



Pain Points for African Vaccine Manufacturing

Workshop on enhancing the sustainability of investment in
African vaccine manufacturing

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Summary

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- Africa's vaccine industry has attracted a lot of attention
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- Contexts across the continent are diverse
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- With numerous stakeholders and varying perspectives.
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- Progress for some has been slow
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- The business case has some holes
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- A few discrete `solutions` can be identified
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- Clarity on demand is urgently required
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- Political forces need to be harnessed for the long-term

In light of the pandemic, vaccine manufacturing in Africa has received attention from many actors

African

- AU Call for New Public Health Order
- PAVM FFA
- AVAT
- HEALTH
- Country specific initiatives
- African Pharmaceutical Technology Foundation
- UNECA (CPPM)
- AfDB Vision 2030
- AU Communiqué
- AU Commission on COVID19 – Biotech Sovereignty

International

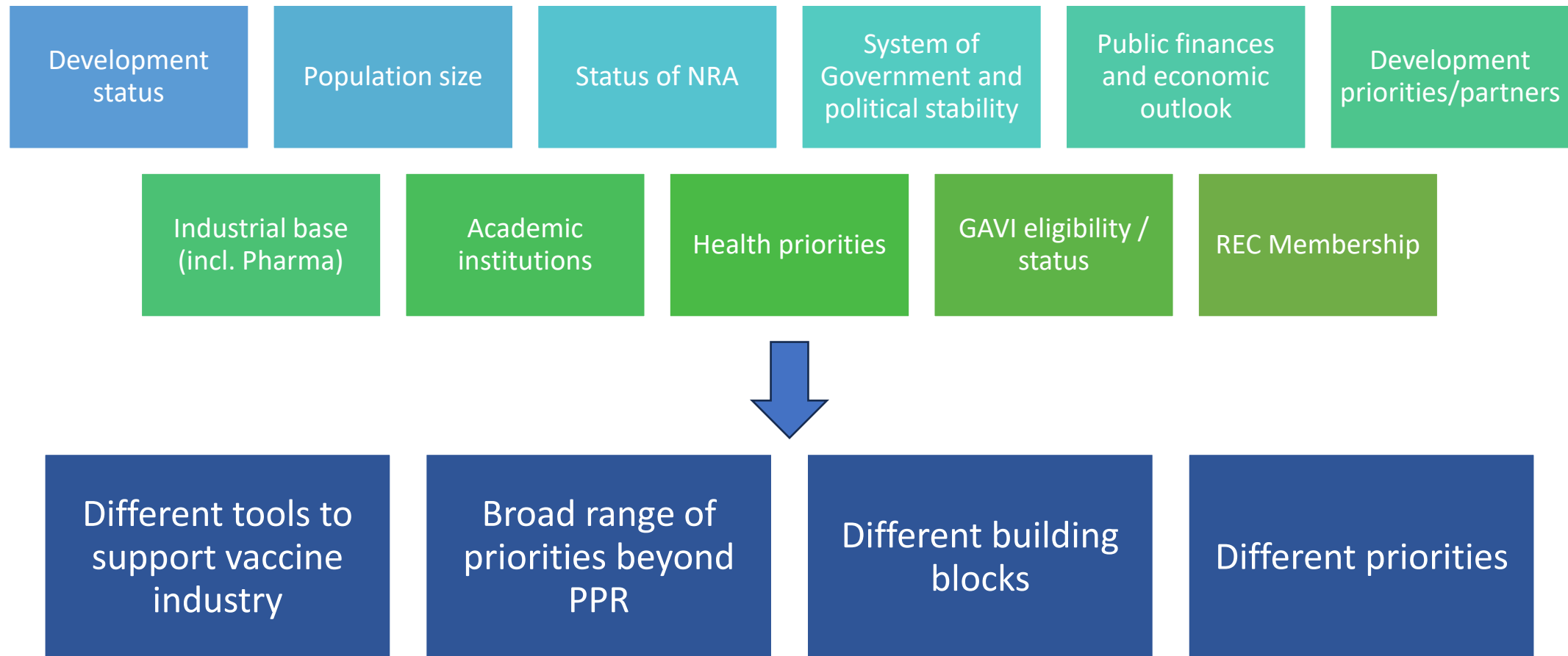
- GAVI - white paper, board decision.
- WHO mRNA TT Hub
- DFI consortium
- Mastercard Foundation
- CEPI, Beyond the 100 day initiative
- BMGF/PATH/CHAI – technical assistance, training,
- UNCTAD
- BMZ/GIZ
- Team Europe (MAV+)
- World Economic Forum
- USAID/PEPFAR

