CHALLENGES TO VACCINE ACCESS: SII PERSPECTIVE

Global Challenges Seminar on Vaccines: accelerating innovation and access

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Factors that condition access to vaccines in countries

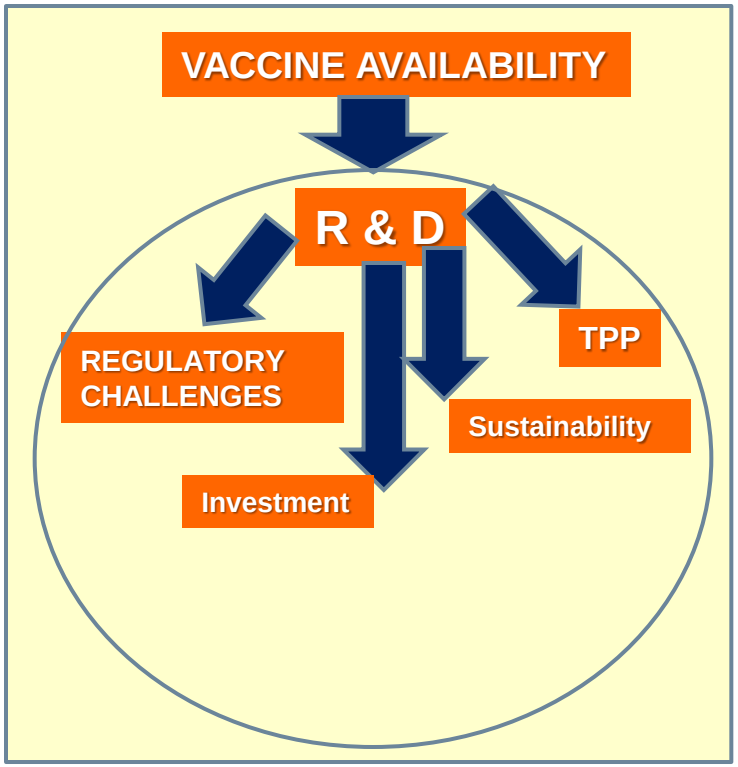
Epidemiologic, financial, Logistic, programmatic considerations

COST/BENEFIT (competing priorities)

