

Regulatory Landscape for Novel Public Health Pesticide Products

International Public Health Pesticide Workshop

19th May, 2009

- Introduction

- Registration process

- Time and cost of registration

- Impact of registration on access and innovation

- Conclusion / next steps

Introduction

- Problem statement:
 - Perceived regulatory burden in bringing Public Health Pesticide Products (henceforth PHPPs) to market
 - Need for all stakeholders, both from an investment and a funding perspective, to clearly understand the nature and scope of the regulatory burden and identify ways to manage it
- Report objective:
 - Identify the impact of the registration process for PHPPs on market access and innovation, through a comprehensive mapping exercise to clarify the existing regulatory landscape, identify roadblocks and quantify the resources required to bring novel products to market
 - Create a fact base for further discussions, starting from this workshop
- Our engagement:
 - The Bill and Melinda Gates Foundation commissioned this report from Dalberg Global Development Advisors between mid February and end of May
 - Working Group included Kate Aultman and Vincent Ahonkhai (Gates Foundation), Kevin Sweeney (EPA), Robert Sloss and Tom McLean (IVCC), Vincent Dartigues (Crop Life), Michael MacDonald (USAID)
 - This presentation summarizes selected key findings for the purpose of this workshop
 - The report is being written and finalized: **your feedback is welcome**

Methodology

- Project focus:
 - Access to innovation in endemic countries
 - Novel PHPPs: new formulation is the product as purchased by the end user and consists of a combination of active ingredient(s), other ingredients and can have different modes of action (the product class)
 - Public health products for vector control, procured through donors' or government funding
 - Regulatory landscape: good understanding of regulatory agencies and key stakeholders, understanding of policy
 - Process to market: focus on registration, with high level insights on product development, stewardship and procurement
- Findings and data in the report have been generated at three different levels and triangulated through interviews with a variety of stakeholders, including manufacturers and donors:
 - High-level international regulatory landscape (by interview): WHOPES, EPA, FAO
 - Five in-depth country studies (with country visits): Tanzania, Zambia, Brazil, Senegal, Nigeria
 - Two country overviews (by telephone interview): China, India

Focus of the report is on formulation innovation within existing product categories using existing AIs due to data availability

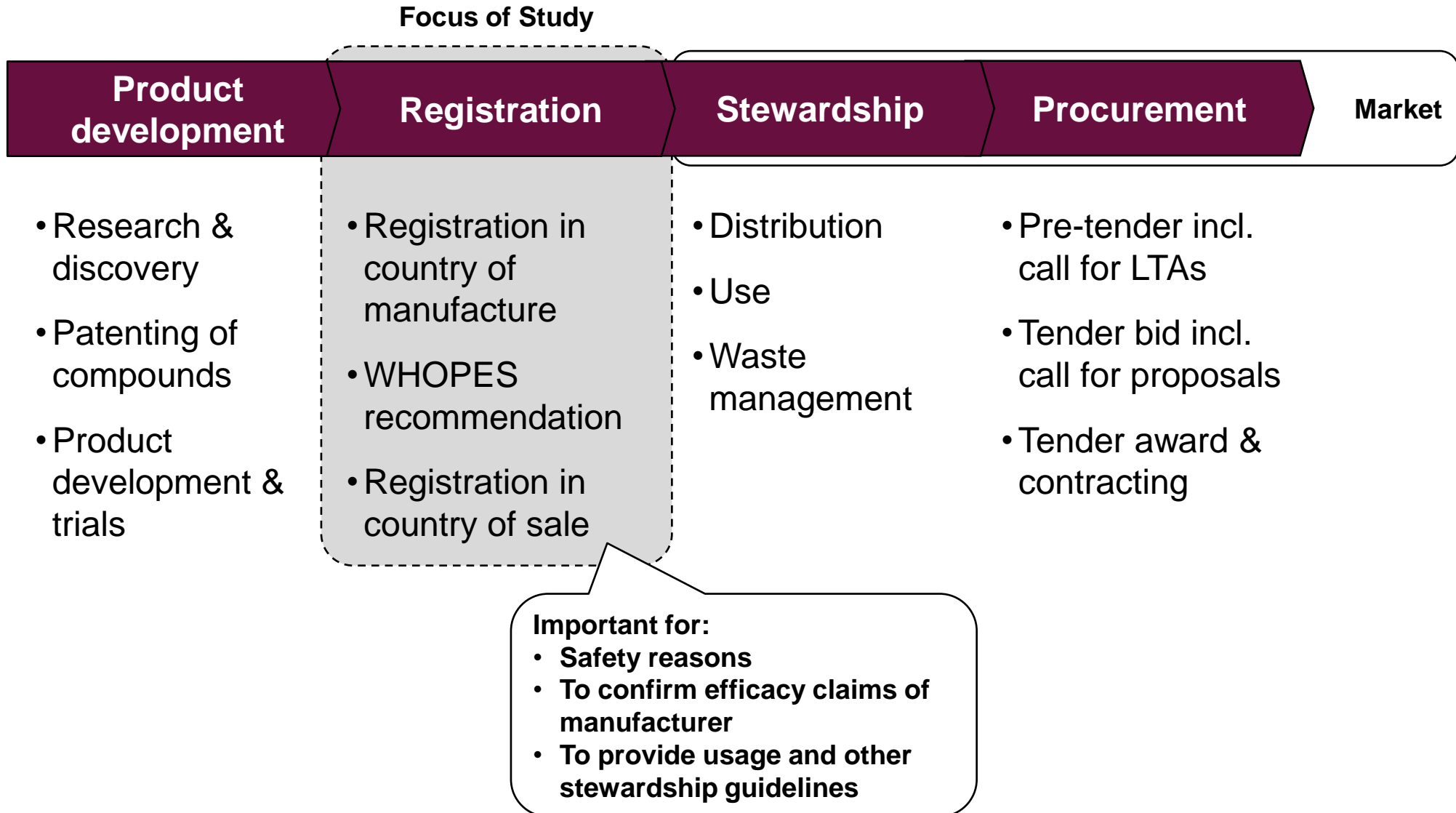
Combinations considered for data collection

| | Existing product category | New product category |
|---|------------------------------------|-------------------------|
| Existing AI (registered for multiple uses) | e.g. a new LLIN | e.g. spatial repellents |
| New AI repurposed from agriculture | e.g. spinosad used for larviciding | - |
| New AI specifically developed for public health | None | None |

Data collected and focus of study

- Most recent innovation has happened within an existing product category using existing AIs (e.g. move from ITNs to LLINs)
- Data collected reflects process for these products
- Other categories only considered at a theoretical level using existing categories as a proxy

