WTO Vaccine Supply Chain and Regulatory Transparency Symposium

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29 June, 2021

Contribution of regulatory alignment and reliance: for improving access to vaccines and facilitating trade

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Kudos to all the regulatory agencies especially EMA, US FDA, MHRA, PMDA, WHO and local NRAs in India, China, Brazil, Korea, Indonesia and South Africa for rising to the occasion, taking several innovative and pro-active steps to beat the unprecedented challenging situation created by the onset of COVID-19 pandemic which enabled fast track development and availability of vaccines worldwide in such a short span of time e.g.

1. EMA had put in place very early in the game, a dedicated expert task force, rapid and rolling reviews to evaluate high-quality applications from companies in the shortest possible timeframes, while ensuring robust scientific opinions.

2. Early scientific advice from regulators helped developers speed up development by receiving prompt guidance and direction on the best methods and study designs to generate robust data.

3. Companies have also expanded manufacturing capacity and large-scale production to facilitate vaccine deployment without delay once approved. Some vaccine developers started manufacturing their COVID-19 vaccine at risk before obtaining a marketing authorization. This allowed them to be ready to distribute doses rapidly enough to meet demand once they were authorized.

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4 Fast-track vaccine EUA by US FDA

On 11th December, 2020 the FDA issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for >16 and within next 7 days on 18th December, 2020 EUA was issued to Moderna's vaccine for >18y
Again in little over 2 months on 27th February US FDA issued EUA to Jansen single shot COVID-19 vaccine to >18y.

Not only this but FDA went on to reissue the letter in its entirety to authorize emergency use of Pfizer-BioNTech COVID-19 Vaccine for individuals 12 through 15 years of age, as well as for individuals 16 years of age and older followed by shelf life extension from 1 to 3 and then 4.5 months at 2-8 degree Celsius.

5 Steps taken by International Coalition of Medicines Regulatory Authorities (ICMRA)

During the ongoing COVID-19 pandemic, ICMRA is acting as a forum to support strategic coordination and international cooperation among global medicine regulatory authorities.

The aim of these activities is to expedite and streamline the development, authorization and availability of COVID-19 treatments and vaccines worldwide. ICMRA members also work towards increasing the efficiency and effectiveness of regulatory processes and decision-making.

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6 World Health Organisation (WHO)

WHO has developed excellent guideline on Good Regulatory Practices and Good Reliance Practices in regulatory decision making: high level principles and recommendations.

International organizations, manufacturers, donors and other vaccine stakeholders could foster implementation of such practices which of course, focus on transparency and reliance among others.

WHO PQ team has expedited reviews of dossiers, done desk audits as well as on site audits and ensured EUL to first vaccine on 31st December, 2020 followed by two more on 15th February, 2021 facilitating roll out of vaccines through COVAX for equitable distribution.

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7 Indian NRA

On 27th March, 2020 in an effort to provide quick access to vaccines and drugs to treat COVID-19, the Drug Controller General of India (DCGI) had announced several measures including expediting reviews and approvals for drugs and vaccines already approved in other countries. The Indian drug regulator will also grant speedy permissions for clinical trials, waiver of data requirement for animal studies and approval of manufacturing licenses within seven days.

On 15th April, 2021 DCGI based on consensus of NEGVAC (National Expert Group on Vaccine Administration for COVID-19) gave permission to foreign produced vaccines having received EUA by US FDA, EMA, UK MHRA, PMDA Japan and/or EUL by WHO may be granted restricted use in emergency situation in India mandating requirement of post approval parallel bridging trial.

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The Outcome so far:

- ✓ **In 324 days: Roll out of first COVID-19 vaccine**
- ✓ **Reaching 177 Countries in <100 days**
- ✓ **~3.3 Billon doses produced & delivered in < 6 months**
- ✓ **> 50% Contribution by DCVMN**

Challenges

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Accelerated development and subsequent expedited Emergency Use Authorization, resulted into several challenges for the COVID-19 vaccine.

Broadly we can classify these challenges in five categories:

Challenge no.1: Different Legislative Requirements for all countries

NOT all countries …

- Have the same legislative framework
- Have the same regulatory requirements
- Have the same regulatory procedures
- Have the same and predictable timelines
- Have the same scientific and regulatory maturity

Challenges

Challenge no.2: Fast development and approvals of COVID Vaccines trigger a number of additional challenges to be managed after initial authorization such as, but not limited to:

- Additional validation process data
- Optimized control strategies
- Additional data gathered from additional number of batches
- Evolving process understanding and then optimizations
- Additional batch sizes/Scale-ups
- Additional manufacturing sites for DS, DP, and excipients
- Additional Clinical and Stability Data generation, triggering changes in product information Management of COVID-19 Variants

Challenges

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Challenge no.3: Absence of Accelerated PAC approval pathway

National Regulatory Agencies all over the globe came up with accelerated approval pathways for COVID-19 vaccines, however they somehow missed to develop such accelerated pathway for post approval changes of such Emergency Use Authorized COVID-19 vaccine, which can result into vaccine availability issue due to delay in review and approval of COVID-19 Post Approval Changes

Challenge No.4: Regulatory Collaboration and Dependency

The most of COVID-19 vaccine registered are based on Technology Transfer and small bridging clinical study that allows in-vivo safety and immunogenicity comparison with originator who conducted global clinical trials is required by local regulators. Such dependency, resulted in to need of reference NRA approval concept.

Local Regulatory Agency seek approval from Reference NRA or any other competent regulatory Agency approval and/or approval from any stringent regulatory agency. For example, Indian NRA relying on Stringent Regulatory Authority Approval before granting their own approval.

Challenges

Challenge no.5: Variation Management

The situation is less clear on how is it going to work for variations and for regular registration once the EUAs expire (these are temporary decisions). Changes required to scale up capacity, including the addition of new production sites may need some attention.

Industry Collaboration

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DCVMN, IFPMA and sister associations have developed and shared with ICMRA a number of globally-focused, recommendations to address the regulatory challenges associated with manufacturing site transfers, that we believe, if implemented, would enable the rapid increase of manufacturing capacity for the production of COVID-19 therapeutics and vaccines. Our collection of recommendations includes near-term priorities for immediate implementation during the current PHE as well as long-term recommendations aimed at establishing a regulatory framework that can more efficiently and effectively respond to future PHEs. Our recommendations can be grouped into the following four categories:

- Streamlined Data Requirements (Near-term and Long-term)
- Regulatory Tools & Mechanisms (Near-term and Long-term)
- Collaborative Review and Recognition Practices (Near-term and Long-term)
- Harmonization through the International Council for Harmonization (ICH)1 (Long-term only)

Impact of Global Collaboration

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You will appreciate that the biggest contribution of regulatory alignment and reliance for improving access to vaccines and facilitating trade would be that Industry could take a huge target of delivering over 11 Billion doses by end of 2021.

Examples of best practices:
What is one thing we should do in the next pandemic?

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Global Regulatory Collaboration: Some of the flexibilities that were tried out during this pandemic proved very successful particularly in user countries. For instance:

Collaborative Review and Reliance Practices could be adopted on a broader basis coupled with rolling reviews and agreements (bilateral or multilateral) between regulators.

Support of expert groups such as the RAG by CEPI, ICMRA and other important international stakeholders is key to promotion and further adoption of some of these options.

What is one thing we shouldn't do in the next pandemic?

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Let’s not wait for the next Pandemic and then start searching for solutions!

We need to Act Now!

Thank You

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