COUNTRY PREPAREDNESS

SUSTAINABLE FINANCING

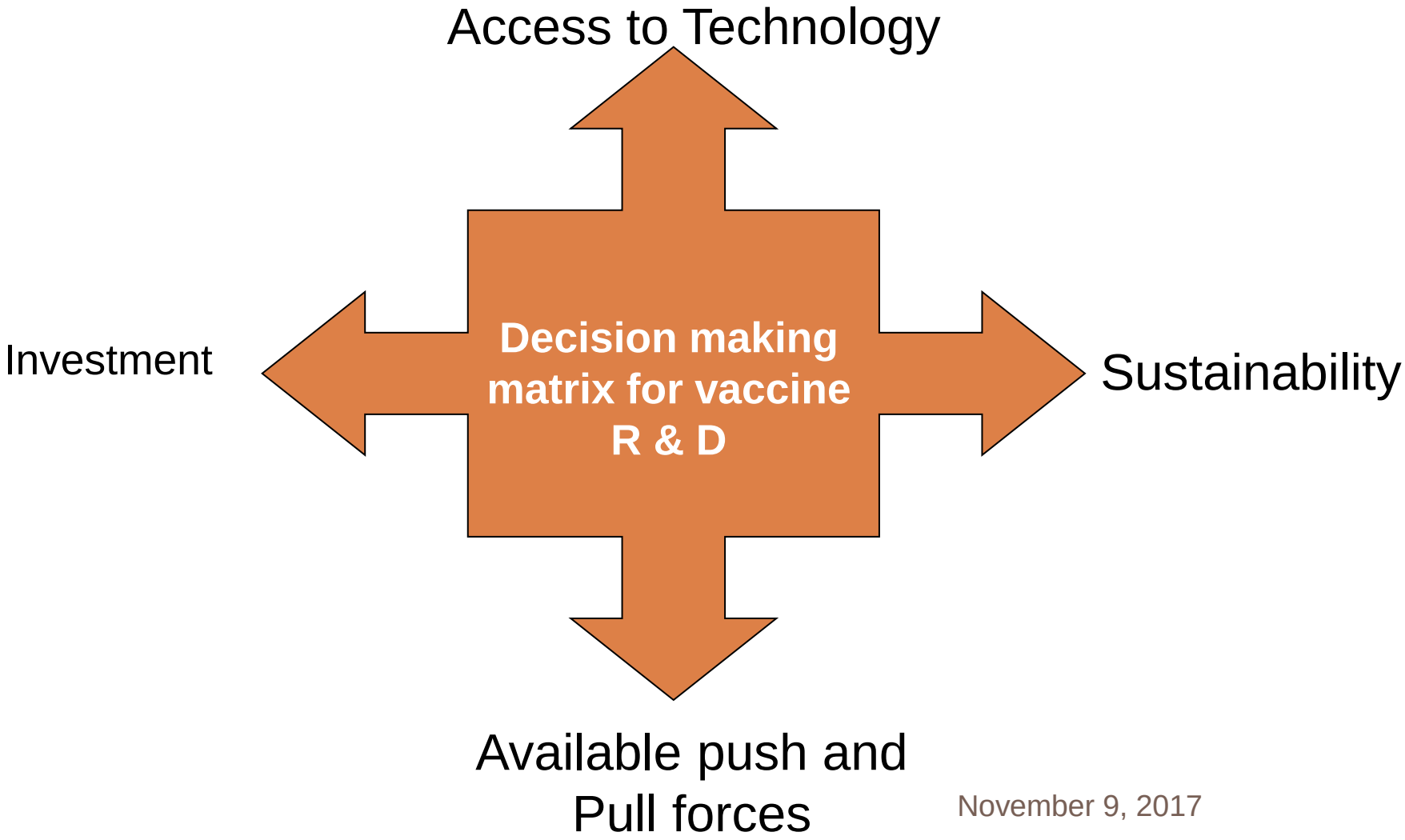
ACCESS



CHALLENGES FOR VACCINE DEVELOPMENT

Serum Institute of India Pvt. Ltd.

Research and Development- Vaccines



SII and Vaccine development

Initial focus was on EPI vaccines- were developed for both bacterial and viral vaccines.

