Extraordinary Virtual

International Conference of Drug Regulatory Authorities (ICDRA)

20-24 September 2021

Plenary 4: Facilitated Registration of Medical Products

22 September 13:00 – 14:00 CET

Co-Moderators

- Dr Nobumasa Nakashima
  - Pharmaceuticals and Medical Devices Agency -- Japan

- Dr Murray Lumpkin
  - The Bill and Melinda Gates Foundation -- United States of America

Panelists

- Dr Rian Extavour
  - Caribbean Regulatory System – Trinidad and Tobago
- Dr Boitumelo (“Tumi”) Semete
  - South African Health Products Regulatory Agency – South Africa
- Dr Gabriela Zenhäusern
  - Swissmedic -- Switzerland

Panelists (continued)

- Ms Nevena Miletic
  - Roche (on behalf of IFPMA) – Switzerland
- Dr Nick Cappuccino
  - Dr Reddy's Laboratories (on behalf of IGBA) – Switzerland
- Mr Deus Mubangizi
  - World Health Organization -- Switzerland

Introduction to Session

- Many “facilitated” registration pathways developed in the years prior to the pandemic
  - Unilateral or mutual recognition agreements (usually trade related)
  - Regional Agencies – EMA, AMA
  - Reliance pathways (WHO CRP, CRS, WHO PQ abbreviated assessments, EMA’s Article 58/EU-M4All, Swissmedic’s MAGHP; etc)
  - Work-sharing (ZaZiBoNa, EAC, ECOWAS, ACCESS)
  - Harmonised technical standards and regulatory processes (ICH)
  - AVAREF – clinical trials application assessments
- Pandemic has been a unique time when these have been used and other regulatory agilities in all aspects of a product’s life cycle have been developed and employed

Introduction to Session

- We saw “quicker” product development and authorisations during the pandemic.
- Are there key learnings from the pandemic we want to take into “business as usual” going forward?
  - What is sustainable in reality? (from regulators and industry perspectives)
  - What is applicable only in the benefit/risk reality of a pandemic and wouldn’t be applicable in a non-pandemic or public health emergency setting? Is the larger community willing to tolerate these higher risks of the unknown when there is not a public health emergency?
  - Can we maintain scientific robustness in product development and regulatory decision-making when going “faster”?

Introduction to Session

- We saw gross inequities in patient access to products during the pandemic even with “faster” product development and regulatory authorisations.

- Faster development and faster regulatory authorisation does NOT mean faster patient access.
  - What have we learned during this pandemic that needs to be addressed for the next public health emergency so that we don’t simply have faster authorisations and still inequity in patient access?

Opening questions to all panelist

- What are the key learnings and regulatory agilities introduced during the pandemic that we should strive to maintain in a post-pandemic setting, i.e. in the ‘new normal, to ensure faster regulatory decisions on medicines and vaccines?
- What should be, from your perspective, the next steps to ensure we maintain the best practices introduced during a pandemic?

Question to Panelists from Industry

- How can industry support? What is the industry doing to ensure faster development and regulatory approvals of needed therapies?

Question to Regulators

- What is the difference between what we could do and what we could NOT do regarding regulatory agility?
- What are, from your perspective, some of the challenges in maximizing available opportunities for facilitated regulatory decisions? What can be done to address these challenges?

Questions from Audience

Major Comments

- New tools like emergency approval, rolling application submissions, remote inspections, digital submission, risk-based approaches, e-signatures, e-CPPs, e-labelling, virtual meetings with simultaneous translation, and lot release reliance on other trusted labs were introduced and their usages should be further promoted as new normal.
- Best practices like regular platforms/forums for collaboration, convergence on scientific advice to industry, regulation through reliance (e.g., WHO Collaborative Review Process, Regional Level Reliance and Work Sharing), Rolling Review, Good communication between stakeholders, and Alignment of Requirements were shared, which should be further utilized to reduce the regulatory burden and accelerate the registration of needed medical products.
- Information and Data Sharing are one of the key elements in reliance, regulatory flexibility and agility. Frameworks should be introduced to ensure efficient and effective information and data sharing (including common dossiers), while properly protecting sensitive information.
- Capacity buildings should be provided in order for member countries to best utilize shared information and data while accounting for local epidemiological context and product version submitted; local/regional distributors or agents to increase awareness of reliance/facilitated mechanisms; and specific topical issues for both industry and regulators.
- Emergency use approaches could be adapted for dealing with drug shortages, orphan drugs, neglected diseases with no available treatment options, and problems caused by restriction in people and/or product movement.
- Need to develop mechanism to capture the impact of regulatory actions (i.e., the time from registration of a product to actual patient access)

Draft Recommendation to Members

- Maintain or develop the best practice introduced during a pandemic in a post-pandemic setting, i.e. in the ‘new normal, to ensure faster regulatory procedure on medicines and vaccines. New possible regulatory tools include emergency approval, rolling application submissions, remote inspections, digital submission, risk-based approaches, e-signatures, e-CPPs, e-labelling, and lot release reliance on other trusted labs.
- Information exchange and data sharing are the bases for reliance-based regulatory activities and decision-making. Members should seek to promote transparency and to conclude confidentiality agreements or equivalent to efficiently exchange actionable information, documents, and data on which regulation through reliance decisions can be informed. The development and implementation of IMS, including the capacity to conduct virtual meetings, at the country, regional and continental level, aligned with international standards, is encouraged.

Draft Recommendation to WHO

- Collect member's experience of regulatory flexibility and agility during the pandemic and provide the best practice or various examples to members for the new normal and next public health emergency.
- Provide the further support for capacity building (both technical and operational) of regulatory procedures to regulators in low and middle income countries so that they can implement WHO's good reliance practices as they institute their own procedures for regulation through reliance.

‘Coming together is a beginning
Keeping together is progress
Working together is success’

By Henry Ford
(ICH 30th Anniversary Publication)

Thank you for your attention!