Case study: Reliance pilot to improve management of Post-Approval Changes (PAC) during the lifecycle of a vaccine

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PAC Reliance Pilot of a Vaccine

Transfer of a legacy WHO prequalified vaccine Filling & Packaging activities

Fill & Pack

Batch Release

37 COUNTRIES IMPACTED

Regulatory approvals:
FROM 4 YEARS to 6 MONTHS
57% of countries (21) participate to the Pilot  (As of 09 Nov 2022)

- Bolivia
- Paraguay
- Singapore
- Taiwan
- Israel
- Germany
- Netherlands
- Canada
- Thailand
- Colombia
- Panama
- Ecuador
- Bolivia
- Chile
- WHO
- Turkey
- Israel
- Jordan
- Saudi Arabia
- Malaysia
- Singapore
- South Africa

19% - Have not responded
24% - Declined the pilot
Focus on Latin American NRAs (As of 09 Nov 2022)

8 ACCEPTED
• Bolivia
• Chile
• Colombia
• Ecuador
• El Salvador
• Guatemala
• Panama
• Paraguay

6 PENDING
• Argentina
• Brazil
• Costa Rica
• Honduras
• Mexico
• Venezuela

3 DECLINED
• Dominican Republic
• Peru
• Uruguay
Success factors (1/2)

1 STANDARD DOSSIER
submitted in all countries
based on EU CTD dossier
content and Health Canada
/ WHO requirements

1 SET OF REQUIREMENTS
For all countries: some local
requirements will NOT be met,
based on scientific rationale

1 TIMELINE
Unique timing for all countries after
approval granted by Health Canada
as the Responsible NRA

1 Q&A DOCUMENT
Unique Q&A document sent to all
NRAs creating transparency

90 calendar days
NRAs’ review

30 cal. days
Sanofi Q&A

30 cal. days
NRAs’ Q&A review

30 cal. days
NRA’s approval
Success factors (2/2)

1 **Language**
Same language: English for all NRAs except administrative local documents

1 **Report**
Health Canada assessment report and Q&A shared with all NRAs as Sanofi authorises to share confidential and unredacted information

0 **No GMP Inspection**
Reliance on the GMP certificate of the French site issued routinely by ANSM

0 **No Testing**
Testing considered as not necessary by Health Canada for this type of change
1 timeline for all countries (1/2)

**STEP 1**: Submission & Approval in Canada

- **2022**
  - Q2: 45 calendar days
    - 26 Apr: Submit standard dossier to Canada
  - Q3: 180 calendar days
    - 15 June: Dossier Screening acceptance
    - Incorporate any changes from screening
    - Include Q&As during Canada review period
  - Q4: Today
    - Approval Target date 12 Dec
    - Send assessment report & CPP to Sanofi affiliates for international submission
    - Assessment Report Sent to Sanofi
    - Approval: Notice of compliance (NOC) issued
1 timeline for all countries (2/2)

**STEP 2**: Submission & Approval in ALL other participating NRAs

- **2022**
  - Q4: 17 Jan
  - **Submission of dossier to all NRAs on the same date**

- **2023**
  - Q1: 17 Apr
  - **NRA review period**
  - Q2: 17 May
  - **Provide Questions (if any) to MAH**
  - Q3: 16 June
  - **Review of Q&As by NRAs**
  - Q4: 17 July
  - **Answer to Questions in a single document provided to all NRAs**

- **2024**
  - Q1
  - **2025**
  - Q4

- **Sanofi**

- **National Reg. Authorities**

- **Filling & Packaging**
  - **Stop in France**
  - **Start in Canada**

- **APPROVAL**
  - **APPROVAL NOT GRANTED**
  - Share rational for refusal
Barriers encountered (1/2)

1 Batch Release site

Only 1 site authorized in the license to release the vaccine

1 Manufacturing Site

Only 1 site authorized in the license to manufacture the vaccine

Grace Period

(time from approval of the Variation to available date of the product)

Fixed grace period of 6/12 months after approval of dossier instead of 18 months required

New Registration required

Several manufacturing sites authorized in the license

BUT alternate site = New Registration

GMP Documentation &/or Inspection

GMP documentation and/or inspection required to add the filling at the French site as no reliance on French authorities’ inspection certificate
Barriers encountered (2/2)

Difficulties to connect with NRAs
NRAs not available due to Covid pandemic & outbreaks

Misalignment of Reliance Principles
Local Legislation does not contain reliance principles
Local reliance legislation not aligned with the pilot

Additional Documentation
Few NRAs joining the pilot requested additional Module 3 documentation that is not part of Standard Dossier

Government Change
Change in government may impact agreement to participate to the pilot
Conclusion

• Challenge to engage NRAs
• Required internal company endeavors
• Great support of external stakeholders

• We welcome NRAs who did not reply yet to still apply (NRAs who first declined are welcome to change their mind !)

Due date: Dec 1st !
Thank you

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