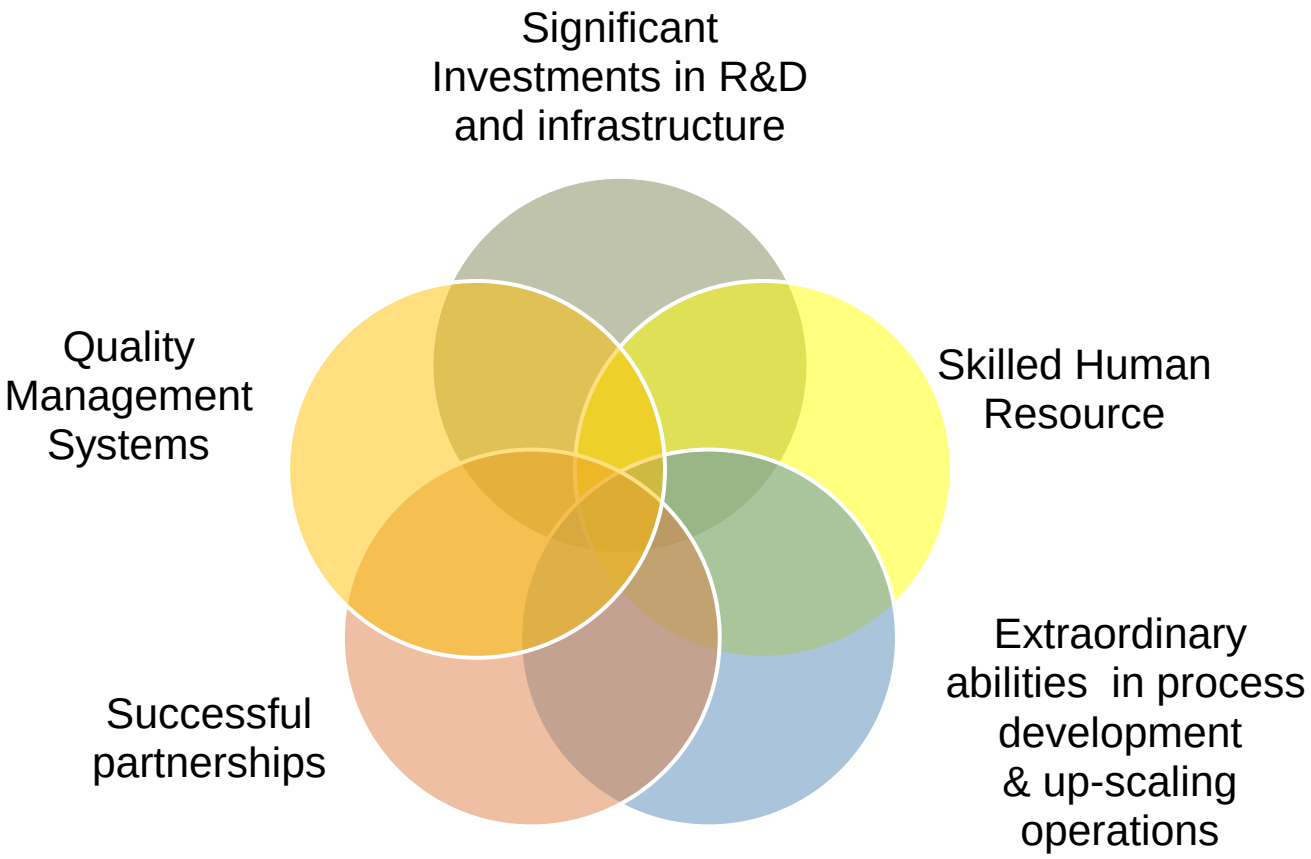
Technological advanced products: e.g polysaccharide conjugate vaccines and recombinant vaccines . (Tech transfers played an important role).

Development of similar monoclonal antibodies (rabies launched 2017, dengue under development).

The objective is to be a world leader in the field of biosimilars. Biosimilars costs are high. The objective is to make them affordable to all.

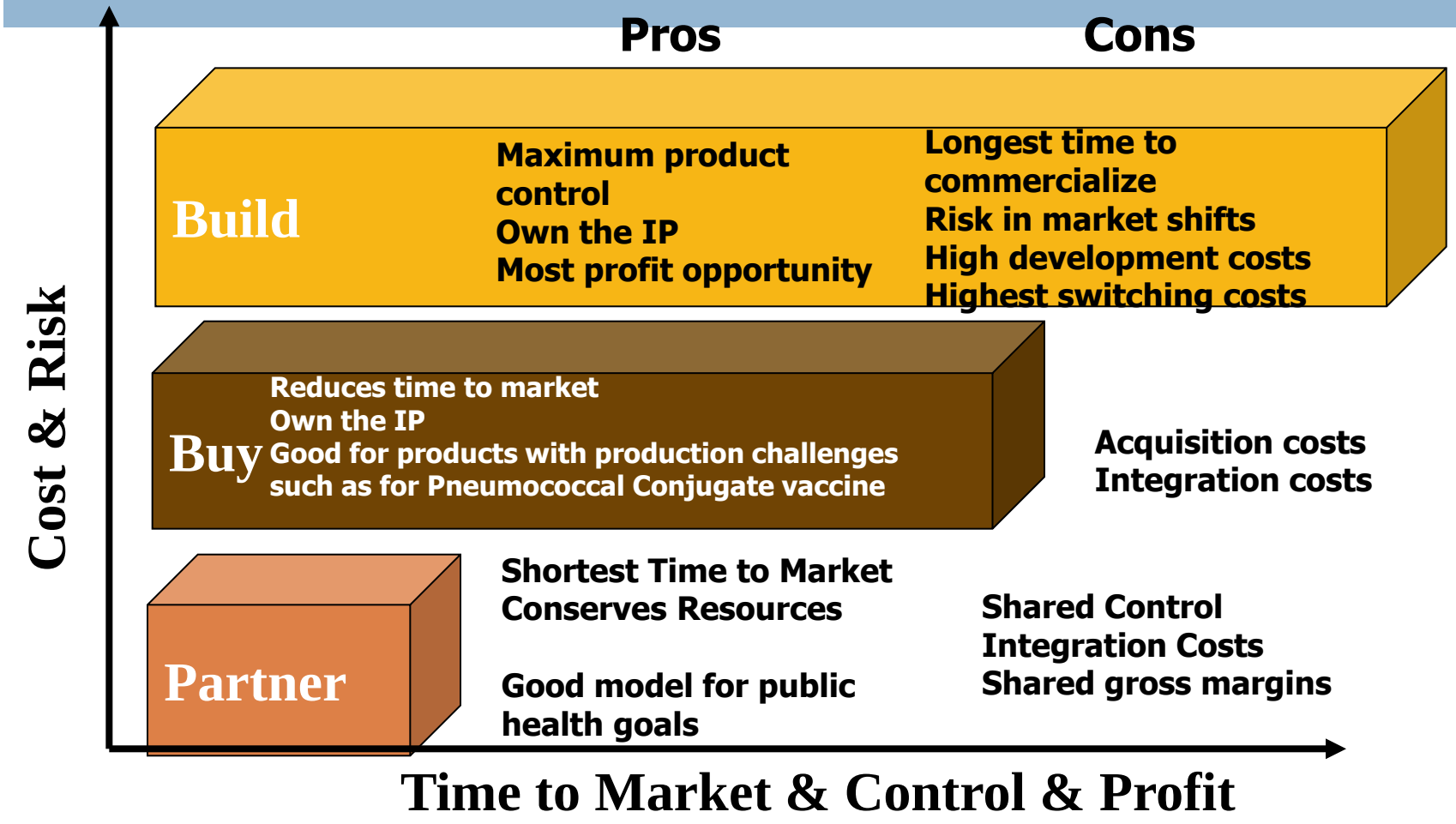
Philosophy of SIIPL: To work on the vaccines which are needed in massive quantities and make them affordable with no compromise in quality.