Registration is an important and necessary step to take novel PPHPs to market



- Introduction

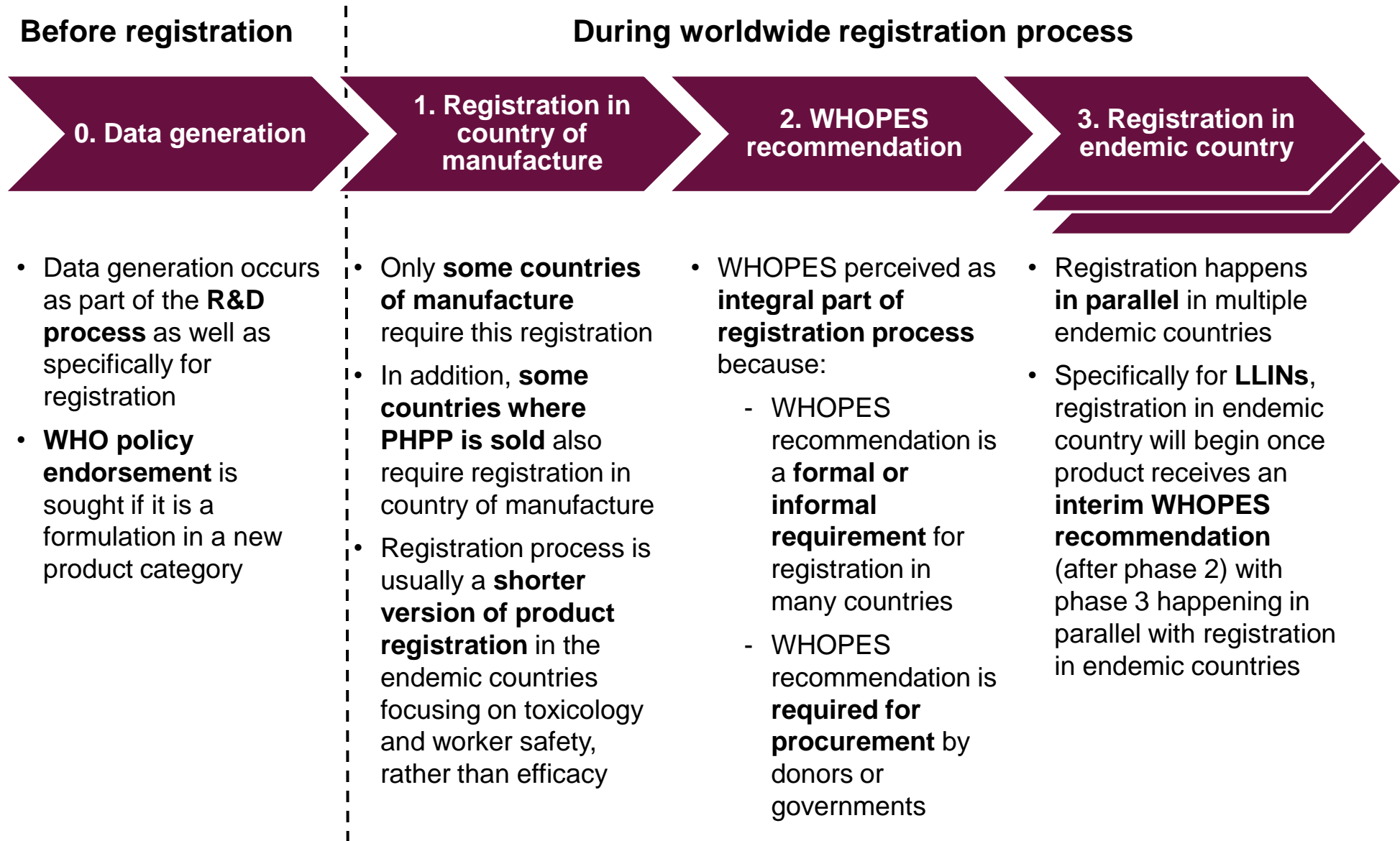
- Registration process

- Time and cost of registration

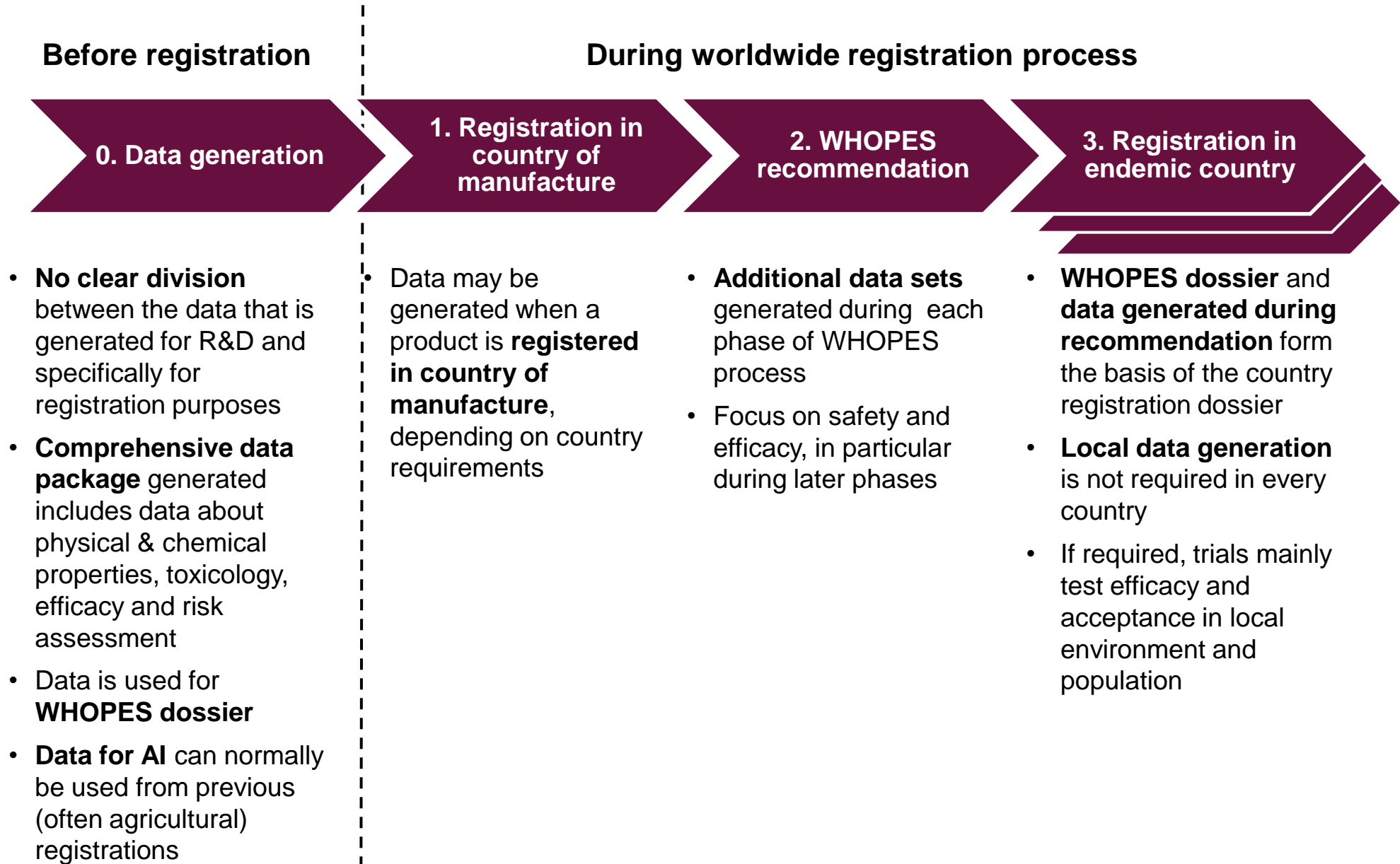
- Impact of registration on access and innovation

- Conclusion / next steps

Registration process for a new formulation has three steps



Data is generated before registration and during each of the steps



WHOPEs process consists of 3 major phases for new formulation to receive recommendation

Process steps

Phase 1

- Laboratory studies:
 - Efficacy, persistence and cross resistance testing
 - Confirmation of basic tox and eco-tox data provided by applicant

Phase 2

- Small scale field studies
 - Mainly efficacy trials
 - Data also gathered on safety, community acceptance and other topics as appropriate

Interim
recommendation →
(only for LLINs)

Phase 3

- Large scale field studies
 - Mainly efficacy trials
 - Data also gathered on safety, community acceptance and other topics as appropriate

Recommendation

**Specification for
technical product and
formulation**

- Based on proposed specifications by manufacturer, the FAO/WHO Panel of Experts (JMPS) issues a specification



WHOPES relies on WHO policy endorsement before considering recommendation of a formulation in a new product category

- Recommendation process at WHO **contains additional steps** from “regular” process for a formulation in a new product category
 - Scientific body of evidence produced by manufacturers and research community
 - WHO looks to research to create policy endorsement for product
 - WHOPES then draws up and refines guidelines based on body of evidence

- Many endemic countries would rely on **WHOPES guidelines** and manufacturers’ data to register a formulation in a new product category
 - *“We are not sure until we see the dossier.”* (Registrar)



Registration process in country also contains three steps, but not always the same sequencing of these steps

Application, inc. sample analysis

- Dossier, local data and additional supporting documentation submitted
- Sample analysis usually conducted

Local data generation can happen prior to or after application is submitted, depending on country of registration

Local data generation

- Data generation in-country is not a pre-requisite for all registration processes
 - If not required, data supplied normally needs to come from trials in similar conditions to country

Evaluation & approval

- Application and any data generated is reviewed by registration authority
- Decision to approve application is normally vetted by committee(s)
- Vast majority of applications are approved, although time taken and conditions of approval vary enormously



Depending on country, different bodies are involved in registration process

| Regulatory Authority sits under... | Example(s) |
|------------------------------------|----------------------------|
| Ministry of Agriculture | Tanzania China India |
| Ministry of Environment | Zambia Senegal |
| Ministry of Health | Nigeria Brazil |

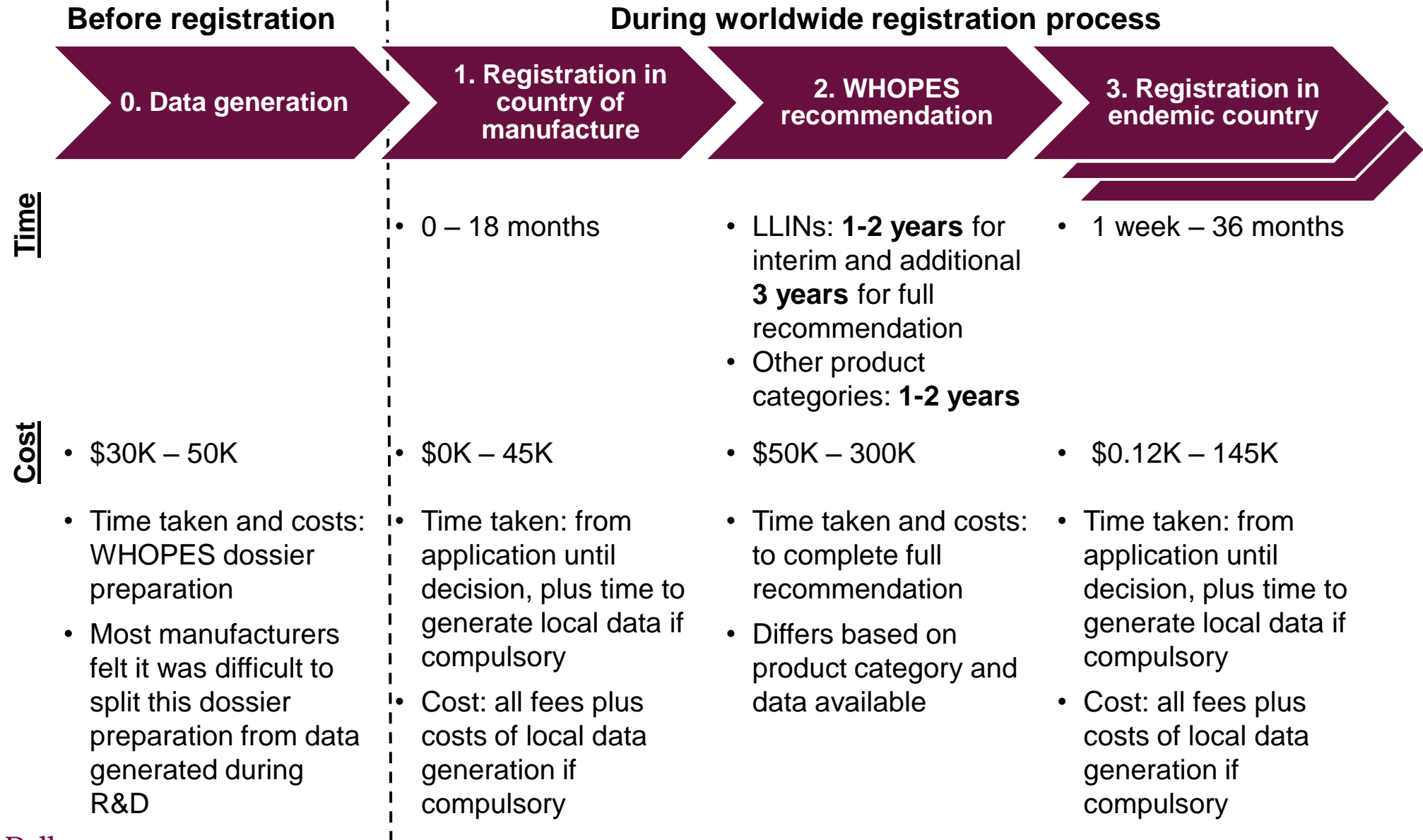
- 
- **Registration of PHPPs often rests with the Ministry of Agriculture due to their role in the registration of pesticides for agricultural purposes**
 - **If registration does not rest with Ministry of Health, there are sometimes informal or formal requirements for interaction**