Industry/Private sector

- EABF Business Declaration
- Berlin Declaration
- EU/EFPIA/IFPMA consultations
- BioNtech and Moderna Investments
- Technology Transfer for COVID19 vaccines
- Technology transfer of legacy products
- AVMI
- FAPMA

- Ostensibly driven by post-pandemic Public Health priorities
- Highly charged political context
- Broader economic development implications recognised but somewhat secondary
- Numerous reports/studies/and events

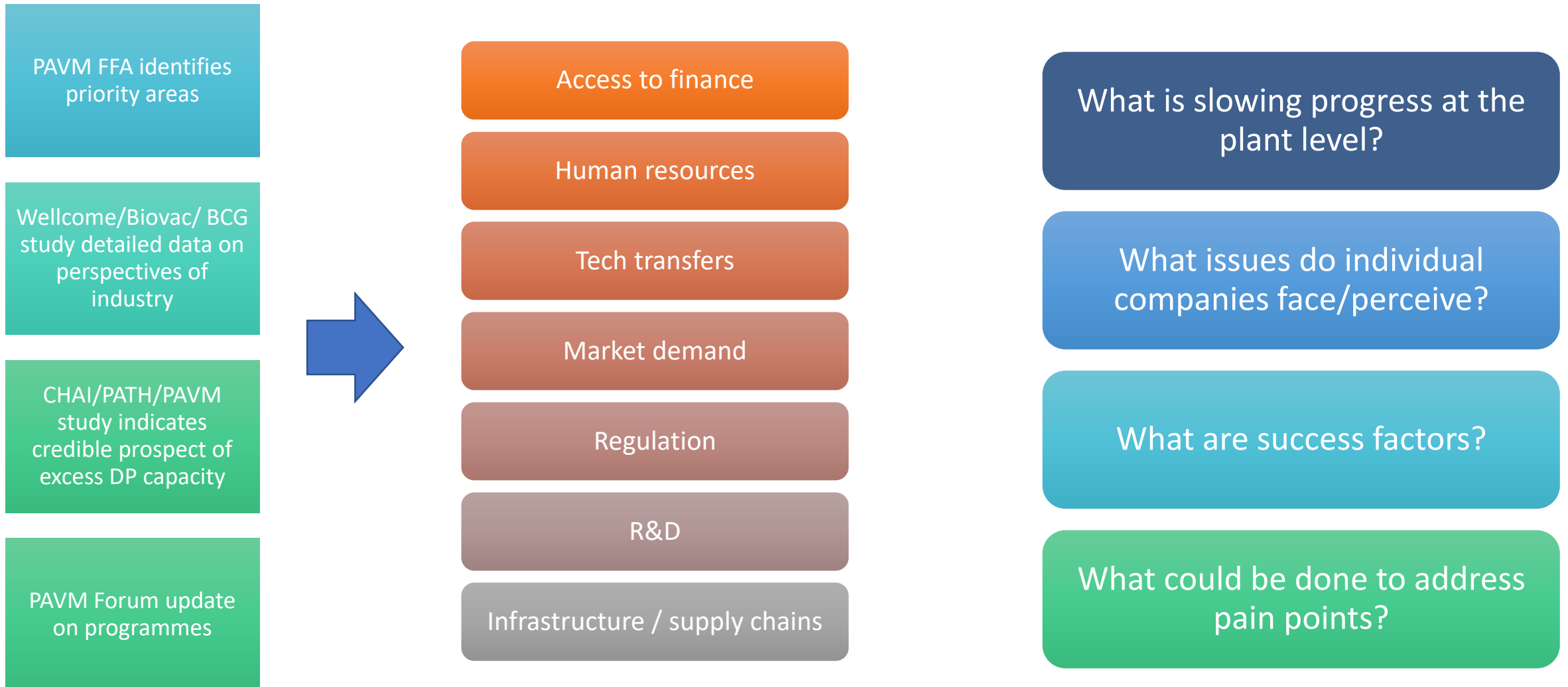
Vaccine Manufacturing initiatives announced across at least eleven AU Member States, each with a unique situation