SII strengths to deliver affordable vaccines



Models of Tech transfer

Build, Buy, Partner: *Benefits and Tradeoffs*



SII is a LEADING EXAMPLE OF SUCH MODELS.

Sustainability- Challenges with EPI vaccines

- Developing country manufacturers' business models are based on economies of scale with strengths in process engineering and process innovations.
- Business largely drives from EPI vaccine supplies to UN agencies.
- EPI vaccine prices are tightly regulated. With many competitors in scope now, price wars are imminent.
- Pricing pressure on manufacturers in near future, will further impact businesses and return investments on R & D on newer vaccines.

Expectations

- **Rationalization on vaccine pricing is required.**

Sustainability- Challenges with new vaccines

- Accessibility to poorest of poor
- No compromise on safety, quality and efficacy of vaccines.
- Ever increasing cGMP expectations and costs on compliance.
- Compared to EPI vaccines, newer vaccines are challenging to develop and manufacture. Long lead times- example- Pneumococcal Conjugate Vaccine: an extremely complex vaccine to develop and manufacture.
- Push and Pull incentives come with expectations of reduced vaccine pricing.
- Rationalization of vaccine pricing- need of the hour.

REGULATORY CHALLENGES

Serum Institute of India Pvt. Ltd.

Regulatory challenges (cont)

- Vaccine registration/ marketing authorization is a prerequisite to introduction of vaccines in any country
- Marketing authorization evaluation, particularly for novel vaccines is challenging
- NRAs in producing and in high income countries usually have the required infrastructure and resources for a proper review
- NRAS in many user countries may not have the required conditions to conduct a meaningful evaluation of such complex products

Regulatory constraints

- Two or three levels of regulatory approval (producing country, WHO-PQ and receiving country)
- Poor recognition of prior evaluation/s performed including WHO-PQ (focuses on DCs needs)
- Unpredictable and usually long review processes in user countries
- Diversity of requirements and dossier formats: significant regulatory affairs resources and time needed to comply with demands from different countries
- Redundant testing and inspections conducted

SII contribution in regulatory issues

- Approached DCVMN, this network in collaboration with IFPMA organized a regulatory working group to identify the magnitude of the diversity in requirements (quantification).