- Introduction
- Registration process

- Time and cost of registration

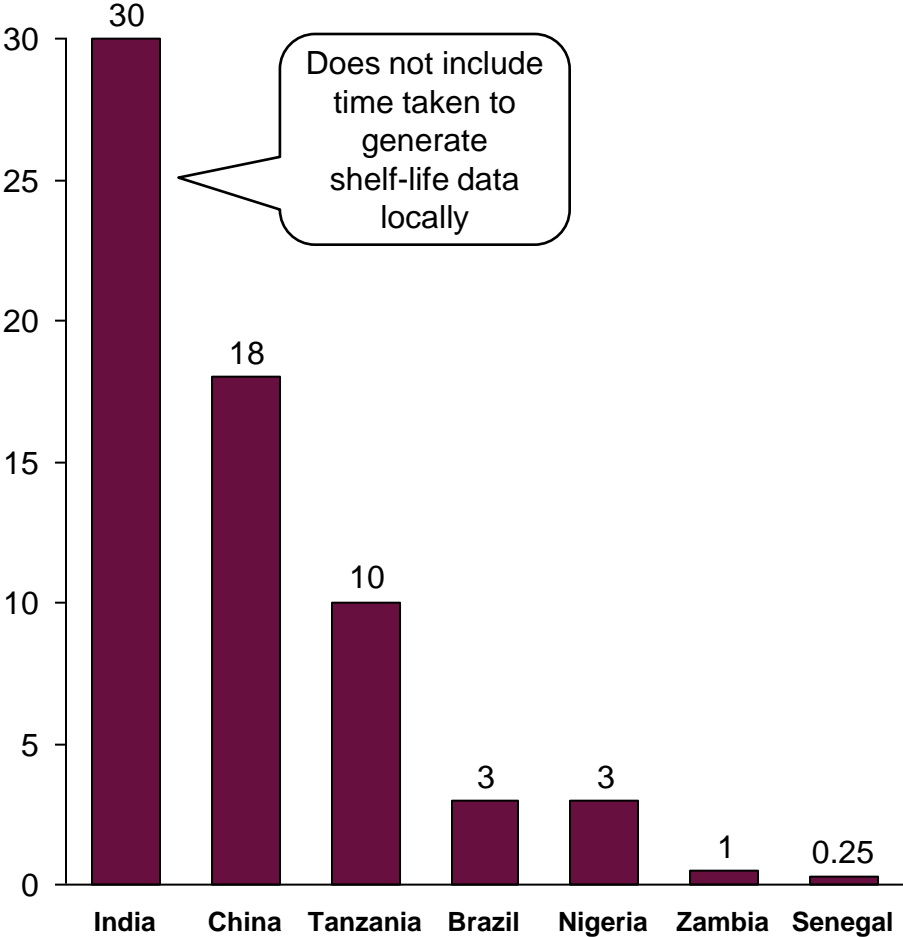
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Time taken and costs to register a formulation

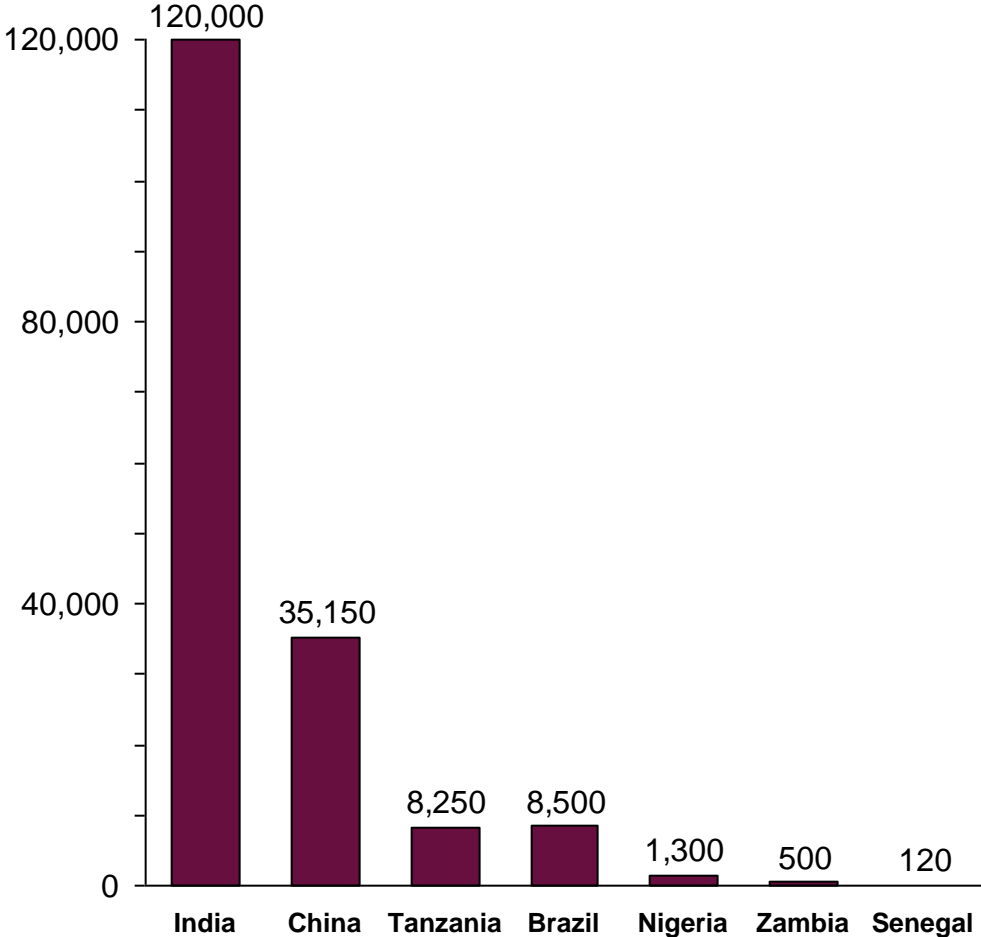


Time taken and costs in formal registration process in countries varies widely

Average time taken (months) for formal process, as reported by registration authority



Average cost (USD) for formal process, as reported by registration authority



Note: India cost data comes from manufacturers as suggested by registration authority
Source: Interviews with registration authorities

Differences between countries are primarily driven by requirement for local data generation and capacity for evaluation of evidence in country

Application, inc. sample analysis

- No major differences in application or sample analysis that affect time taken or costs

