the sanitary regulation or CCAyAC (Commission of Analytical Control and Enlargement of Coverage).

http://dof.gob.mx/nota_detalle.php?codigo=5555923&fecha=29/03/2019

VACCINES – Batch Release



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General requirements for Vaccines Release

Documentary and ordinary route	
Documents	**Administrative**: Application, Payment Rights **Establishment**: Sanitary License and Responsible pharmacist notice **Manufacturer**: GMP certificate **Import**: License, Motion, Aerial Guide, Inovice, Packing list, temperature records, clearance of goods letter. **Batch**: Protocol, analytical manufacturer certificate, authority of origin release, photos of packaging and labels

Simplified Process.

Documentary review documental for every batch Analysis to 1 of 4 batches.

Release procces with analysis

Period of release is determined by the type of vaccine.

The analysis by quality monitoring can apply to any batch already released by simplified process.

AGREEMENT for Guidelines to authorize the distribution or sale of batches of biological products.

https://www.dof.gob.mx/nota_detalle.php?codigo=5352631&fecha=16/07/2014

Glossary

- BCG: Bacillus de Calmette and Guérin (Tuberculosis Vaccine)
- CCAyAC: Commission of Analytical Control and Enlargement of Coverage
- CIS: Integral Service Center
- CMN: New Molecules Committee
- COFEPRIS: Federal Commission for Protection against Health Risks) Comisión Federal para la Protección contra Riesgos Sanitarios)
- D.D.: Distinctive denomination
- DTP: Anti-diphtheria-Antitetanus-Anti-pertussis (Diphtheria, Pertussis and Tetanus Vaccine)
- FSC: Free Sale Certificate
- GMP: Good manufacturing practice
- IMPI: Mexican institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial)
- WHO: World Health Organization

Contact

Integral Service Center

- QFB. Carolina Ibarra Ramírez (cibarra@cofepris.gob.mx)

New Molecules Committee

- Dra. Hilda Durán Álvarez (hduran@cofepris.gob.mx)

Sanitary Registration

- QFB. Emanuel Rojas Romero (erojas@cofepris.gob.mx)

Importation license

- QA. Maribel Bernal Saldívar (mbernal@cofepris.gob.mx)

Vaccines Release

- QFB. Virginia Ramírez Martínez (vramirezm@cofepris.gob.mx)

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