  Working group focused on:

  - Comparison of CTD dossiers from different countries to assess level of divergence or similarity
  - Comparison of application forms of 8 countries
  - Comparison of evaluation process in 134 countries

NOTE: Reg. Affairs experts from 10 companies (7 from DCVMN and 3 from IFPMA participate in the WG

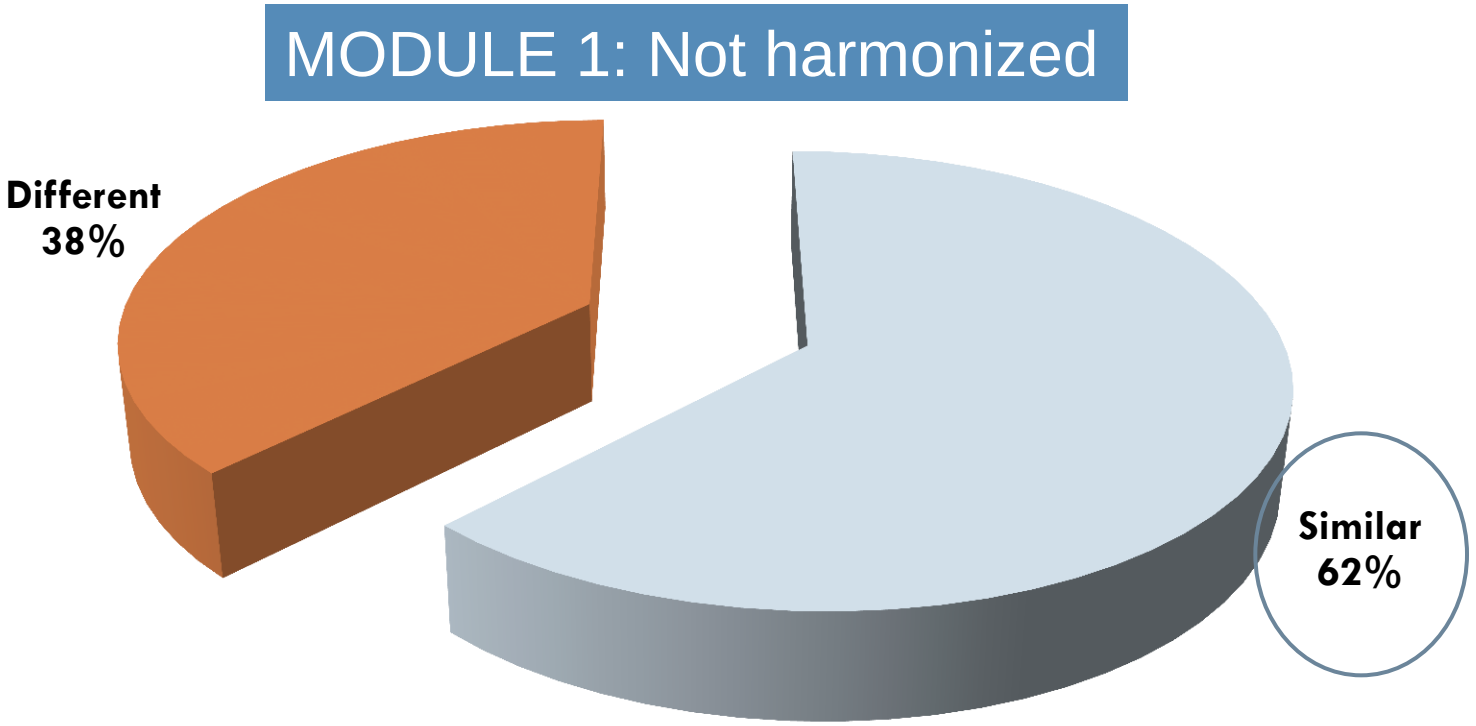
Countries included in the CTD comparison exercise

- **Module 1 (not harmonized):** CTDs of Australia, China, Europe, the Gulf Cooperation Council (GCC), India, Jordan, PAHO, Tanzania, Thailand, the United States (US) and the (World Health Organization (WHO) are compared to each other

- **Modules 2-5 (harmonized):** CTDs from ASEAN, PAHO, India, Jordan FDA and Thai FDA are compared to the ICH CTD as implemented by US FDA.