Local data generation

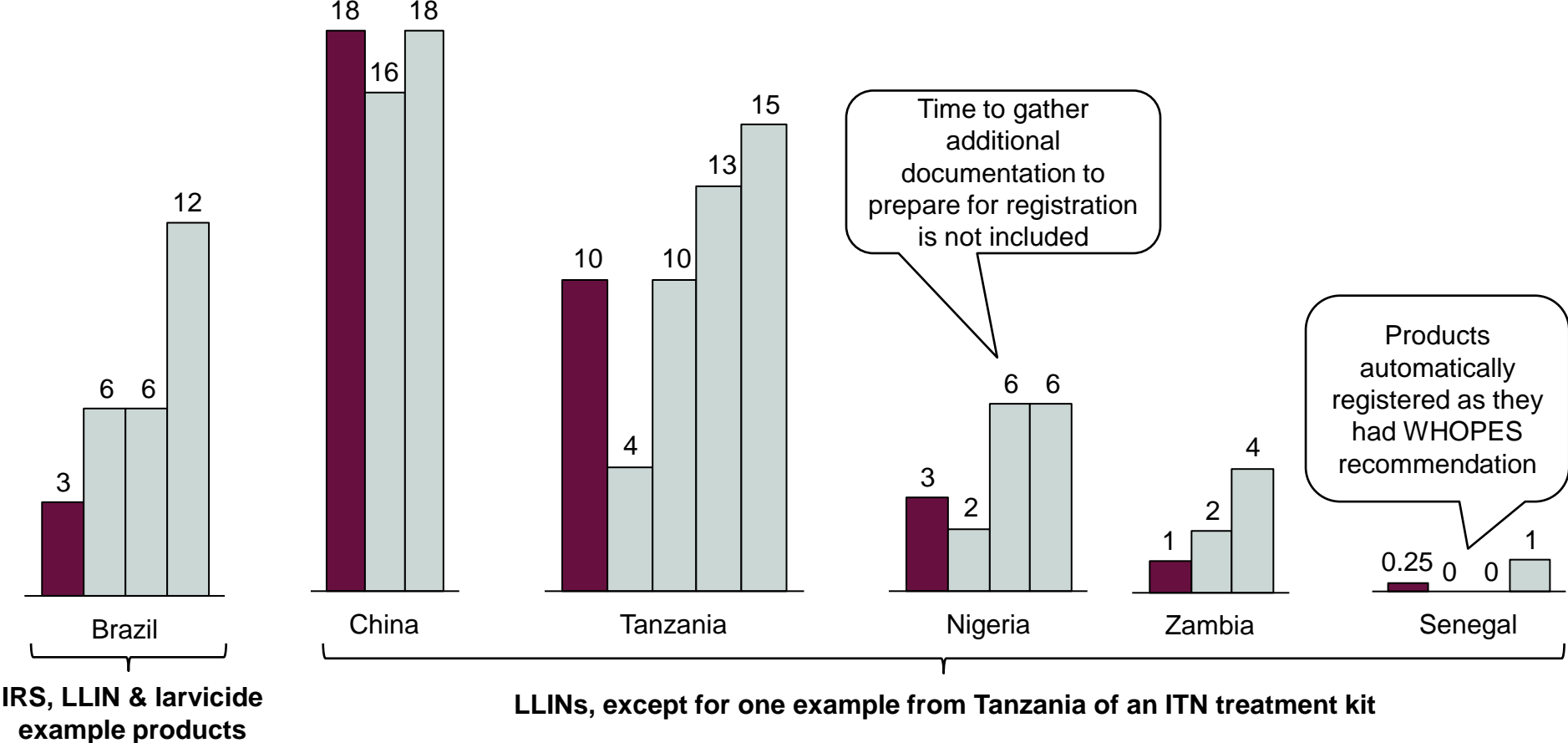
- Largest variance in both cost and time is determined by whether countries **require local data generation** and **how extensive the trials** are
 - Trials normally look to test efficacy and community acceptability; sometimes cover toxicology
 - Local trials are usually conducted by government approved laboratories

Evaluation & approval

- Time taken is also affected by ability to **evaluate dossiers** in a timely fashion in each country
 - Committees meet infrequently which can delay decision making
 - Lack of capacity of staff in-country to review information

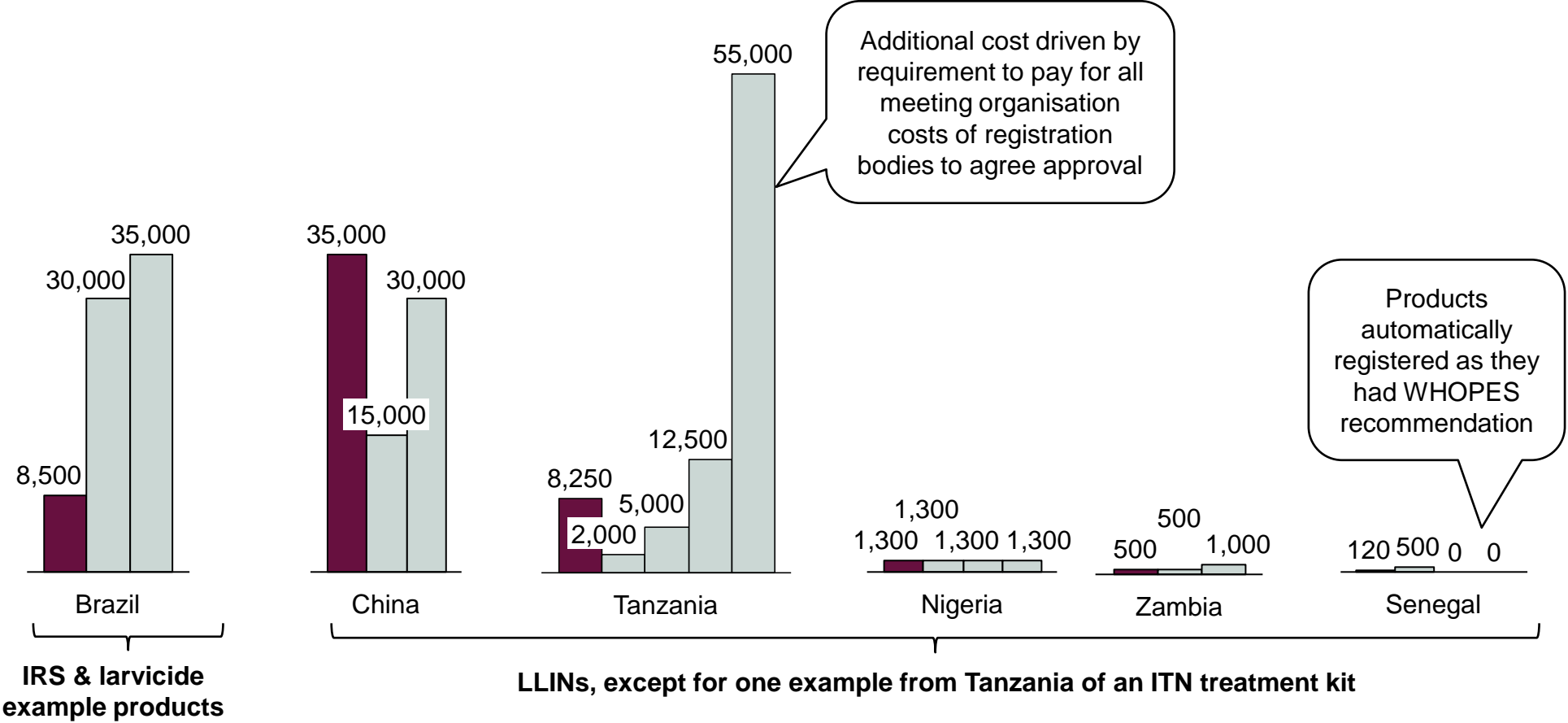
Manufacturers often experience different times taken for registration vs. formal process

Average time taken to register any product, as reported by national registration authority
 Actual time taken to register specific product(s) in country, as reported by manufacturers



And different costs for registration vs. formal process

■ Average cost (USD) to register any product, as reported by national registration authority
■ Actual cost (USD) to register specific product(s) in country, as reported by manufacturers



Note: Manufacturer experience does not cover additional costs of company registration, use of local consultants, agents or lawyers and assembling additional documentation

Sources: Interviews; CropLife Study

Differences between actual and formal experience are primarily driven by variances between local data generation and evaluation processes

Application, inc. sample analysis

- **Incomplete dossiers, additional documentation and unexpected requirements** can cause delays during the application process

Local data generation

- Local data generation can often take longer and cost more due to **availability of scientists, lack of technical facilities and varying quality of experiments**

Evaluation & approval

- **Approval process** can also be delayed
 - **Committees not meeting** as scheduled, or
 - Not always clear to manufacturers what causes approval delays
- Need to **interact with other bodies** outside of registration authority, e.g. National Malaria Control Programme, can add time to process

- Manufacturers also can incur **additional costs and time** not captured here:
 - Use of **local registration consultants** – often necessary because manufacturers cannot stay apprised of shifting registration
 - **Company registration** in country or cost of **local agent/distributor**

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Registration process can be a roadblock to market access in a specific country

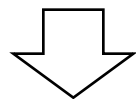
- **High registration fees** and **costs for obligatory data generation** in country have prevented smaller manufacturers from registering in specific countries
- **Additional costs** also play a part in decision making for manufacturers:
 - **Hiring local consultant** – complexity of registration process and frequent changes in requirements can mean that this becomes necessary
 - Obligation to **register company** locally or hire a **local distributor/agent**
- Registration process clearly increases **time to market** for products; manufacturers may consider the time it takes in specific countries as a reason not to sell product in that country
- **Uncertainty of outcome** in some countries could also cause manufacturers not to register or sell products

Harmonization of registration schemes aims to facilitate access to all markets

- Efforts to **harmonize registration processes** through regional bodies have **not been widely applied** in endemic countries
- **SEARCH** scheme to **harmonize all dossier requirements** between countries in southern and eastern Africa
 - In practice, dossier requirements have not been harmonized by country authorities and manufacturer experience suggests that dossiers required are still different
- Standard registration process through single authority in place for **agricultural pesticides** in the Sahel countries through **CILSS** – current plans to broaden scheme to include PHPPs
- **MERCOSUR** in Latin America and **ECOWAS** in West Africa are both currently discussing possibility of **harmonization of registration schemes**
 - First step to have common dossier requirements with potential to standardise registration scheme through single body