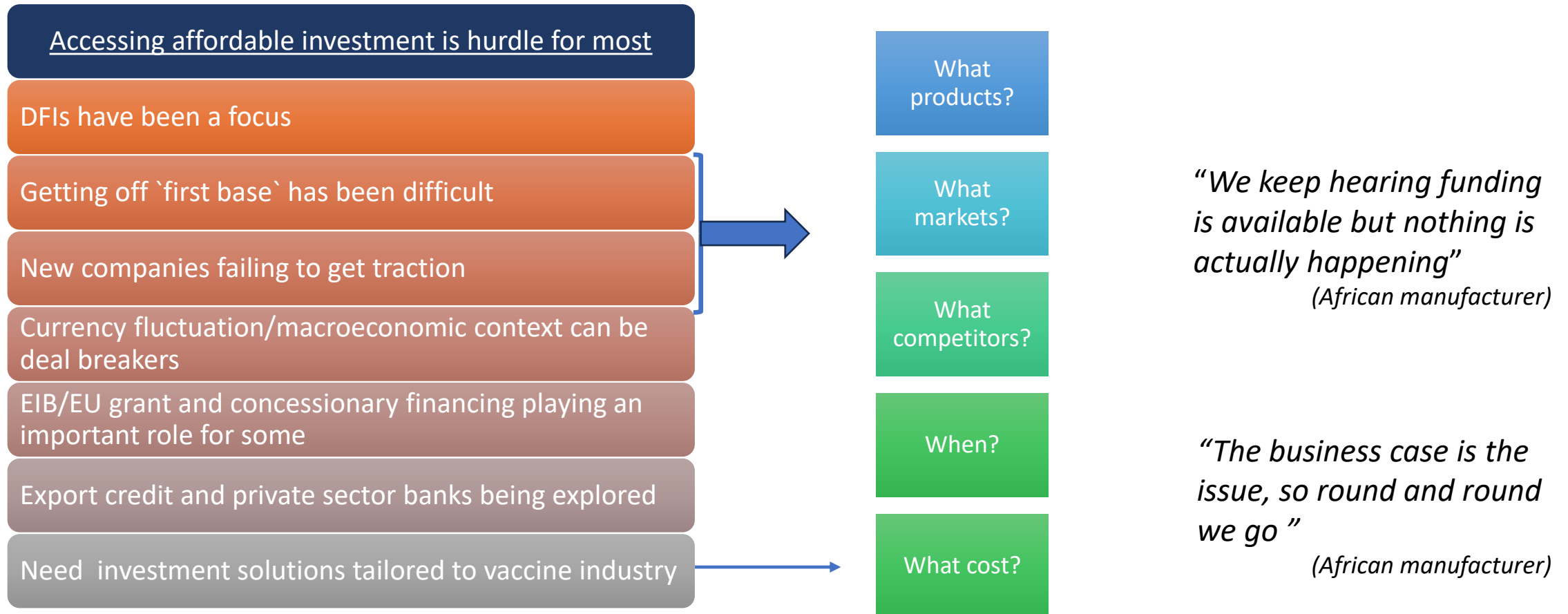
With at least thirty different companies and unique business propositions

Variable	Range
Stage of development	Established, repurposing existing capacities, new entrant
Stage in value chain	<u>Drug product</u> , drug substance, product development, discovery.
Capacity	Up to 600m doses per year
Source of Technology	mRNA TT Hub, DCVMN, MNC, other (e.g. Oxford Uni)
Business Model	CMO, licensing, `Biosimilar vaccines`
Other business units	Dedicated vaccines, generics, LVP, SVP, biosimilars.
Ownership	Public sector, African private sector, MNCs, PPP
Investment requirement	\$10m - \$500m
Target markets	Domestic+, GAVI, sub-region, region, international
Products	GAVI Priority, EPI, other (e.g. influenza)

Where do these initiatives stand and what challenges do they face?



Initial conversations indicate access to finance is a major challenge and that the business case has holes



Issues with the business case vary

“If we don't sell to GAVI then it's do or die”

(African manufacturer)

Product/technology:

- Collapse in COVID19 demand undermined many initial propositions
- different experiences with tech transfer
- MNCs a valued partner for established companies
- Sanofi stands out from a new entrant perspective
- Tech transfer fees being sought (\$1.5-2m), even for CMO model
- Secondary packaging and F&F for biosimilars and being explored

Market/demand:

- Companies want off-take terms for domestic market
- RSA PCV situation shows importance of political will across government.
- GAVI market has the volumes, but concerns if 'it is the only game in town'.
- PQ is rate limiting for market entrance even for some non-GAVI mkts
- 'PPM and AVAT are just taking too long'

Cost/Competition

- Some require subsidy others think they can compete as is
- GIZ Study indicates a range for conversion costs and disparities between regions
- Internal competition a concern e.g. in PCV, and given disparities in investment
- Supply side incentives can be important, though difficult to get.
- Imports often benefit from incentives