Contents and format (numbering) were compared

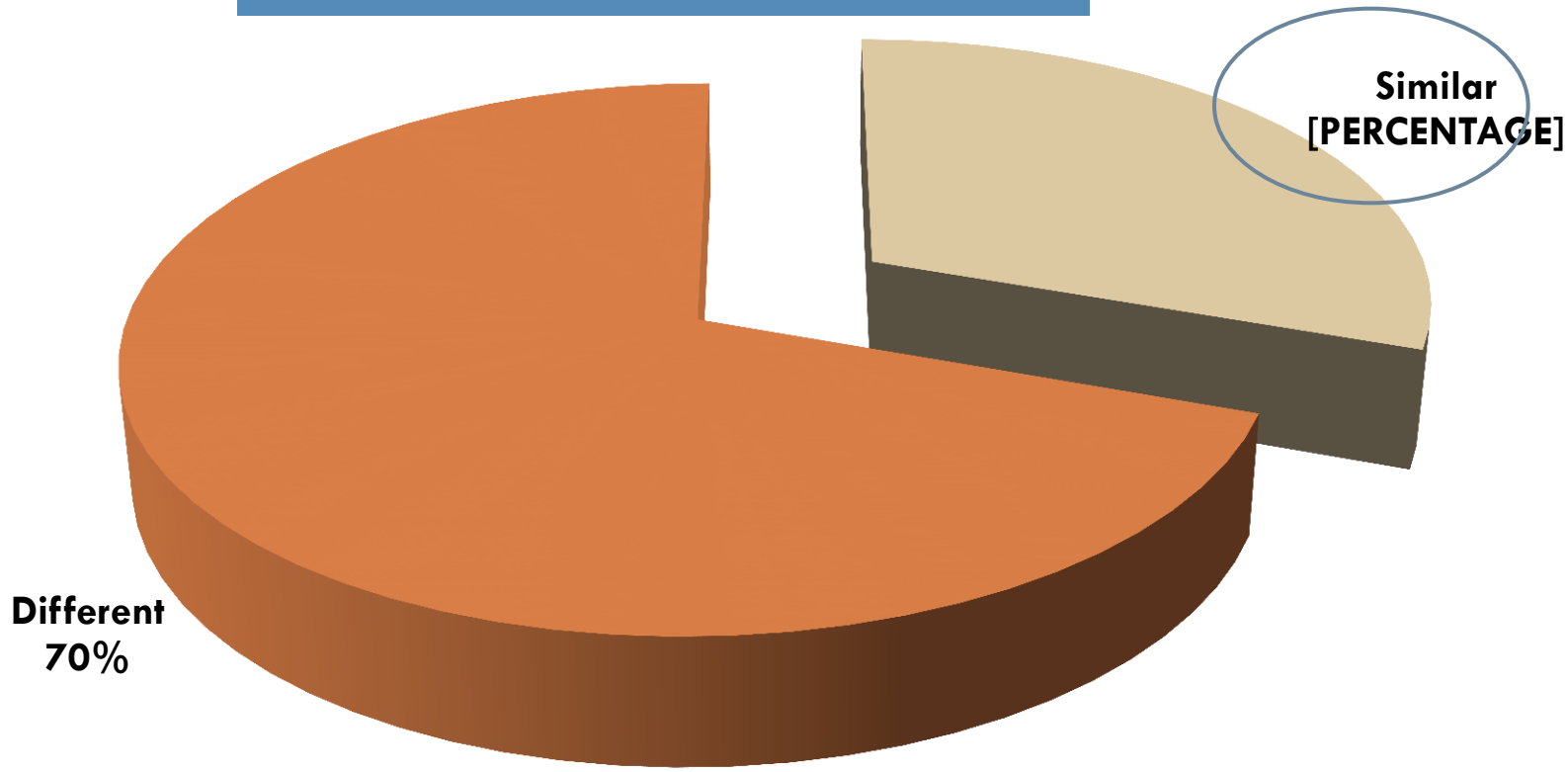
COMPARISON OF CTD MODULE 1 CONTENT FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO