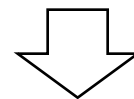
Return on investment drives innovation; registration has different degrees of impact on ROI

| | New formulation in existing category | New formulation in new product category | New formulation using AI developed for public health |
|---|--|---|--|
| Overall Investment | <ul style="list-style-type: none"> • Time: 4-6 years • Cost: \$1.5-6M | <ul style="list-style-type: none"> • New formulation in existing category + time and costs to build body of evidence to get WHO policy endorsement | <ul style="list-style-type: none"> • Time: 10 years • Cost: \$60-200M |
| Registration component of investment | <ul style="list-style-type: none"> • Time: at least 2 years • Cost: \$110-740K | <ul style="list-style-type: none"> • New formulation in existing category +/- time to establish new WHO PES guidelines | <ul style="list-style-type: none"> • Process to register is unclear • Unlikely to be major component of overall investment |
| 2006 market size | <ul style="list-style-type: none"> • Bed nets: \$400M • IRS: \$120M • Larvicides: \$90M • Spatial sprays: \$140M | <ul style="list-style-type: none"> • \$90 – 400M if substitute • If additional category, size is unclear but is driven by donor funding | <ul style="list-style-type: none"> • \$750M in 2006 and still growing for all formulation sales in public health market |

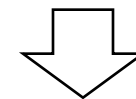


- **Time taken for registration is 33%-50% of time taken to market**

- **Registration cost is on average 10-15% of overall investment**



- **WHO process adds uncertainty to time and cost of overall investment as well as registration component**



- **Low ROI creates large disincentive to develop new AIs**

Uncertainty of the registration process for an AI developed for public health causes concern

- Innovation of AI specifically for public health is being driven primarily by **product development partnerships**, such as the IVCC, because of the low ROI for manufacturers
- **Uncertainty** about what the **process to register** an AI specifically for public health would look like is a cause for concern for these bodies
 - How are current trends in the regulatory environment for agricultural pesticides going to affect public health AI registration?
 - Which regulatory process will products with new public health AIs have to go through?
 - What will it take to develop registration process for a public health AI?

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Conclusions

- Registration is a major step in process to market
 - Country registration and role of WHOPES recommendation
 - Variation across countries for cost, time and data requirements
 - Within countries, differences between formal and de facto requirements
- Registration impacts manufacturers' market entry strategy...
- ... and has varying degrees of impact on their decisions for investment in innovation
 - Incremental formulation innovation: addressing regulatory burden could bring increased market competitiveness
 - Formulation innovation in new product category: getting WHO policy endorsement and creating WHOPES guidelines create uncertainty
 - AI innovation: lack of clarity on how registration would occur is a concern

Next steps

- Your feedback is appreciated, and will be incorporated in the final version of the presentation and report
 - Please see any member of the Dalberg team during the conference, or
 - Email serena@dalberg.com, sarah.harvey@dalberg.com and susanne.frick@dalberg.com

- The extended version of this report will be published by The Bill and Melinda Gates Foundation later this summer
 - Please check the Gates Foundation website at: www.gatesfoundation.org

Appendix

Appendix

- Registration process – additional information
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- Time and cost of registration – additional information
-
- Impact of registration on access and innovation – additional information
-
- Methodology and interviewees

International standards & guidelines play different roles in registration process for PHPPs

| Name | Focus | Importance to formulation registration | Importance to AI registration |
|--|---|--|-------------------------------|
| WHOPEPES | Tests, guidelines and recommendations <ul style="list-style-type: none"> Establishes and publishes specifications for technical material and related formulations for PHPPS Reviews efficacy & safety reports of PHPPs Sets guidelines for laboratory and field evaluation for PHPPs Product recommendation viewed as compulsory by majority of donors | * * * * | * * * * |
| FAO – Global Harmonization | Guidelines and harmonization <ul style="list-style-type: none"> International Code of Conduct on distribution and use of pesticides FAO Pesticide Management Guidelines Specifications and Quality Control Standards | * * * | * * * |
| National and regional authorities | Standard setting <ul style="list-style-type: none"> Several national and regional authorities (e.g. US-EPA, INDIA-CIB&RC, EU-ECB, NAFTA-TWP) who provide their frameworks as a model | * * | * * * * |
| OECD | Work sharing, harmonization and standard setting <ul style="list-style-type: none"> Developed Good Laboratory Practices (GLP) Work sharing and reduction of duplication costs among 30 member states Harmonizing of data and testing requirements for registration of pesticides | * * * | * * * |
| Various bi-lateral collaborations | Collaboration <ul style="list-style-type: none"> Harmonization of registration to improve mutual market access (e.g. CHINA-ICAMA collaboration with US-EPA) | * * | ** |
| Codex Alimentarius | Standard setting <ul style="list-style-type: none"> Code for food developed and administered by the WHO and FAO Relevant for pesticides only in relation to pesticide residues in food | * | * |

Appendix

- Registration process – additional information

- Time and cost of registration – additional information

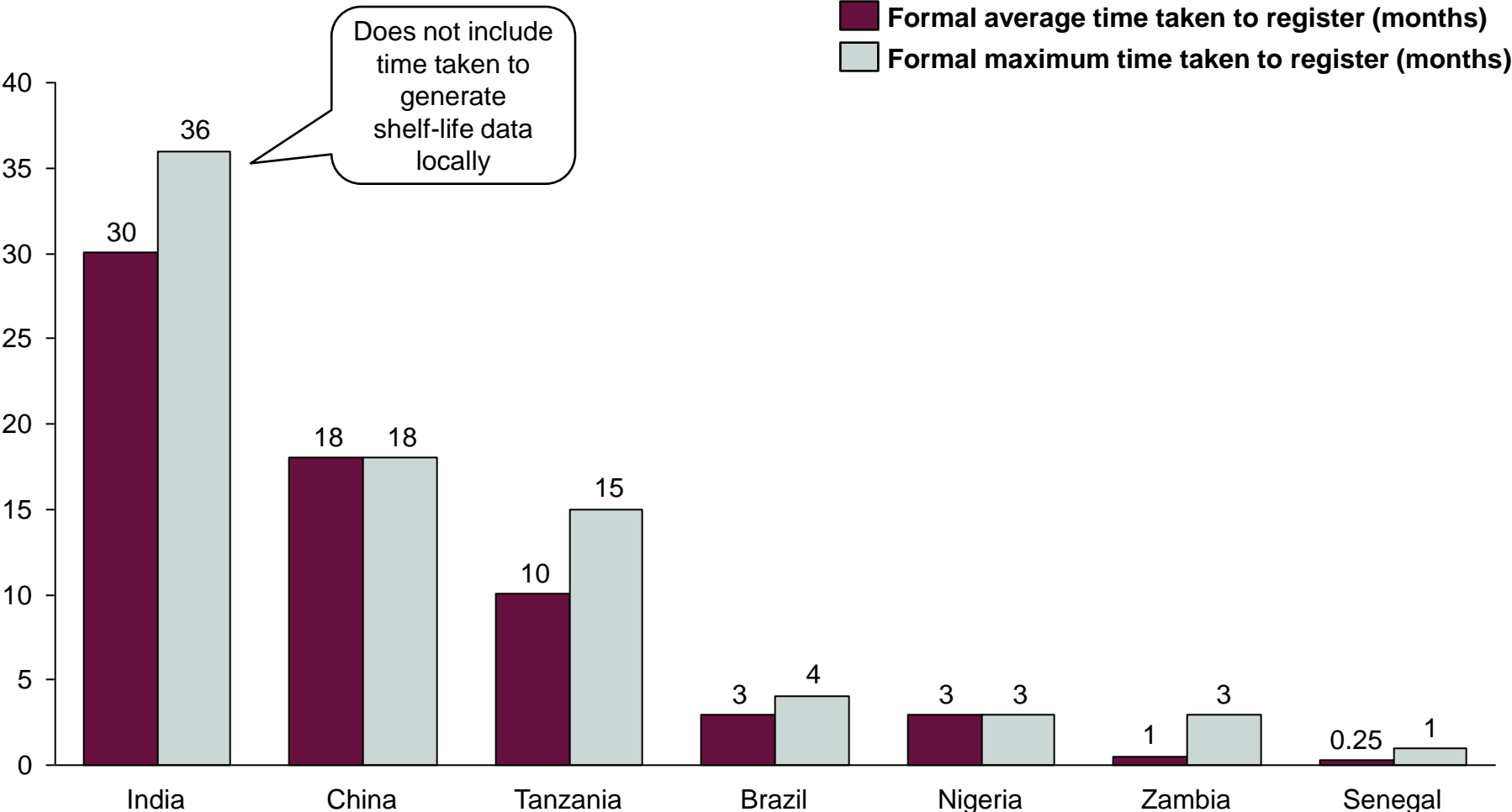
- Impact of registration on access and innovation – additional information