Some general themes
can be identified

*“Everyone is depending on GAVI
and the EPI. Would suggest not to
enter unless there is political
leadership”*

(African Industry Leader)

Political will is a must

Post pandemic momentum beginning to wane

GAVI can play an important role in short to medium term

Private sector is finding solutions

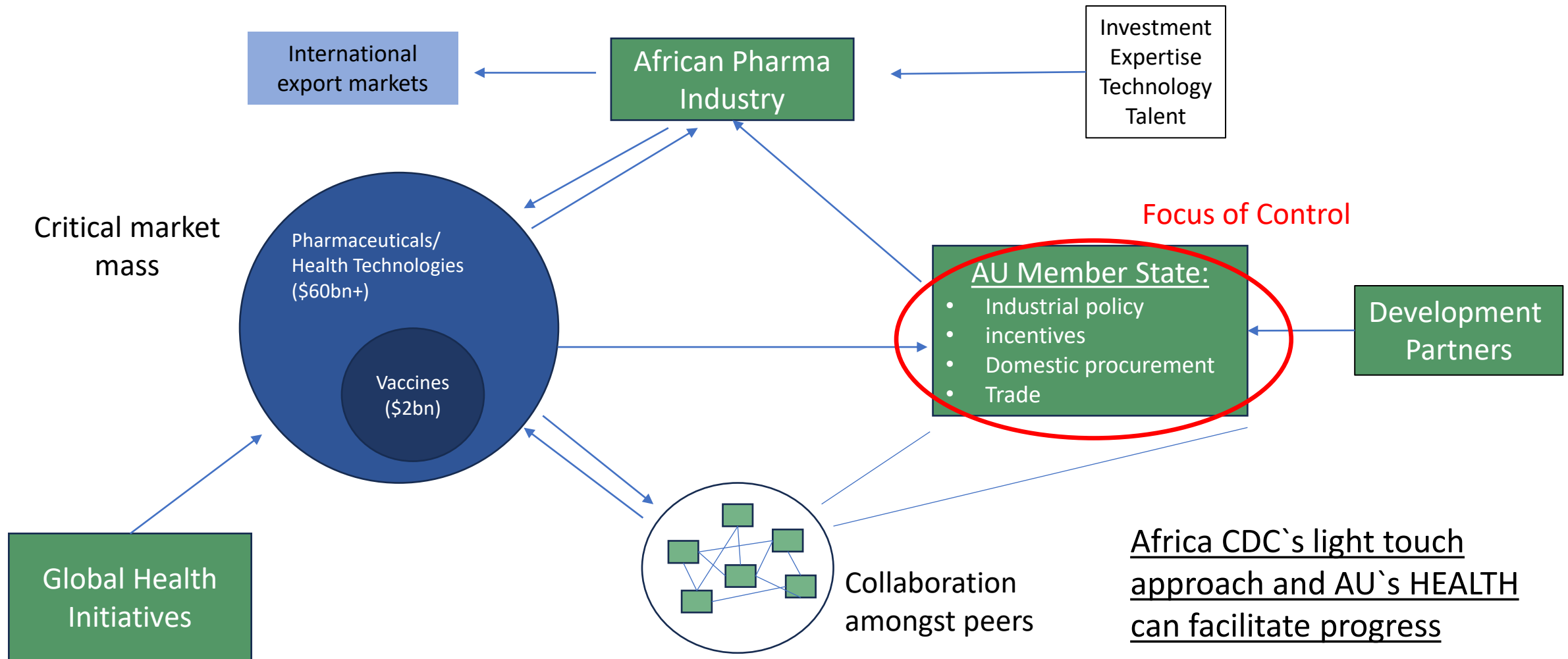
Expedited market access (reg) is required

Pooling of demand needs careful consideration

Clarity on the market is urgently needed

AU Member States should have a key role to play

The approach to coordination and a market based model are key to success



Conclusion

“What PAVM has achieved is quite remarkable”

(African Industry Leader)

- Situation is complex with many moving parts
- A lot of interest in recent years
- However progress for some has been slow
- Access to Finance appears to be the key pain point
- In part a result of holes in the business case
- Expedited market access (e.g. PQ) is a needed `solution`
- Addressing broader business case a bit more involved
- Clarity on demand is urgently required
- Broader economic objectives can harness political forces

The light touch approach of PAVM/HEALTH a good basis for market based progress in the long term.

“There have been lots of activity over the last couple of years, now is when the rubber hits the road”

(African Industry Leader)

Thank you