



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the patient

National Agency for Food and Drug Administration and Control (NAFDAC)



- MANDATE: regulate and control the manufacture, importation, exportation, **distribution**, advertisement, sale and use drugs, cosmetics, chemicals, detergents, medical devices and packaged water
- The NAFDAC ACT places the burden of drug **distribution, sale, use** and security on the Agency.



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ACCESS, AFFORDABILITY and EQUITABLE DISTRIBUTION (*Lessons Learned*)

- Unused past experience of a system that eliminated polio and stopped measles transmission
- Inefficient commercial delivery systems that worked so well during the H1N1 outbreak.
- Lack of maximization of health workers
- Science not shared, the vaccine not provided on time, the assistance not given as at when due
 - Results in suffering in some countries.
- Global and National

Gayle *et al*, National Academy of Sciences, Engineering and Medicine, USA



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NATIONAL

- COVAX
- CACOVID (Supported by Africa-based banks)
- Proposed Plan for local manufacturing with Public-Private Company
 - One of the six spokes in Africa
 - South Africa – Hub
- Ongoing talks with two other private companies



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Regulatory Review Pathways for Covid-19 Vaccines

Depends on the source of the vaccine. Review pathway may include any the following:

1. Reliance

- Products listed under the WHO EUL Procedure
- WHO EUL decision as a basis for an abridged review

2. Full review

- ✓ Standard review process that includes fast-track review
- ✓ New application previously licensed by non-listed NRAs

| | COVID-19 VACCINE | REVIEW PATHWAY | REVIEW PERIOD* |
|----|------------------|------------------------|----------------|
| 1 | Covishield | Reliance | 5 |
| 2 | Pfizer BioNTech | Reliance | 5 |
| 3 | Janssen | Reliance | 5 |
| 4. | Moderna | Reliance | 5 |
| 5. | Sinopharm | Reliance | 5 |
| 6. | AstraZeneca Bio | Relance | 5 |
| 7. | Sputnik V | Full review | 180 |
| 8. | Covaxin | Full review & Reliance | 360 |
| 9. | Novavax | Reliance | 5 |

* Working days: From the time access to dossier was granted to when review was concluded.



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COVID-19 Yearly Vaccinations - Data as at 16th July 2022

Source: Daily Call-In Data



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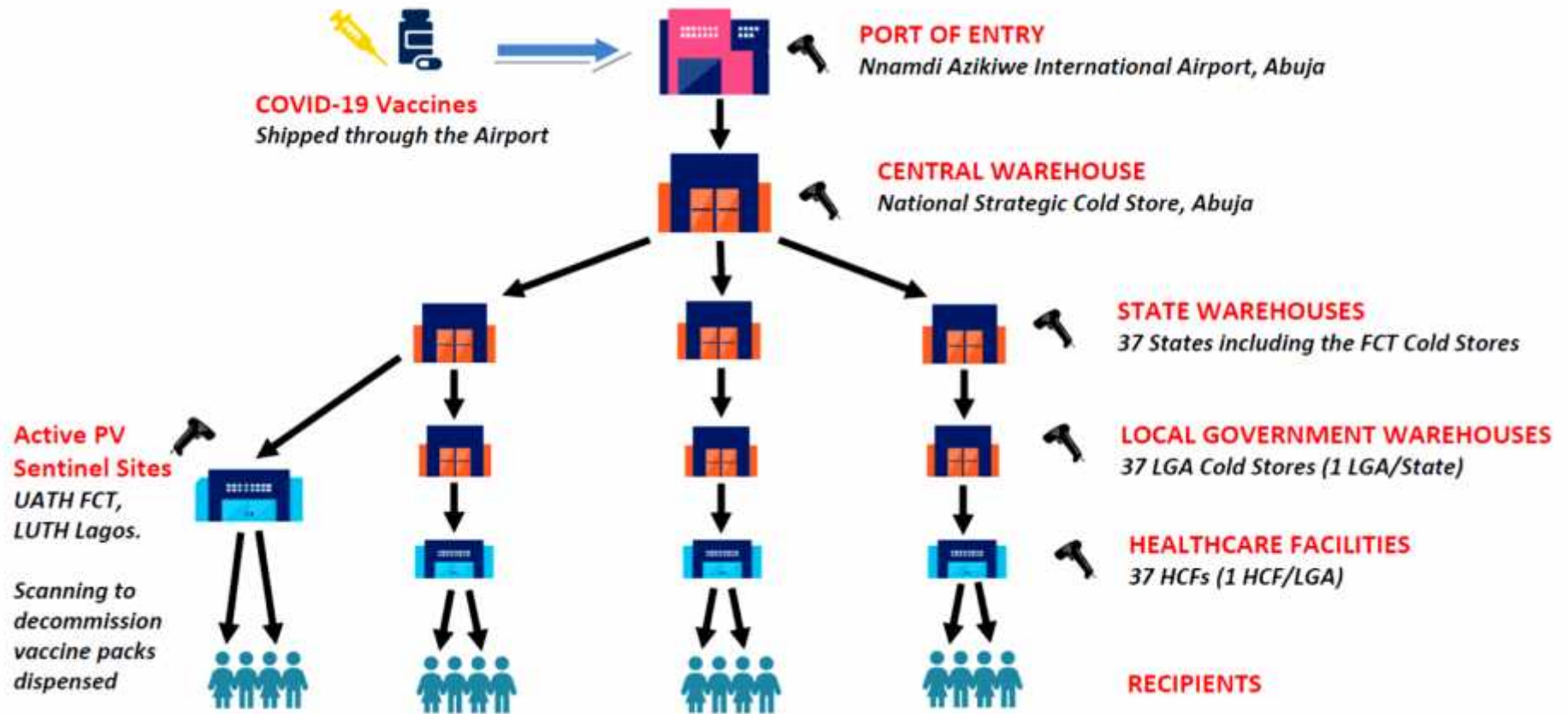
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COVID-19 VACCINES RECEIVED IN NCLVB-NAFDAC AND LOT RELEASE ISSUANCE AS AT 10-06-2022