- Methodology and interviewees

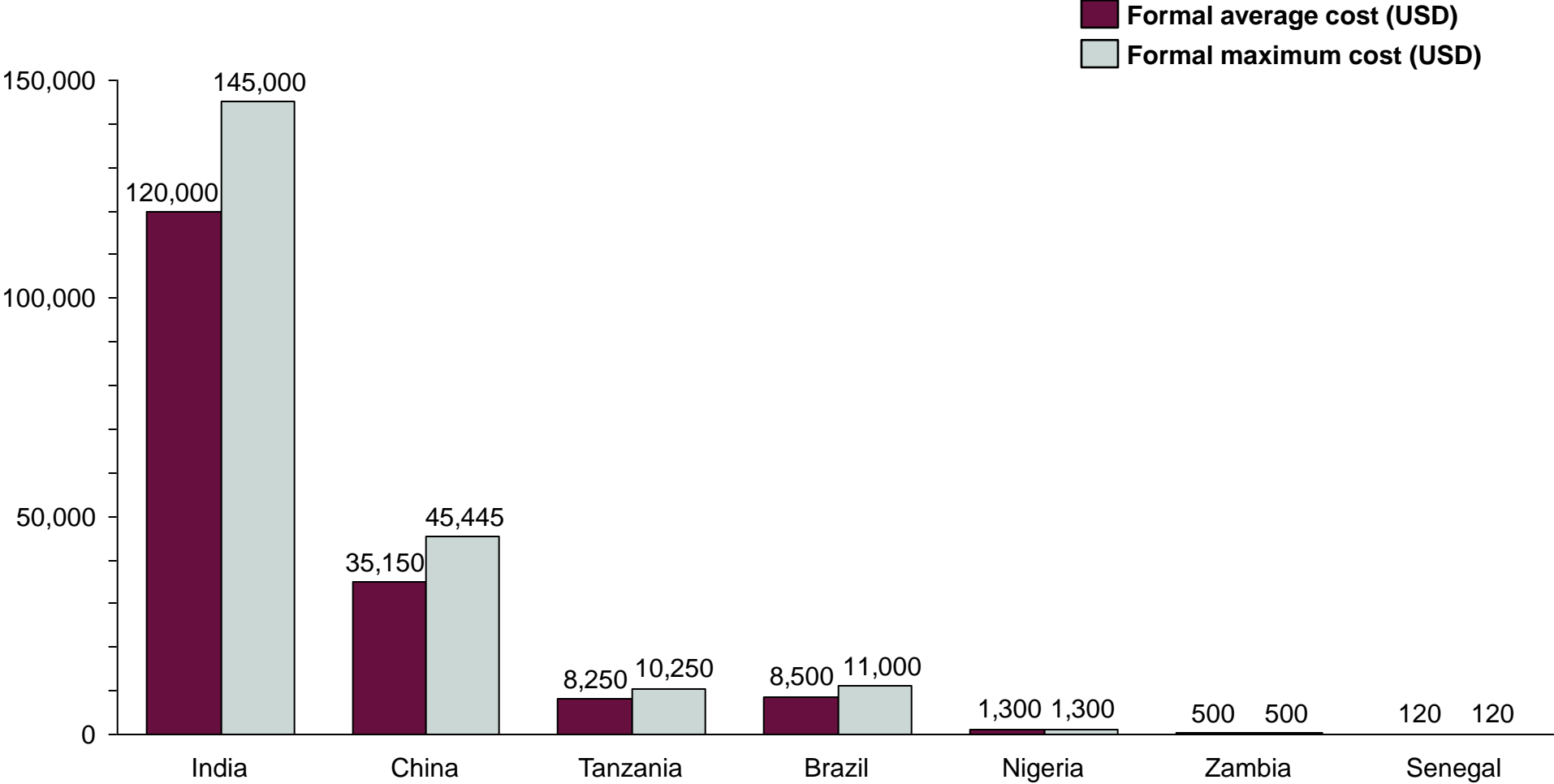
While basic dossier categories and requirements are similar in most countries, some require additional data to be generated locally

| Key categories | Sample components | Comments | Sample variance at country level |
|----------------------------------|---|--|--|
| AI data sheet | n/a | All current AIs commonly registered/ known | |
| Physical and chemical properties | Formulation type Storage stability Flammability Etc. | <ul style="list-style-type: none"> Basic laboratory analysis in most countries in order to test authenticity of product | <ul style="list-style-type: none"> India: shelf-life data to be generated locally Brazil: shelf-life data to be generated locally |
| Toxicology | Sensitization Inhalation Etc. | <ul style="list-style-type: none"> Mainly reliance on data generated outside the country | |
| Efficacy | Efficacy under different ecological settings Persistence Handling and application Etc. | <ul style="list-style-type: none"> Data category that is most often required to be generated at local level | <ul style="list-style-type: none"> Tanzania: efficacy tests in experimental huts and at the community level (incl. community acceptance) for 8-9 months India: Large scale tests in different locations over various seasons |
| Risk assessments | Hazard assessment Human risk Animal risk Environmental risk Etc. | <ul style="list-style-type: none"> Environmental data less relevant at country level (with exception of DDT for which strategic environmental assessments are often required) | |

Time taken in formal registration process in countries varies widely



Costs between countries' formal registration processes also varies significantly



Note: Indian data comes from manufacturers and not registration authority
Source: Interviews with registration authorities

Time taken and costs vary between countries because of the differences in the number and complexity of steps in the registration process

| | Application, inc. sample analysis | Local data generation | Evaluation & Approval |
|-----------------|--|---|--|
| India | <ul style="list-style-type: none"> • Time taken: - • Cost: \$2 | <ul style="list-style-type: none"> • Time taken: 12-18 months • Cost: \$110K-145K | <ul style="list-style-type: none"> • Time taken: 12-18 months • Cost: \$0 |
| China | <ul style="list-style-type: none"> • Time taken: 3 months for efficacy trial permit • Cost: ~\$75 for permit | <ul style="list-style-type: none"> • Time taken: 12 months • Cost: ~\$35K-45K | <ul style="list-style-type: none"> • Time taken: 3 months for interim¹ 12 months for full • Cost: ~\$75 for interim ~\$370 for full |
| Brazil | <ul style="list-style-type: none"> • Time taken: average 3 months for entire process • Cost: ~\$400-4000 | <ul style="list-style-type: none"> • Cost: ~\$4.5K-7K | <ul style="list-style-type: none"> • Cost: \$0 |
| Tanzania | <ul style="list-style-type: none"> • Time taken: 14 days • Cost: \$150 | <ul style="list-style-type: none"> • Time taken: 2-9 months • Cost: \$7K-10K | <ul style="list-style-type: none"> • Time taken: 2-5 months • Cost: \$100-150 |
| Nigeria | <ul style="list-style-type: none"> • Time taken: 3 months for entire process • Cost: ~\$650 | <ul style="list-style-type: none"> • Not usually required | <ul style="list-style-type: none"> • Cost: ~\$650 |
| Senegal | <ul style="list-style-type: none"> • Time taken: 1 day • Cost: \$0 for registration ~\$120 for sample analysis | <ul style="list-style-type: none"> • Not required | <ul style="list-style-type: none"> • Time taken: 3-4 days • Cost: \$0 |
| Zambia | <ul style="list-style-type: none"> • Time taken: 1-3 months for entire process • Cost: ~\$500 for entire registration • Local trials are not required if data submitted is satisfactory (normally data is sufficient) | | |

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- Methodology and interviewees

Methodology: total registration cost estimation for new formulation

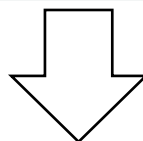
| | Assumptions | Formulation | |
|--|---|-------------------|-------------------|
| | | Low case | High case |
| WHOPEs dossier creation | <ul style="list-style-type: none"> • Cost to produce dossier | ~\$30 000 | ~\$50 000 |
| WHOPEs recommendation | <ul style="list-style-type: none"> • Cost to get full recommendation (phase 3) • Low case: cheapest larvicide example • High case: most expensive LLIN example | ~\$50 000 | ~\$300 000 |
| Registration in country of manufacture | <ul style="list-style-type: none"> • Low case assumes production registration is neither required in country of manufacture or in any endemic countries • High case assumes registration in highest cost country of manufacture (currently China) | ~\$0 | ~\$45 000 |
| Registration in endemic countries | <ul style="list-style-type: none"> • Assumes product is only used to combat one endemic disease (example of malaria used here) • Low case assumes registration in 20% and high case in 100% of malaria endemic countries¹ | ~\$30 000 | ~\$345 000 |
| TOTAL REGISTRATION COSTS | | ~\$110 000 | ~\$740 000 |

Note: ¹ 35 endemic countries represent 98% of malaria burden (Roll Back Malaria Report)

Sources: Interviews; CropLife Study

Methodology: costs for in-country registration in malaria endemic countries

| | Countries with lower registration costs | Countries with medium registration costs | Countries with higher registration costs | Exception |
|-----------------------------|---|---|---|--|
| Country example | Zambia | Tanzania | Kenya | India |
| Cost of registration | \$500 (avg) | \$8 250 (avg) | \$20 000 (avg) | \$120 000 (avg) \$145 000 (max) |
| # countries | 21 countries (60%) | 6 countries (17%) | 7 countries (20%) | (3%) |
| | <ul style="list-style-type: none"> • Angola • Burundi • Chad • Cote d'Ivoire • Guinea-Bissau • Liberia • Mozambique • Rwanda • Somalia • Togo • CAR • Congo • Guinea • Malawi • PNG • Sierra Leone • Sudan • Uganda • Nigeria • Senegal | <ul style="list-style-type: none"> • Cameroon • Niger • DRC • Myanmar • Bangladesh | <ul style="list-style-type: none"> • Ghana • Benin • Ethiopia • Burkina Faso • Mali • Indonesia | <div style="border: 1px solid black; border-radius: 15px; padding: 10px; width: fit-content; margin: 10px auto;"> <p>Registration costs are exceptionally high in India therefore was not placed in any of the categories because of the distortion it would create</p> </div> |

