EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Supply Chain Integrity

Progress of strategic priority

Summit of Heads of Medicines Regulatory Agencies Symposium, Kyoto 27 October 2017

Presented by Prof. Guido Rasi on 27 October 2017
Executive Director

Supply Chain Integrity @ ICMRA

Current focus on Track and Trace (T&T) systems

Objectives:

- Consistent and focused collection of information on existing and planned T&T systems not limited to ICMRA members
- Analysis of the information received
- Use of information to develop ICMRA recommendation in order to facilitate international alignment of T&T systems to foster future interoperability

Vision:

- Global interoperability of T&T systems

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ICMRA working group has worked on this topic in the last 2 years

- EMA lead, Brazil, Canada, China, Ireland, Italy, Russia, UK, WHO

Deliverables:

✓ Information gathering exercise - Completed (April 2017)

✓ Analysis of the information collected - Completed (June 2017)

✓ Recommendation on Alignment of Existing and Planned Track and Trace Systems to Allow for Interoperability - Completed (September 2017)

ICMRA Kyoto meeting:

➢ Recommendation adopted, to be published soon

Analysis of Survey Information

- Information was received from 24 regulatory authorities
- 80% of systems aim to fight Spurious and Falsified products to enter the supply chain and reach the patients
  - 80% of systems to be implemented in the next 2 years
  - At least 67% use or will use global coding standards
  - Regulatory authorities / government either own data or have access to data stored
  - Implementation costs are an issue with potential impact on availability of medicines
  - Legal obstacles (access to data and confidentiality) are main challenges to interoperability of the systems

ICMRA Recommendations

Recommendations on Alignment of Existing and Planned Track and Trace Systems to Allow for Interoperability

Interoperability in this context includes interconnectivity among regulators

Main aspects covered:

1. Discussion of main prospective benefits for public health arising from interoperability of T&T systems
2. Main challenges to reach interoperability
3. Recommended common technical features to enable interoperability
4. Proposed next steps

Common Technical Features for Interoperability

Standardized information included in the data carrier

- International product identifier (independent of name of product in the various regions)
- International batch number
- Expiry date

Common global data coding standard

Common data carrier (e.g. 2D data-matrix)

Next Steps

Agreement and Publication of recommendations

Engage with stakeholders and leverage existing resources who could implement the recommendations:

Work towards convergence

- Develop more detailed guidance on common technical features enabling interoperability
- Identify solutions to enable exchange of confidential information through T&T systems
- For countries with no system, refer to these recommendation for new systems to be interoperable
- For countries with existing systems, use upgrades and technological necessary evolution to converge and interoperability of T&T systems

Any questions?

Further information

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