

'The Pharmaceutical Manufacturing Plan for African - pathway to Local Production of Generic Medicines in Africa??

IP FORUM – Gallagher Estate, Midrand

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26th February 2013

Outline

- Overview of Africa's healthcare challenges
- Overview of African pharma industry
- The Pharmaceutical Manufacturing Plan for Africa (PMPA) – the Road Ahead
 - History, Objectives, Vision
 - PMPA Solutions to Grow Africa-based Industry
- Conclusion



Overview of state of Africa's Healthcare systems

High Disease Burden (current)

- 25% of the global disease burden
 - 75% of the global HIV/AIDS pandemic
 - 90% of the malaria cases and deaths
 - 9 countries (excluding North Africa) among the 15 countries with the highest TB burden in the world.
 - MDR-TB and XDR-TB rated among the highest in the world.
 - Significant child mortality – diarrhoeal, measles, URTI etc

High Disease Burden (2030 Projections)

Diseases	Number
Hypertension	60 mil
Diabetes	18.6 mil
Cancer	1 mil (new cases annually)
Other (CNS, CVS, Resp.)	Will surpass HIV / AIDS as leading cause of death

Source: WHO AFRO, Colin D Mathers & Dejan Loncar. *Projections of Global Mortality and Burden of Disease from 2002-2030*. PLoS Medicine Nov 2006, Vol. 3, Issue 11

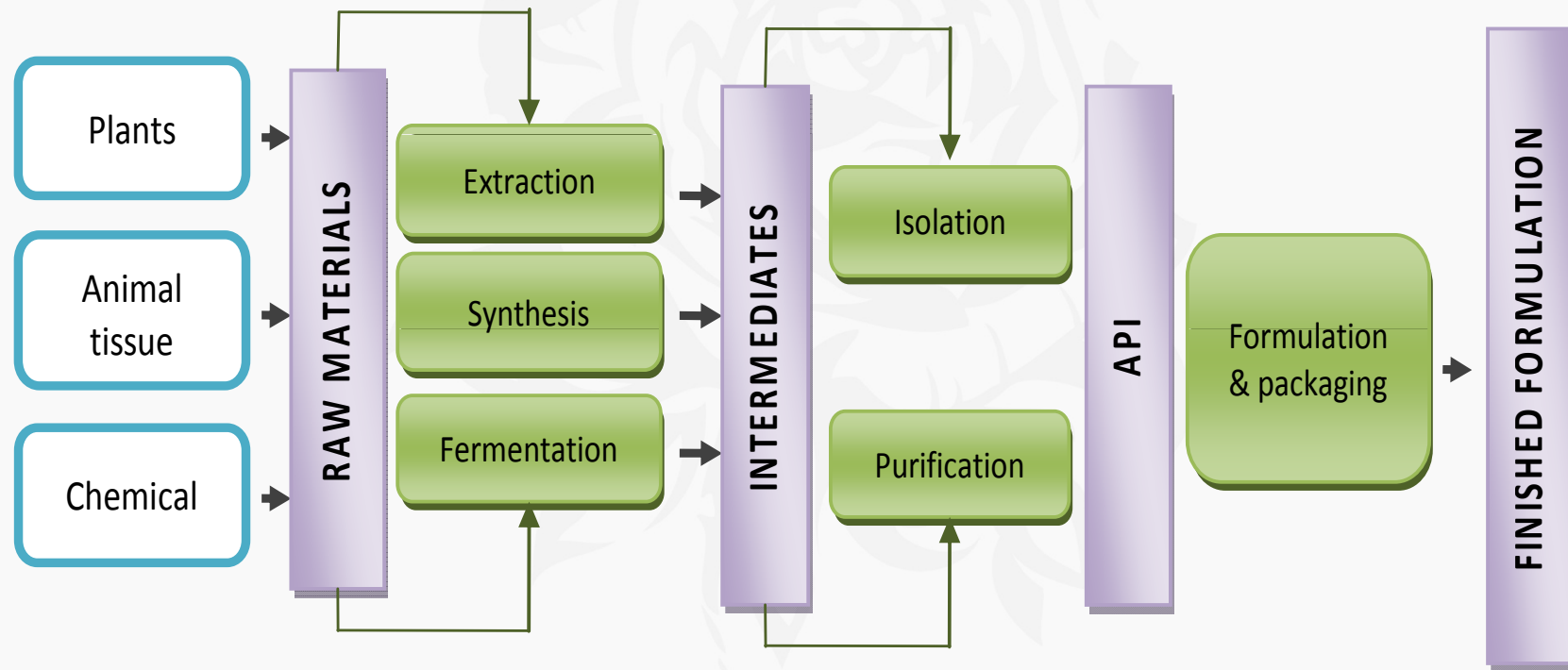
Significant Healthcare challenges

- Poor healthcare infrastructure
 - Software – Shortage of healthcare HR
 - Hard ware – clinics, hospitals, labs, supply chains inadequate
 - Inadequate quality systems -- limited access
- Limited healthcare funding
 - Limited National budgets
 - Donor dependence (? fatigue)



