LNCT
Learning Network for Countries in Transition

World Health Organization

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Country status

World Health Organization

Alireza Khadem, WHO/RSS

World Health Organization

ARMENIA

8 to 10 June 2015

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Function 1: Marketing Authorization and Licensing Activities

Indicators	Sub-Indicators achieved	Sub-Indicator expected	Sub-Indicators percent
MA01: System for marketing authorization and licensing for manufacturing activities	2.5	3	83
MA02: Quality Management System for marketing authorization and licensing activities	1	3	33
MA03: Human resource management	2	3	67
MA04: Submission of Marketing authorization and manufacturing license applications	3	3	100
MA05: Assessment of Quality, Safety and Efficacy (Q,S,E)	2.5	5	50
MA06: GMP assessment during marketing authorization process	2	2	100
MA07: Requirements for variations to be submitted and assessed	2	2	100
MA08: Clear and comprehensive information on authorized products	2	2	100
MA09: Same criteria/standards for evaluation of marketing authorization applications for products regardless of the source	1	2	50

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GEORGIA

27 to 29 October 2014

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Function 1: Marketing Authorization and Licensing Activities

Indicators	Sub-Indicators achieved	Sub-Indicator expected	Sub-Indicators percent
MA01: System for marketing authorization and licensing for manufacturing activities	2	3	67
MA02: Quality Management System for marketing authorization and licensing activities	0	3	0
MA03: Human resource management	1	3	33
MA04: Submission of Marketing authorization and manufacturing license applications	1.5	3	50
MA05: Assessment of Quality, Safety and Efficacy (Q,S,E)	5	5	100
MA06: GMP assessment during marketing authorization process	0	1	0
MA07: Requirements for variations to be submitted and assessed	0.5	2	25
MA08: Clear and comprehensive information on authorized products	2	2	100
MA09: Same criteria/standards for evaluation of marketing authorization applications for products regardless of the source	1.5	2	75

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MOLDOVA

10 to 14 February 2014

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Function 1: Marketing Authorization and Licensing Activities

Indicators	Indicators achieved	Indicator estimated	Indicators percent
MA01: System for marketing authorization and licensing for manufacturing activities	2.5	3	83.33
MA02: Quality Management System for marketing authorization and licensing activities	2	3	66.67
MA03: Human resource management	2.5	3	83.33
MA04: Submission of Marketing authorization and manufacturing license applications	2	3	66.67
MA05: Assessment of Quality, Safety and Efficacy (Q,S,E)	3	5	60
MA06: GMP assessment during marketing authorization process	2	2	100
MA07: Requirements for variations to be submitted and assessed	1.5	2	75
MA08: Clear and comprehensive information on authorized products	1.5	2	75
MA09: Same criteria/standards for evaluation of marketing authorization applications for products regardless of the source	1.5	2	75

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MACEDONIA

29 to 31 January 2019

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02-REGISTRATION AND MARKETING AUTHORIZATION (MA)

Indicators	Sub-Indicators achieved	Sub-Indicators expected	Sub-Indicators percent
MA01 Legal provisions, regulations and guidelines required to define regulatory framework of registration and/or marketing authorization.	11.5	13.0	88.0%
MA02 Arrangement for effective organization and good governance.	2.0	2.0	100.0%
MA03 Human resources to perform registration and marketing authorization activities.	3.0	4.0	75.0%
MA04 Procedures established and implemented to perform registration and/or marketing authorization	7.5	10.0	75.0%
MA05 Mechanism exists to promote transparency, accountability and communication.	1.5	4.0	38.0%
MA06 Mechanism in place to monitor regulatory performance and output	1.0	2.0	50.0%

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SERBIA

29 to 31 January 2019

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02-REGISTRATION AND MARKETING AUTHORIZATION (RMA)

Indicators	Sub-Indicators achieved	Sub-Indicator expected	Sub-Indicators percent
MA01 Legal provisions, regulations and guidelines required to define regulatory framework of registration and/ or marketing authorization.	12	12	100
MA02 Arrangement for effective organization and good governance.	2	2	100
MA03 Human resources to perform registration and marketing authorization activities.	4	4	100
MA04 Procedures established and implemented to perform registration and marketing authorization.	10	10	100
MA05 Mechanism exists to promote transparency, accountability and communication.	2	3	67
MA06 Mechanism in place to monitor regulatory performance and output.	1.5	2	75

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UZBEKISTAN

21 - 23 Sep 2015

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Function 1: Marketing Authorization and Licensing Activities

Indicators	Sub-Indicators achieved	Sub-Indicator expected	Sub-Indicators percent
MA01: System for marketing authorization and licensing for manufacturing activities	2	2	100
MA02: Quality Management System for marketing authorization and licensing activities	2.5	3	83
MA03: Human resource management	3	3	100
MA04: Submission of Marketing authorization and manufacturing license applications	2	2	100
MA05: Assessment of Quality, Safety and Efficacy (Q,S,E)	3	4	75
MA07: Requirements for variations to be submitted and assessed	2	2	100
MA08: Clear and comprehensive information on authorized products	2	2	100
MA09: Same criteria/standards for evaluation of marketing authorization applications for products regardless of the source	1.5	2	75