| | TOTAL NUMBER RECEIVED | LOT RELEASE CERTIFICATES ISSUED | COMMENT |
|---------------------|-----------------------------|---------------------------------------|---|
| COVISHIELD | 10 | 6 | Initially, 3 batches were released with one certificate. One batch shipped from South Africa was issued a "Letter of Rejection" due to unsatisfactory Protein content. |
| JANSSEN | 64 | 64 | |
| PFIZER/ BIONTECH | 33 | 33 | |
| ASTRAZENECA | 30 | 29 | Initially, 2 batches were released in one certificate. |
| MODERNA | 22 | 10 | Initially, 7 batches and 5 batches were released with one certificate each |
| TOTAL | 159 | 142 | |

Lot release Certificate: based on document review and selected (safety and quality-indicating) test parameters in accordance with ISO/IEC: 17025 Standard

Traceability for AstraZeneca COVID-19 Vaccines Traceability: Supply Chain Map & Safety Monitoring

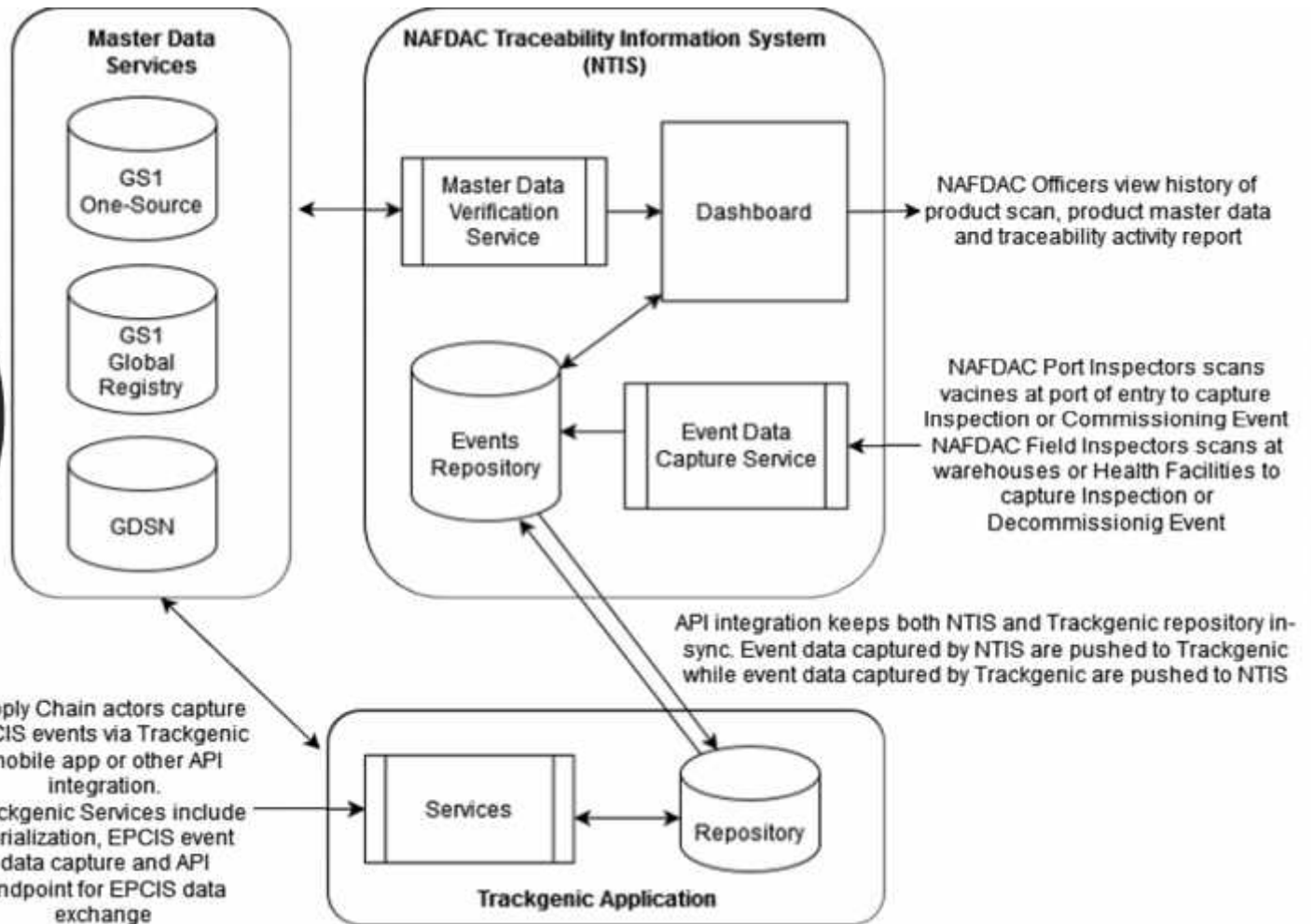


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Nigeria National Traceability Information System Architecture