State of African
Pharma - Challenges
and Opportunities

Pharmaceutical Production Process



Source: Metanoia Consulting Pty Ltd (SA)

State of African Pharma

- Africa imports more than 95 percent of API and roughly 75 percent of finished formulations.
- ~38 countries have pharmaceutical manufacturing
- Only 2 with limited API production
 - API Production is the source of Security of Supply
- Various global players active through agencies / distributorships etc
- Big pharma moving plants to centres of excellence globally

African Pharma Challenges

■ **Policy Incoherence**

- Health vs. Industrial vs. Finance / Treasury priorities: Technocrats in key support ministries have limited knowledge of the pharma sector

■ **Lack of Regulatory capacity**

- Lack of resources
- Lack of autonomy, financial independence & frequent incidences of political interference

■ **Lack of Regulatory Harmonization**

- Varying legal and regulatory frameworks
- Delayed registrations
- Increased costs due to need to customise regulatory processes

African Pharma Challenges

■ Counterfeit and Substandard medicines

- USP (2011) - 30 to 50 percent of malaria medicines in some markets are counterfeit and as many as 84 percent in countries sampled on the continent were substandard.
- WHO (2011) - 28.5 percent of the medicines sampled failed to comply with specifications (anti-malarials)
- Direct consequence of the lack of adequate regulatory capacity and proper enforcement

■ Lack of Specialised Pharmaceutical Skills

- Unresponsive training – institutions mostly offer generalist science and retail oriented Pharmacy degrees
- Challenges with external recruitment – e.g. permits

African Pharma Challenges

■ Access to technology

- Absence of home grown - and difficulty in accessing foreign technologies
- Lack of academia / R&D institute & industry interface
- ***The Indian experience – government's catalytic role!!!!***

■ The Pandemic blindside

- Priority given ***LARGELY*** to the three pandemics
- Local production prejudiced by the perceived ease with which African countries can access affordable quality medicines from low cost producers in the east – albeit only for the epidemics

African Pharma Challenges

▪ **Lack of affordable Finance and Incentive Schemes**

- Commercial banks reluctant to offer loans to the industry - interest rates ~ 25-30%
- Absence of well developed stock markets
- Investors have little appetite for the pharmaceutical industry - amounts made available often insufficient for pharmaceutical upgrades (counterfeits / weak regulation / Asian tigers / uncompetitive against local non-GMP firms)
- Unreasonable lending requirements e.g. IFC demands WHO PQ before they can advance a loan – yet loan necessary to assist companies to upgrade for international GMP (? agenda)

African Pharma Challenges

■ **Governance and business culture**

- Founders reluctant to give up control or dilute their influence.
- Poor record keeping – challenges with business evaluations
- Poor governance

■ **Lack of market data / intelligence and information**

- Lack of proper market data - multiple and poorly regulated channels through which products enter and leave the market & unofficial/unlicensed dispensing points
- Public procurement data non existent

Supporting industries & associated infrastructure



African Pharma Challenges

- **Weak or non-existent related and supporting Industries**

- Raw materials, tooling and machine spare parts
- CRO's and BE centers
- Unregulated, fragmented and grossly inefficient pharmaceutical distribution chains
- Utilities unreliable
- Underdeveloped and unresponsive financial and legal infrastructure

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About the PMPA

PMPA Background & Key Milestones

Year	Place	Milestone
2005, July	Abuja	Original decision to develop a PMPA
2007, July	Accra	Initial Plan endorsed by Heads of State
2011, March	Algiers	CAMI Roundtable on local production and incorporation of sector in AIDA
2011, Sep to 2012, April	Vienna	Inception workshop, data gathering, country visits & strategic plan development
2012, May	Geneva	Adopted by the Conference of African Minister's of Health (CAMH) – wide support from stakeholders, UN Agencies, other potential partners
2012, July	Addis	Endorsed by Heads of State of State and Government
2012, Oct /Dec	Vienna / CT	High level meeting with Heads of Agency, AUC, Donors, Political leadership, FAPMA etc

Core objectives

- Support local pharmaceutical manufacturing to:
 - increase access to affordable quality medicines
 - ensure sustainable supply of essential medicines
 - improve public health outcomes
 - promote industrial and economic development