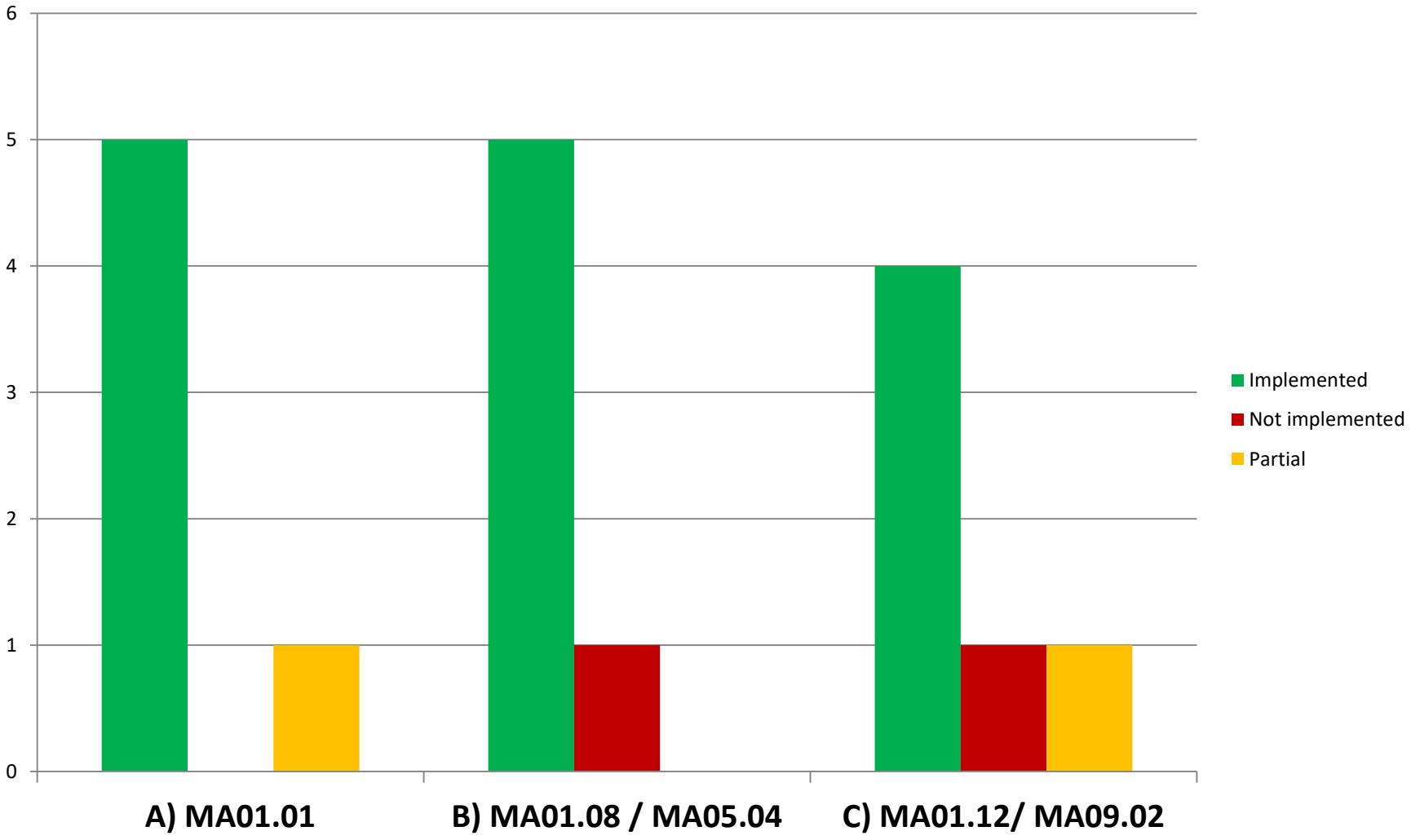
Status of some important sub-indicator re MA function

- MA01.01: There are legal provisions that require the receipt of a registration and/or marketing authorization (MA) before placing the product on the market.

- MA01.08: Legal provisions and/or regulations allow the NRA to recognize and/or rely on MA-relevant decisions, reports or information from other NRAs or regional and international bodies

- MA01.12: There are established guidelines that cover circumstances under which the routine MA procedures may not be followed (e.g., for public- health interest)

Status of some important sub-indicator re MA function



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Country regulatory requirements

1. Is there a policy, procedures and/or mechanisms for recognition and reliance on decisions of other NRAs, organizations or procurement agencies, etc.?

2. Is there a specific regulatory pathway to register/authorize PQ vaccines?

3. Do the legal provisions enforce registration/authorization of PQ vaccines in your country? (all PQ vaccines are registered already)

4. Are there established guidelines that cover circumstances under which the routine Marketing Authorization/registration procedures may not be followed (e.g., for public- health interest)

Country regulatory requirements (cont.)

5. There is a vigilance system to report, analyze and provide feedback/decisions on Adverse Events Following Immunization (AEFI) cases?

6. Is it necessary to conducts a GMP inspection for the purpose of registration of a PQ vaccine?

7. Is it necessary to test the vaccines either for the purpose of registration or lot release?

8. Is it necessary to conducts a clinical trial for the purpose of registration of a PQ vaccine?

9. Is it necessary to review the summary lot protocols (SLP) of the PQ vaccines before releasing them to the market?

Thank you

World Health Organization

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Regulatory Systems Strengthening (RSS)

Regulation of Medicines and Other Health Technologies (RHT)

World Health Organization (Geneva, Switzerland)

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