Comparability	Similar	Different	Total
Number of items	189	114	303

COMPARISON OF CTD MODULE 1 NUMBERING FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO

MODULE 1: Not harmonized



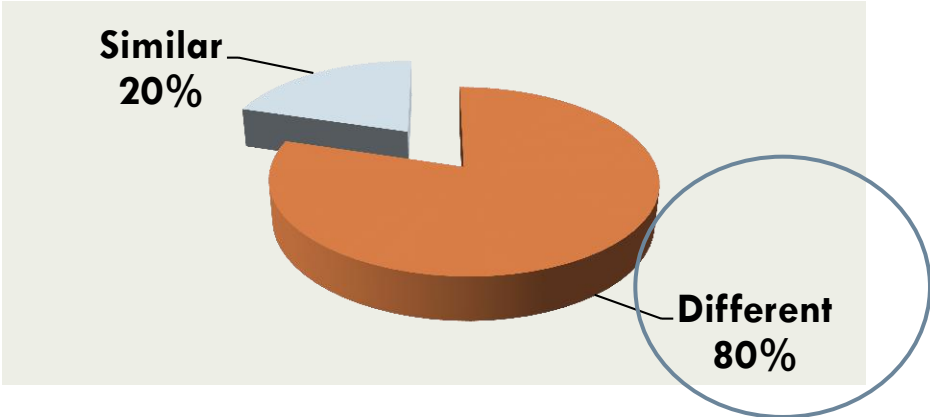
Comparability	Same	Different	Total
Number of items	92	211	303

CTD CONTENT: ASEAN, INDIA, JORDAN, PAHO AND THAILAND Vs. ICH (FDA)

Overall Comparison Modules 2-5

	Number of items PAHO Vs ICH (FDA)	Number of items INDIA Vs ICH (FDA)	Number of items JORDAN Vs ICH (FDA)	Number of items ASEAN Vs ICH (FDA)	Number of items THAILAND Vs ICH (FDA)	Total
Different	333	334	308	353	332	1660
Similar	101	103	84	27	108	423
Total	434	437	392	380	440	2083
% similarity	23	24	21	7	25	20
% difference	77	76	79	93	75	80