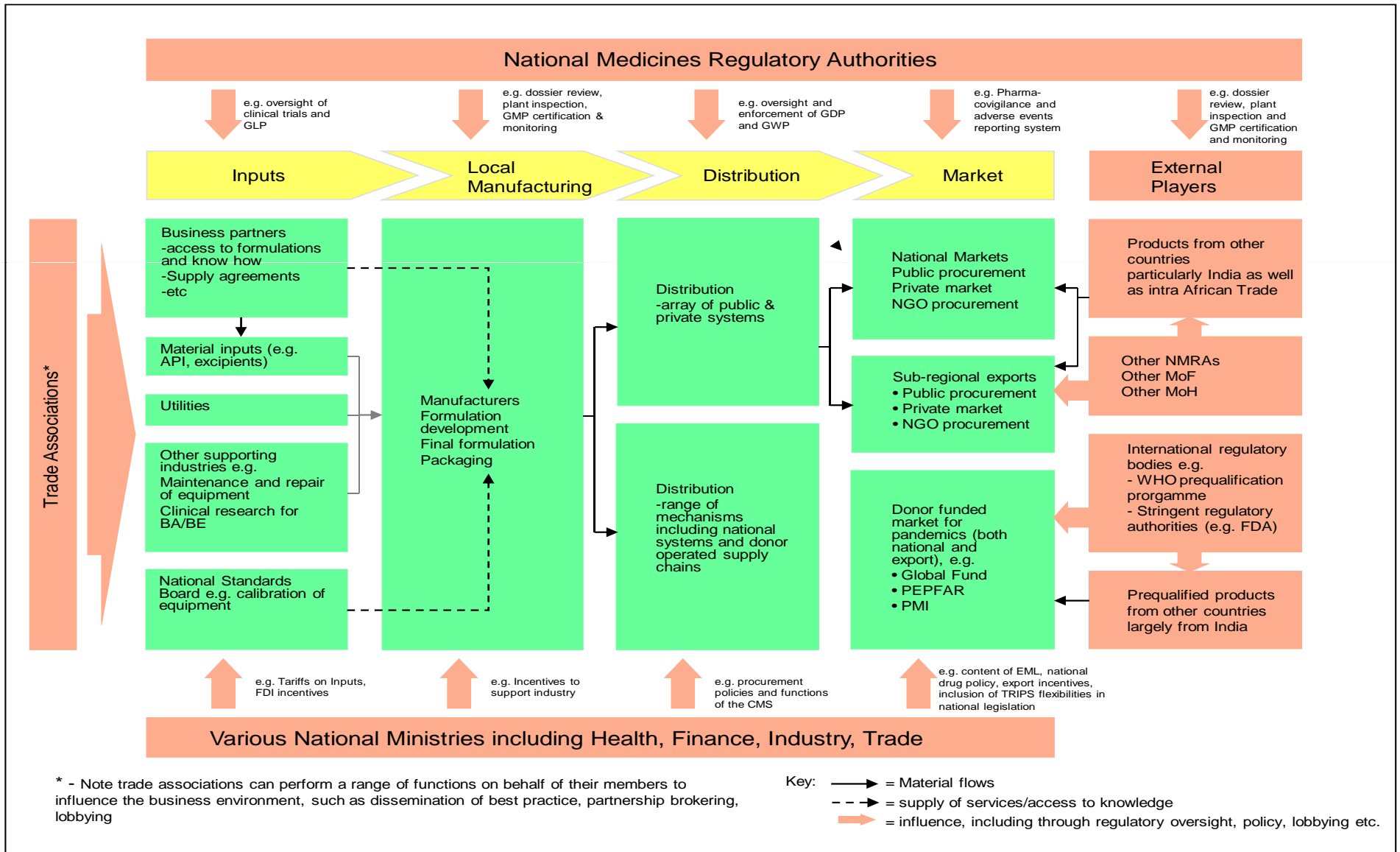
PMPA Vision

To develop a competitive and enduring integrated pharmaceutical manufacturing industry in Africa, able to respond to the continent's need for a secure and reliable supply of quality, affordable, accessible, safe and efficacious medicines.

