

Need for improved post-marketing surveillance in receiving countries and suggestions on how to monitor safety of newly introduced vaccines

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Meeting with vaccine manufacturers

5 April 2011



**World Health
Organization**

SCOPE and MAGNITUDE: ALL WHO REGIONS , 332 country visits FOR ASSESSING/REASSESSMENT & FOLLOW UP: 1997-2010

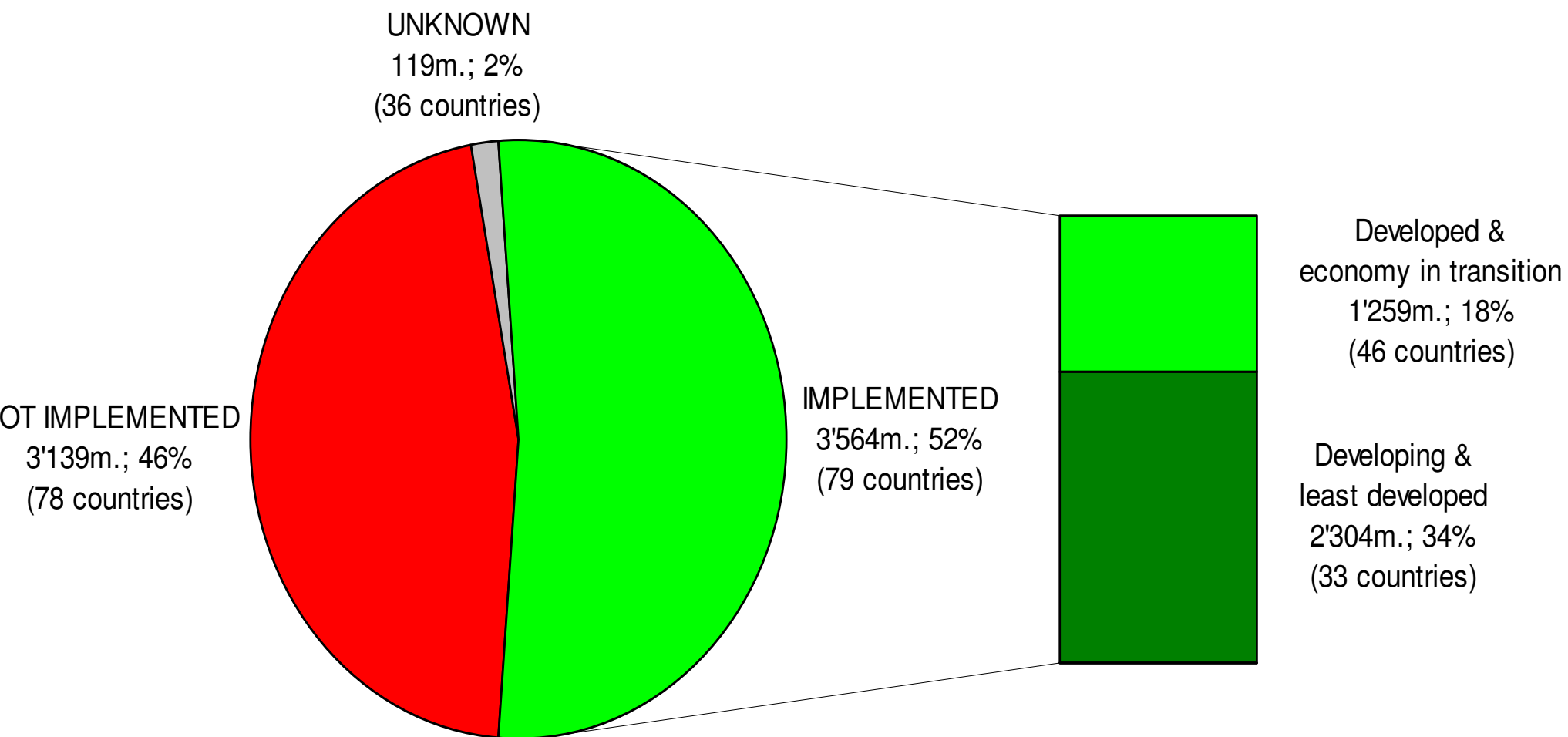


8 components to the AEFI PMS function

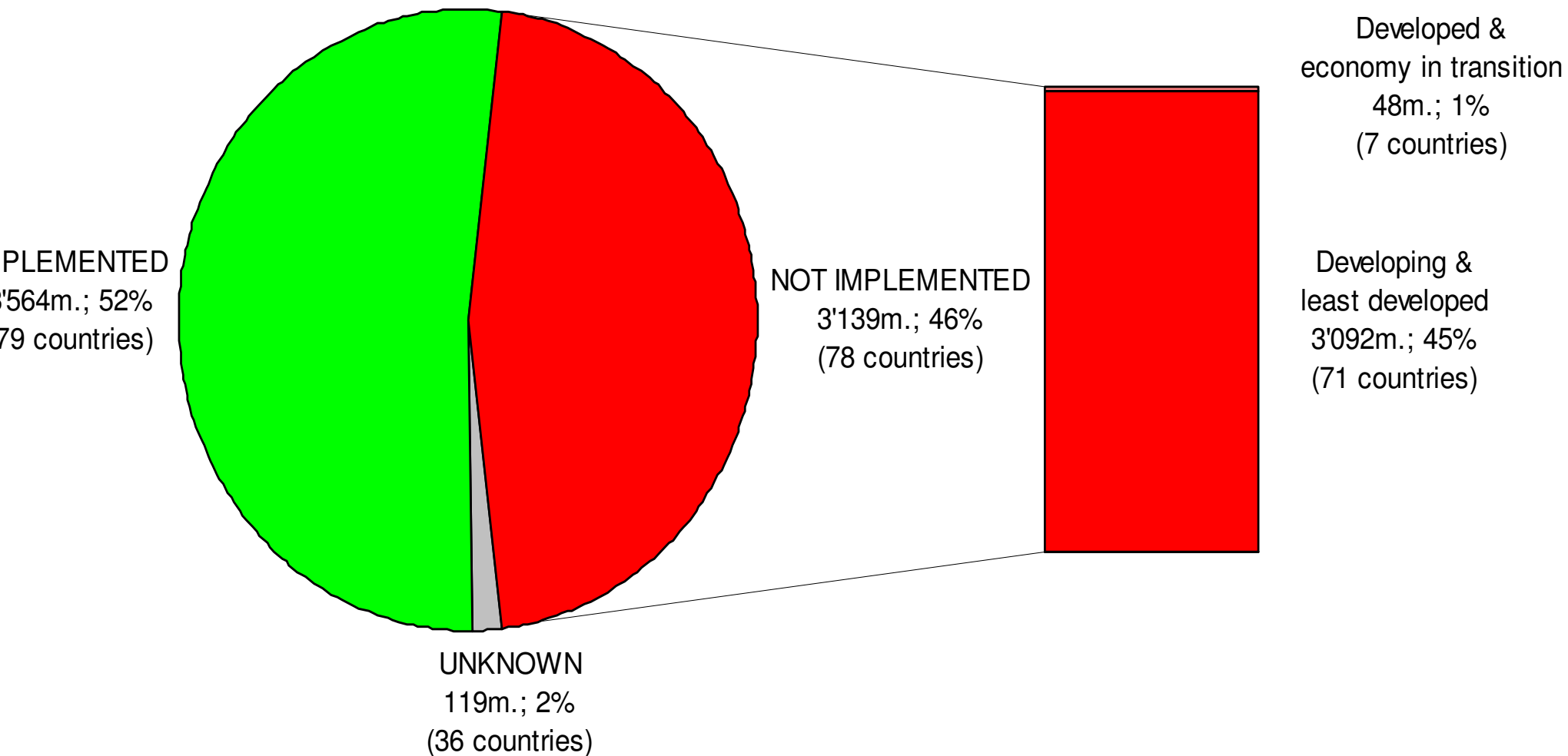
1. Regulation/guidelines.
2. Quality management system.
3. Roles of key stakeholders.
4. Human resource management.
5. System to review vaccine safety events.
6. Capacity to detect vaccine safety.
7. Regulatory outcome.
8. Feedback and communication.