EPCIS: Electronic Product Code Information Services

GDSN: Global Data Synchronisation Network

API: Application Programming Interface

Product GTINs Detected by Scanning Events

Commissioning Other Events

Show **5** entries

Search:

| GTIN | Batch | Expiry Date | Brand Owner | No. of Packs |
|----------------|---------|-------------|-----------------|--------------|
| 00359267100023 | 32021BA | 2022/01/31 | Pfizer-BioNTech | 64 |
| 00359267100023 | 32125BA | 2022/01/31 | Pfizer-BioNTech | 259 |
| 00359267100023 | 33040BD | 2022/06/30 | Pfizer-BioNTech | 2 |
| 00359267100023 | 34005BD | 2022/06/30 | Pfizer-BioNTech | 236 |
| 00359267100023 | FJ1617 | 2022/02/22 | Pfizer-BioNTech | 364 |

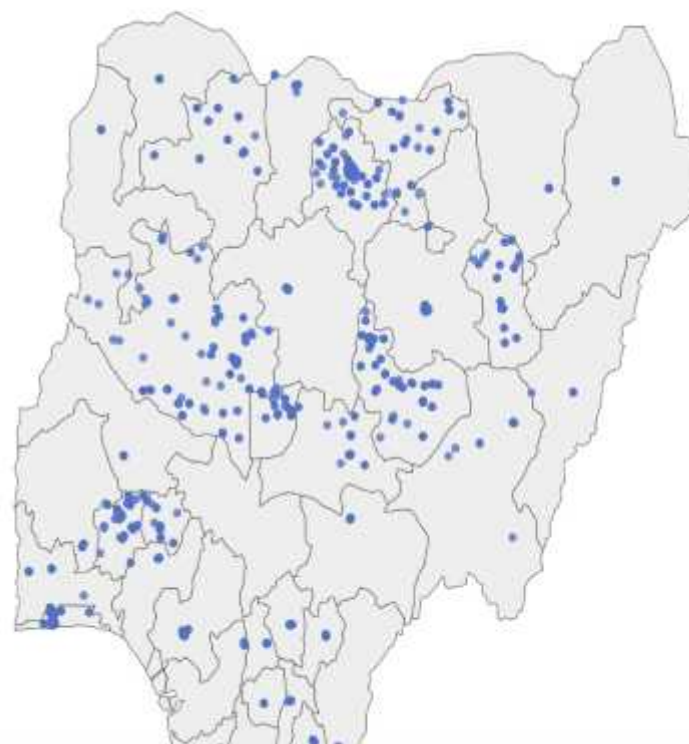
Showing 1 to 5 of 68 entries

Previous **1** 2 3 4 5 ... 14 Next

Data: Total Number of secondary packs scanned across all facilities

Distribution of Product Items across States

Items Last Scan Location



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