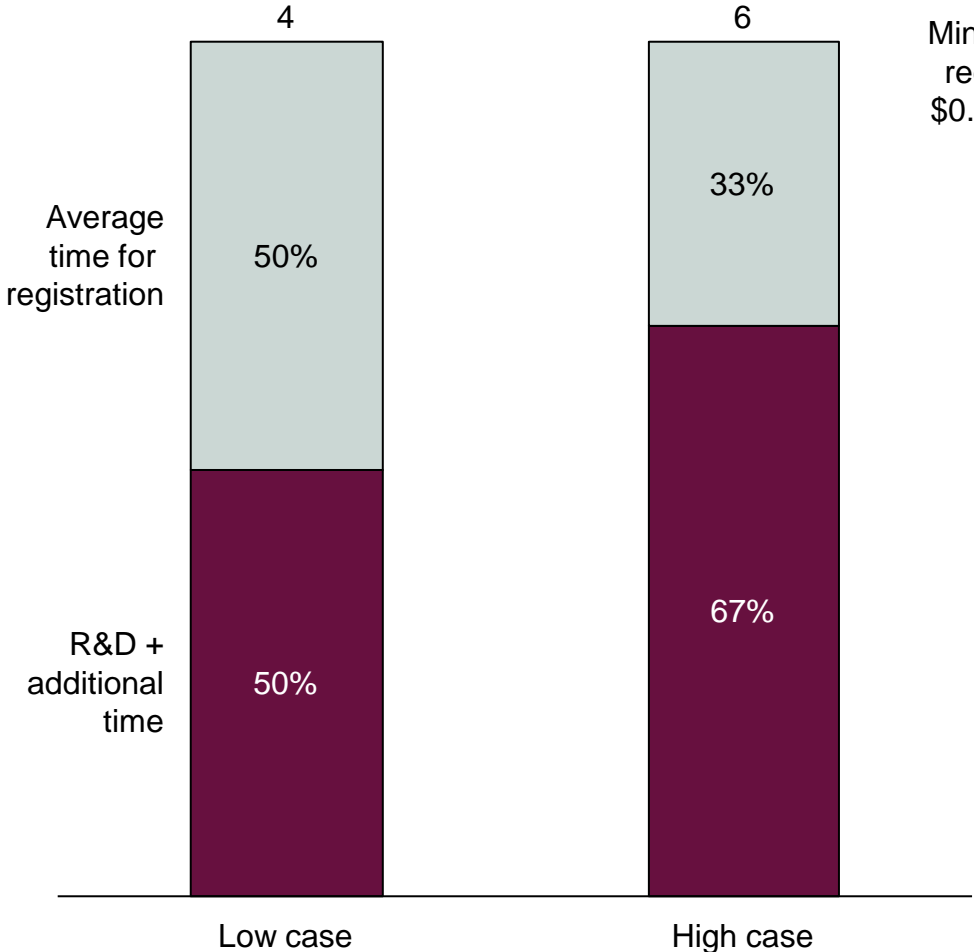


Low case scenario: register in 20% of countries (5 lower, 1 medium and 1 high cost)

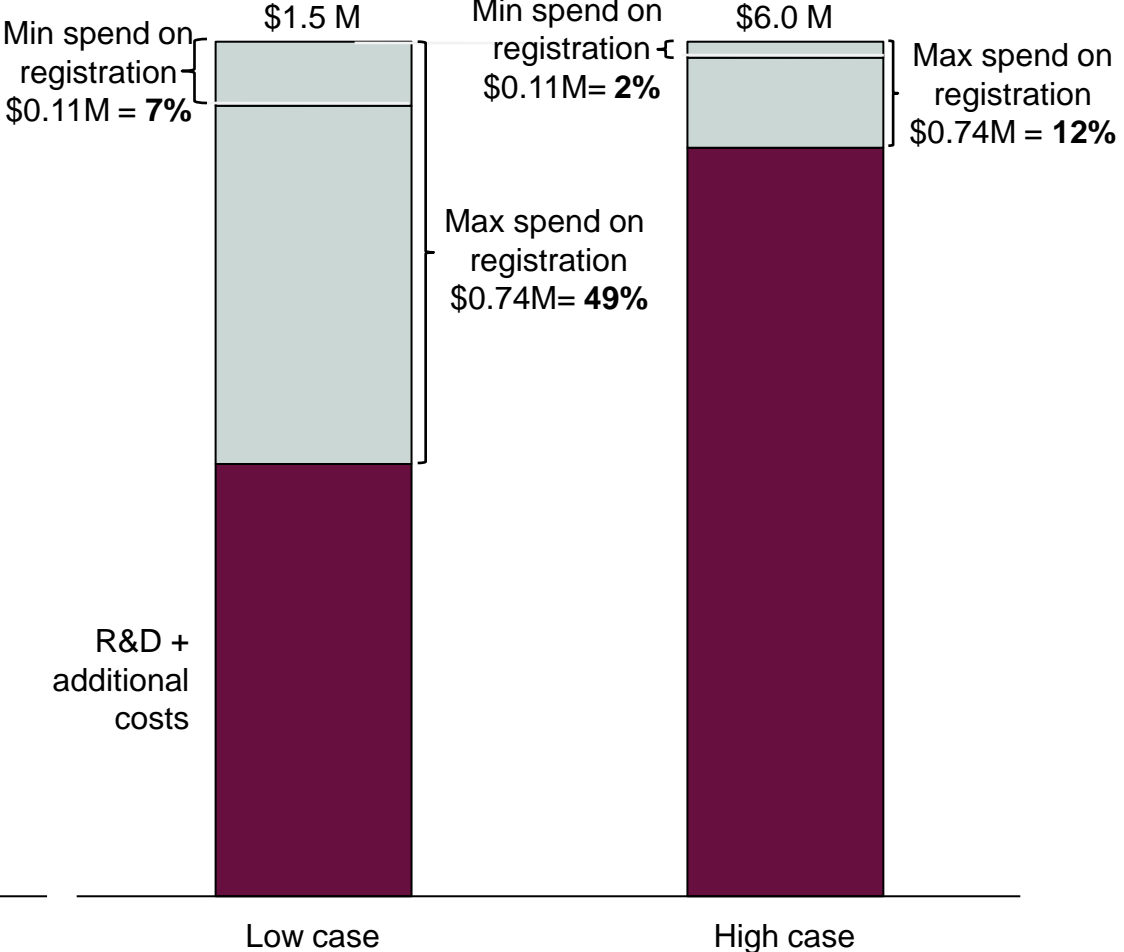
High case scenario: register in all countries, including India

For new formulations with an existing AI, the costs and the time taken for registration are significant factors in the process to market

Time to market (years)



Costs to market (\$M)



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- Registration process – additional information
- Time and cost of registration – additional information
- Impact of registration on access and innovation – additional information

- Methodology and interviewees

Methodology

Data collection through country visits

- In depth country studies in five countries: Brazil, Nigeria, Senegal, Tanzania and Zambia
- Desk search and 18+ interviews conducted in each of these countries with different stakeholders including regulatory authorities, representatives of the ministries of health, manufacturers, donors and NGOs

Data collection through country phone interviews

- High level overviews for 2 countries: China and India
- Desk search and 1-3 phone interviews conducted per country with different stakeholders including regulatory authorities, representatives of the ministries of health, and manufacturers

Other key stakeholders

- Three objectives for stakeholder interviews:
 - Triangulate data from country visits
 - Understand regulatory landscape at global level
 - Understand other major drivers for innovation and access
- 30+ interviews conducted with manufacturers, donors, WHO representatives, FAO representatives, IVCC representatives and other experts

Criteria for country selection

| | <i>Disease burden</i> | <i>Sophistication of regulatory system</i> | <i>PHPP revenue (2006)</i> | <i>Regional representation</i> | <i>Local manufacturer base</i> | <i>Other</i> | |
|---------------------|-----------------------|--|----------------------------|--------------------------------|--------------------------------|---|-----------------------------|
| Tanzania | High | Medium-High | \$17.5M | East Africa SADC | Yes | • Strong agreement to include from interviews | Country Visits |
| Zambia | High | Low | \$6.0M | Southern Africa SADC | No | | |
| Nigeria | High | Medium | \$7.5M | West Africa ECOWAS | Yes | • Strong agreement to include from interviews | |
| Senegal | High | Low | <i>Not known</i> | West Africa CILSS ECOWAS | No | • Important to include francophone country | |
| Brazil | High | High | \$7.6M | Latin America | Yes | • Strong agreement to include from interviews | |
| India | Medium | High | \$54.7M | Asia | Yes | • Strong agreement to include from interviews | Telephone Interviews |
| China | Low | High | <i>Not known</i> | Asia | Yes | • Large generic market | |
| South Africa | Low | High | <i>Not known</i> | Southern Africa SADC | Yes | • Might have an influence at a regional level | Still to be included |