STRENGTHENING NATIONAL REGULATORY AUTHORITIES (NRA) POST-MARKETING/AEFI SURVEILLANCE AND DEVELOPMENT STATUS : TOTAL POPULATION AS OF 2009



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Indicator PM06: Capacity to detect and investigate significant vaccine safety issues - Critical

Group of countries	Number of Countries	Number of Countries with data available	Number of Countries with Indicator Implemented	% Implemented (of those with data available)	% Implemented out of the total countries in the region
A. Industrialized	48	48	45	94	94
B. Upper middle income	39	13	5	38	13
C1.Lower middle income	57	17	5	29	9
C2.Low income	49	17	2	12	4

Indicator PM06: Capacity to detect and investigate significant vaccine safety issues - Critical

WHO region	Number of Countries	Number of Countries with data available	Number of Countries with indicator implemented	% Implemented (of those with data available)	% Implemented out of the total countries in the region
AFR	45	12	1	8	2
AMR	29	5	3	60	10
EMR	15	6	2	33	13
EUR	24	12	3	25	13
SEAR	11	9	2	22	18
WPR	21	3	1	33	5

Indicator PM06: Capacity to detect and investigate significant vaccine safety issues - Critical

DTP3 coverage	Number of Countries	Number of Countries with data available	Number of Countries with Indicator Implemented	% Implemented (of those with data available)	% Implemented out of the total countries in the region
<50%	5	1	0	0	0
51-70%	15	2	0	0	0
71-80%	17	4	0	0	0
81-85%	19	6	2	33	11
86-90%	10	3	1	33	10
>90%	79	31	9	29	11

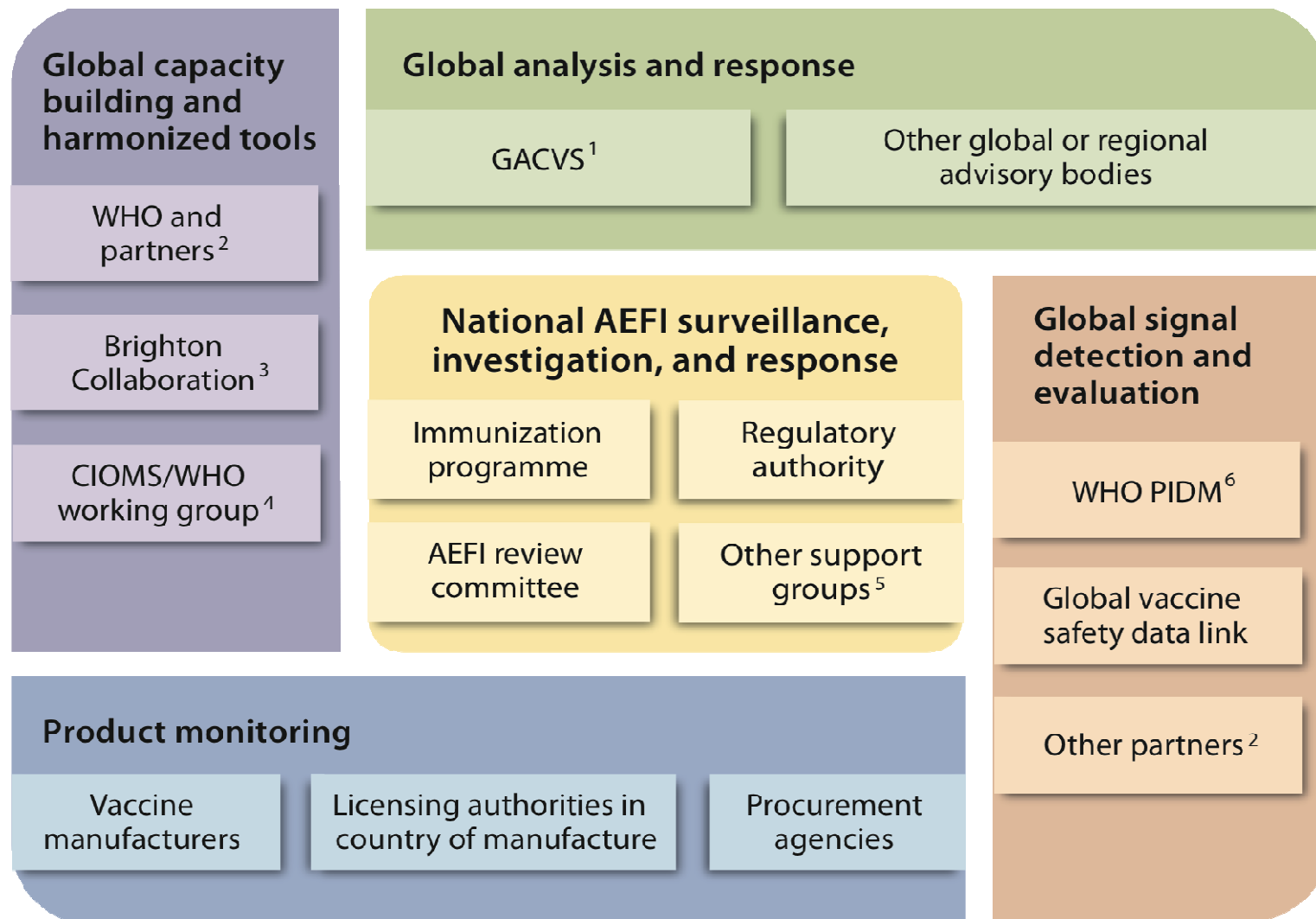
Indicator PM06: Capacity to detect and investigate significant vaccine safety issues - Critical