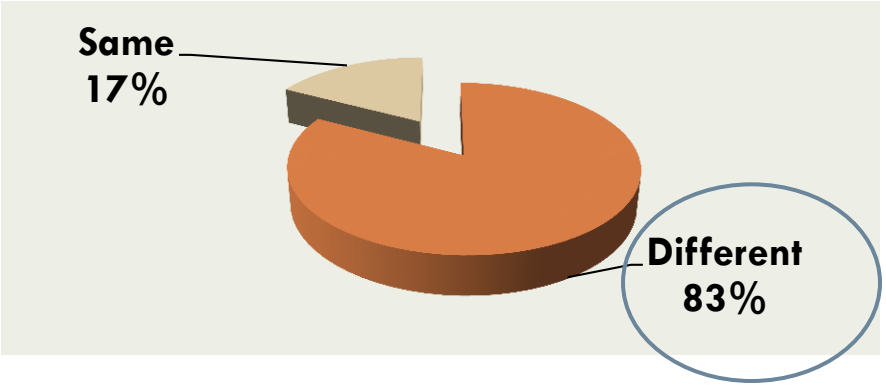
MODULES 2-5: Harmonized



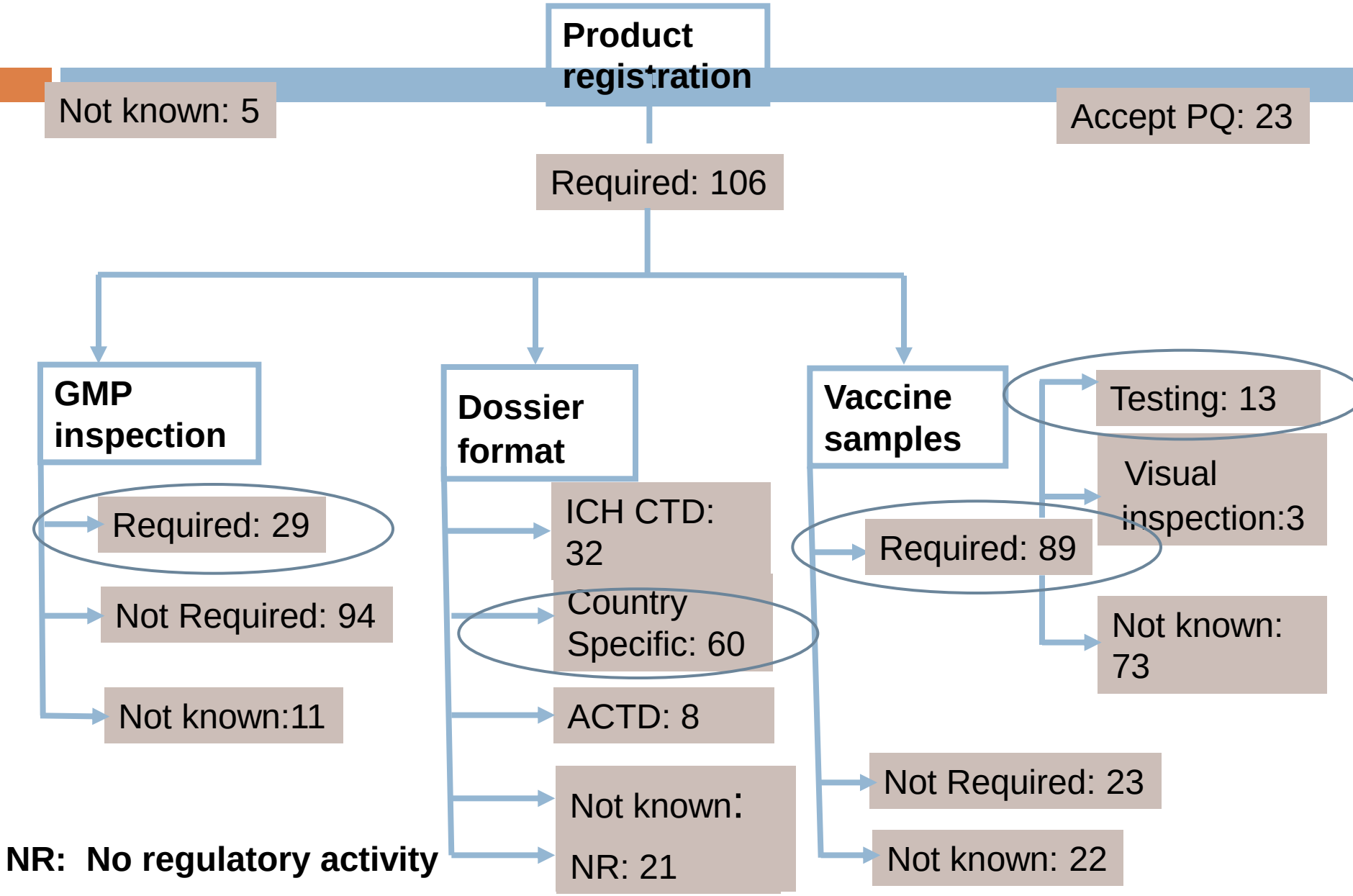
CTD NUMBERING: ASEAN, INDIA, JORDAN, PAHO AND THAILAND Vs. ICH (FDA)
Comparing All Modules 2-5

	Number of items PAHO Vs ICH (FDA)	Number of items INDIA Vs ICH (FDA)	Number of items JORDAN Vs ICH (FDA)	Number of items ASEAN Vs ICH (FDA)	Number of items THAILAND Vs ICH (FDA)	Total
Different	286	346	313	366	269	1580
Same	96	69	63	0	102	330
Total	382	415	376	366	371	1910
% similarity	25	17	17	0	27	17
% difference	75	83	83	100	73	83

MODULES 2-5: Harmonized



Vaccine registration process



POTENTIAL FOR IMPROVEMENT

Next steps include publication of this data and development by the WG of a proposal for improvements to be shared with stakeholders (WHO, ICH, economic blocks, etc) with support from UNICEF, GAVI, MSF, regulatory networks, etc.


Thank you