Global stakeholder interviews completed

| Agencies | Manufacturers | Donors |
|---|---|---|
| <ul style="list-style-type: none"> • Susan Jennings, EPA • Marion Johnson, EPA • Davis Kable, EPA • Kathy Monk, EPA • Lois Rossi, EPA • Kevin Sweeney, EPA • Mark Davis, FAO • Kate Aultman, Gates Foundation • Vincent Ahonkhai, Gates Foundation • Robert Sloss, IVCC • Tom McLean, IVCC • Dr Morteza Zaim, WHO • Rajpal Yadav, WHO • Mark Rowland, WHOPEX Expert Committee • John Gimnig, WHOPEX Expert Committee | <ul style="list-style-type: none"> • Nicolas Jamme, Arysta • Prishen Latchmanan, Arysta • Rose Peter, Arysta • Vincent Dartigues, Bayer • Magdel Mellet, Bayer • Markus Diehl, BASF • Egon Weinmueller, BASF • Morten Boisen, Cheminova • Inge Jensen, Cheminova • Henrik Pedersen, Cheminova • Alex Schwartz, Cheminova • William Jany, Clarke Mosquito • Robert Farlow, CropLife consultant • John Fitt, Dow • Mark Coffelt, Dupont • Ole Skovmand, Insect Control • Trine Sig, Intection • Rob Fleuren, Registration Consultant • Adam Flynn, Sumitomo • John Lucas, Sumitomo • Peter Dieterle, Syngenta • Helen Pates Jamet, Vestergaard Fransen • Mikkel Vestergaard, Vestergaard Fransen | <ul style="list-style-type: none"> • Sonali Korde, USAID • Michael Macdonald, USAID • Julie Wallace, USAID • Dr Tala Jallow, Global Fund • Jeanette Rennie, World Bank |

Tanzania interviews completed

- Dr Alexander Mwita, Programme Manager, National Malaria Control Programme
- Nick Brown, Team Leader ITN cell, National Malaria Control Programme
- Charles Llewellyn, Population and Health Officer, USAID
- Naomi Kaspar, Project Management Specialist – PMI, USAID
- Jessica Kafuko, PMI Technical Advisor, USAID
- Dr Mahdi Ramsan, Chief of Party, RTI
- Shobha Sadasivaiah, USAID Consultant on DDT registration
- Hiiti Sillo, Tanzanian Food and Drug Authority
- Stephen Magesa, National Institute for Medical Research (NIMR)
- Andrew Kitua, Director General, NIMR
- John McIntyre, Country Director Tanzania, Uganda and Burundi, World Bank
- Dominic Haazen, Lead Health Policy Specialist, World Bank
- Donald Mneney, Procurement Specialist, World Bank Tanzania
- Jonathan Ak'habuhaya, Registrar of Pesticides, Tropical Pesticides Research Institute
- Dr S Msangi, Senior Research Scientist, Tropical Pesticides Research Institute
- Pierre Guillet, Vector Health International Ltd
- Binesh Haria, COO, Vector Health International Ltd
- Binu Sahadevan, Manager, Sunflag
- Mahenye Muya, Managing Director, Suba Agro Trading
- Dr Abdulai Tinorgah, Chief Young Child Survival and Development, UNICEF
- Sebastian Ndandala, Deputy Head of Procurement, Ministry of Health
- Tim Piper, MEDA
- Jane Miller, PSI
- Anthony Haji, representative of Syngenta and TMTL
- Dr Frank Masha, Moshi Hospital

Zambia interviews completed

- John Milliner, USAID
- Allen Craig, Resident Advisor, PMI
- Oliver Lulembo, Resident Advisor, USAID/ PMI
- Dr Elizabeth Chizema, Programme Manager, National Malaria Control Programme
- Chadwik Sikaala, IRS specialist, National Malaria Control Programme
- Moonje Shimskowa, Logistic Officer, National Malaria Control Programme
- Cecilia Katebe, ITN specialist, National Malaria Control Programme
- Victoria Mupwaya, Acting Director and CEO, Environmental Council of Zambia
- James Mulolo, Senior Inspector, Environmental Council of Zambia
- David Kapindula, Senior Inspector, Environmental Council of Zambia
- Riaan Nel, Bayer Cropscience
- Mark Edwardes, Bayer Cropscience
- Maxas Bweupe, Croplife Representative Zambia Mana Agrochemicals Zambia Ltd.
- Sadik Seedat, Vestergaard Frandsen Representative Zambia, Melcome Marketing & Distributors LTD.
- Todd Jennings, MACEPA
- Arturo Sanabria, JSI
- Dr Masaninga, UNICEF
- Fay Venagas, Path

Brazil interviews completed

- Paulo Roberto Rangearo Peres, Specialist in health surveillance regulation, ANVISA
- Michele Gragnolati, Country Sector Leader, World Bank
- Fernando Llanos, Dengue Programme, PAHO
- Haroldo Bezerra, PAHO
- Tatiany Silva, Bayer
- Dr Ladislau, Head of National Malaria Control Programme, Ministry of Health
- Paulo Cesar da Silva, National Programme for Dengue Control
- Vinicius Augusto Coelho, Technical Assistant Vector Control, Bayer
- Flavio Hirata, Agronomist, Allier
- Fabio Domingues, Regulatory Affairs, VIGNA
- Carolina Amaral, Regulatory Analyst, VIGNA
- Carolina Estevam, Regulatory Coordinator, VIGNA
- Mr Arnaldo Massariol, Director of Registration, Cheminova
- Thiago Meneses, Pharmaceutical Consultant, COVISA
- Elysabeth Almeida, Manager, COVISA
- Raquel Moraes, Licensing, Rio de Janeiro State Government Body for Health
- Edmilson Silva, Fiocruz (Instituto Oswaldo Cruz)
- Paulo Vilarinhos, Sumitomo
- Fernanda Cristiane Salla, Bioagri Laboratory
- Ricardo, Fersol
- Joana Godinho, Senior Health Specialist, World Bank
- Luis Claudio, Toxicology Board
- Franklin Suchicital, PAHO representative

Senegal interviews completed

- Dr Matar Camara, Policy & Health Financing Specialist, USAID
- Racine Kar, UNICEF
- Cheikh Ndao, Service Nationale de l'Hygiene
- Tonia Marek, Health Programmes Specialist, World Bank
- Eric J. Yoboue, Senior Procurement Specialist, World Bank
- Sidy Diop, Procurement Consultant, World Bank
- Dr Moussa Thior, Coordonnateur, Programme National de Lutte contre le Paludisme
- Mouhanadin Sour, Legal Specialist, Direction Centrale des Marches Publiques
- Dr El Hadji Seck, Advising Doctor, Direction Centrale des Marches Publiques
- Mamadou Nbaye, Spécialiste en passation de marchés, Direction Centrale des Marches Publiques
- Maguette Kane Diop, Directeur, Direction Centrale des Marches Publiques
- Mr Ba, Directeur General, Valdafrique
- Marcel van Beek, Vestergaard Fransen
- Manuel Urrutia, Representative for Africa, Netmark
- Ueno Shuhei, Japanese Development Agency
- Dr. Papa Birama Ndiaye, Pharmacie Nationale d'Approvisionnement
- Mme Traore, SenChim
- Ousymane Faye, Professor of Entomology, University of Dakar
- Aita Sec, General Manager for Chemical Products, Commission Nationale de Gestion des Produits Chimiques
- Amadou Guèye, Chief of Party, RTI
- Mme Traore, SenChim
- Dr Demba Farba Mbaye, CILSS
- Baba Gadj, CERES Locustox

Nigeria interviews completed

- Jiru Bako, Technical Manager Health, Crown Agents
- George Oligbo, Logistics Consultant, Crown Agents
- Joe Odogwu, Society for Family Health
- Olaronke Ladipo, Society for Family Health
- Ernest Nwokolo, Society for Family Health
- Mariane Ngoulla, Health and HIV/AIDS Adviser, ECOWAS commission
- Godwin Aigenagbon, Head R&D, Yakubu Gowon Centre
- Ambassador M.B. Ekpang, Deputy Chief Executive, Yakubu Gowon Centre
- Dr. Sofola, National Coordinator, National Malaria Control Programme
- Caroline Vanderick, Programme Director, SUNMAP
- Maxwell Kolawole, SUNMAP
- Ayodeji Oluwole Odutolu, World Bank
- Hashim Ubale Yusufu, Director Enforcement, NAFDAC
- Pharm, Ariz Chinwe Madukwe, Director, Registration & Regulatory Affairs
- K.O. Ade-Abolade, Pesticide Registration Team, NAFDAC
- Martins A. Awofisayo, Managing Director, Harvestfields (Bayer and Clarke representative)
- Charity Ekemita Obe, Country Manager Vector Control, Syngenta
- Oluwole Adeusi, Country Manager, Netmark
- Kim Rasmussen, Regional Director, Vestergaard Frandsen
- Jeremy Wright, Croplife Nigeria

Country overview interviews completed

| India | China |
|--|--|
| <ul style="list-style-type: none">• Dr R.S. Sharma, National Vector Borne Disease Control Programme• Yogesh Kumar, Rallis International• Dr Sandhya Kulshrestha, Secretary, Central Insecticides Board & Directorate of Plant Protection | <ul style="list-style-type: none">• Gu Baogen, Deputy Director General, ICAMA• Edward Medalla, BASF |