Health Expenditure (US\$ per person per year)	Number of Countries	Number of Countries with data available	Number of Countries with Indicator Implemented	% Implemented (of those with data available)	% Implemented out of the total countries in the region
<25	38	16	2	13	5
25-75	81	22	4	18	5
>75	26	9	6	67	23

Indicator PM06: Capacity to detect and investigate significant vaccine safety issues - Critical

HDI	Number of Countries	Number of Countries with data available	Number of Countries with Indicator Implemented	% Implemented (of those with data available)	% Implemented out of the total countries in the region
Very High	2	1	1	100	50
High	38	16	4	25	11
Middle	41	14	5	36	12
Low	42	13	1	8	2
NA	22	3	1	33	5

PMS network encompasses all activities to support national systems



Blueprint development process

4 steps

Situation analysis

Feb-Dec 2010

Surveys (experts, regulators, industry)

Systematic analysis of NRA assessments

Descriptive analysis of a sample of national systems

Assessment of existing international initiatives

Generation of cost parameters

Draft blueprint

Jan-Jul 2011

Strategic plan

Budget

Principles for managing implementation

Global vaccine safety meeting

Sep 2011

Review landscape analysis

Discuss blueprint components

Revised blueprint

Sep-Dec 2011

Endorsement

Fundraising

Adjust milestones to initial resources

Vision for the Global Vaccine Safety Blueprint

All countries ensure effective vaccine safety monitoring and response so that unwanted vaccine reactions are minimized and public confidence in vaccination is maintained.



Three levels of engagement for the Global Vaccine Safety Blueprint

- Building capacity for effective vaccine safety monitoring so that all low- and middle-income countries have at least a minimal capacity.
- Enhancing the level of vaccine safety activity in countries that manufacture vaccines and in early introducers of newly available vaccine so that these countries have the ability to carry out active surveillance and database studies.
- Fostering international collaboration and encouraging global strategic planning so that national systems are adequately supported, all vaccines are under adequate post-marketing surveillance and vaccine safety information is shared internationally.



Minimal capacity at country level (as of 29 March 2011)

Vaccine safety monitoring structure:

- a national system of spontaneous reporting with a national database of AEFI reports;
- a national AEFI advisory committee;
- a clear communication strategy for routine communication and crisis communication;
- a national vaccine pharmacovigilance centre with designated staff collaborating with the WHO Programme for International Drug Monitoring;
- links to external technical support if required.

Managerial requirements:

- a proper regulatory framework (provisions for monitoring and management of AEFI),
- clear lines of accountability identified for the conduct of vaccine safety work;
- a management plan is developed, periodically evaluated and revised in order to ensure continuous quality improvement in the conduct of national vaccine safety activities;
- a commitment to sharing information on vaccine safety with other countries.

International resources considered for Blueprint

- Capacity building:
 - Decentralized pool of experts (institutional development, crises management, training).
 - International research groups (active surveillance projects and computerized databases).
 - Global rumour monitoring.
 - Global AEFI database.
- Standards:
 - Harmonized methodologies.
 - Case definitions.
 - Updated safety profiles for prequalified vaccines.
- Electronic tools:
 - Communication of vaccine safety issues.
 - Case verification and sharing of data.
- Quality improvement:
 - Best practices registry.
 - Performance indicators.
- Expert advice:
 - Independent advice on global vaccine safety issues.
 - Expert advice on implementing Blueprint strategies.



Anticipated challenges

- Ownership from national stakeholders.
- Making institutional planning attractive.
- Integrating project approaches with systems building.
- Adapting methods and definitions to local clinical practices.
- Enhancing collaboration between regulatory authorities and immunization programs.
- Endorsement from WHO governing bodies.



More anticipated challenges

- Communicating about vaccines-related risks.
- Defining milestones and priorities.
- Agree on common reporting formats (definitions, dictionary, language...).
- Attracting new players and making space.
- Clear rules of engagement with industry.
- Sufficient and predictable funding...