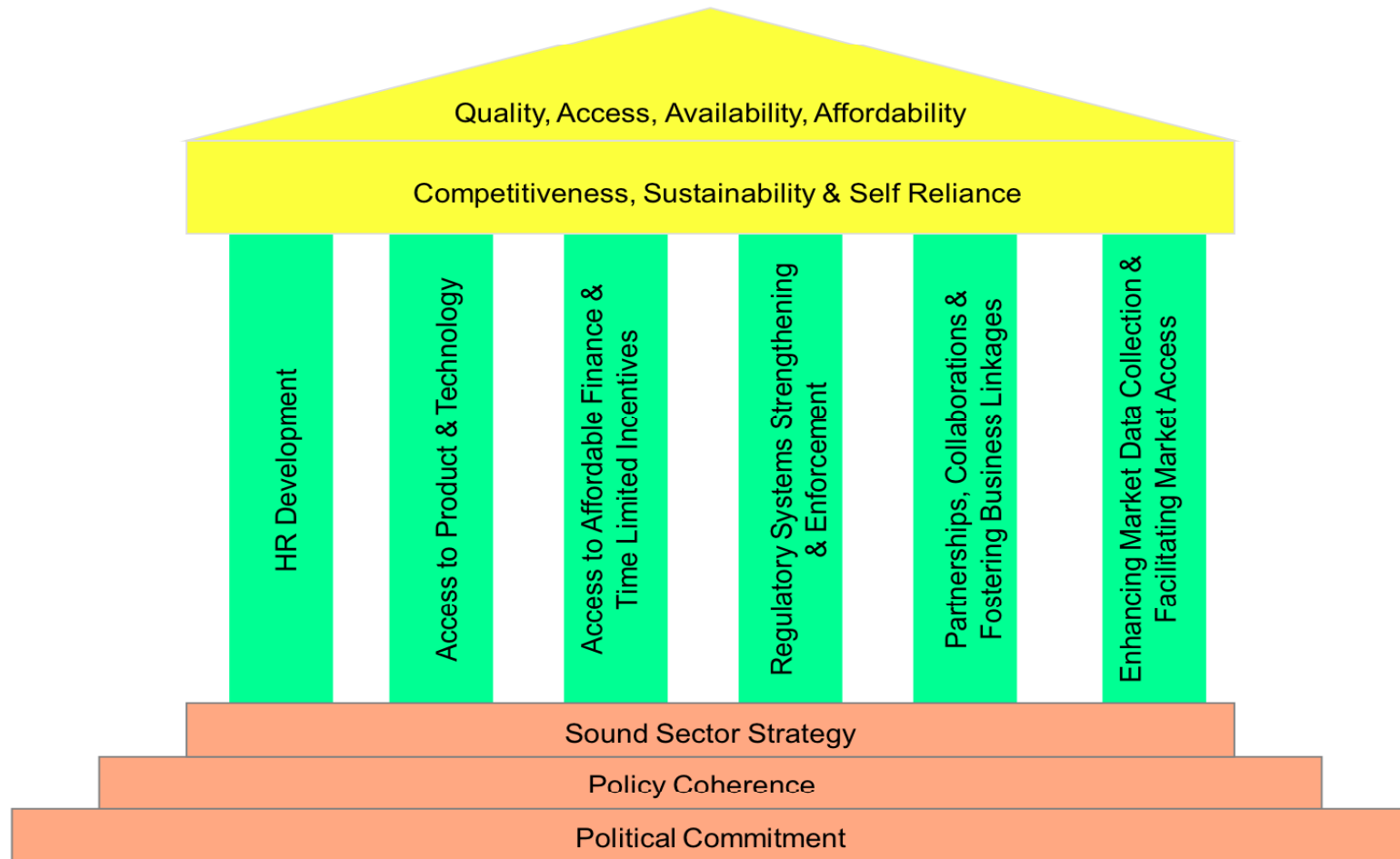


PMPA Package of Solutions for Growing the Africa based Industry

Pharmaceutical 'System'



PMPA Package of Solutions



HR Development

Key objective:

To build capacity to meet skills requirements for local production of affordable and safe quality medicines

Key Interventions:

- ❑ Training of:
 - **NMRAs** (all aspects of Quality - GMP, GDP, GLP, GWP, policy etc.)
 - **Pharmaceutical companies** (e.g. formulation, GMP, Lean manufacturing, business management, plant operations)
 - **Govt policy makers** (e.g. policy development & coherence)
- ❑ Facilitate the review & reorientation of science/pharmacy/engineering curricular at institution of higher learning

HR Development

- **Professional & short courses (< 1 year)**
 - Who - Industry experts, International organisations (e.g. USP, WHO, SRAs)
 - How - Trade associations & NMRA's
 - Where - Centres of excellence
- **Long term courses (> 1 year)**
 - Specialised tertiary institutions (e.g. St Lukes, University of Ibadan, UZ, UCT etc)
 - Centers of Excellence (e.g. ANDI)

Access to Products & Technology

Key objective:

Assist African companies to access and acquire best in class technology & improve product portfolios

Key interventions:

- Working with CoEs, develop formulations and diffuse technology to GMP compliant companies
- Working with UNDP/UNCTAD/ARIPO etc., exploit TRIPS flexibilities to supply donor funded markets in LDC's
- Negotiate directly with patent holders for voluntary licences
- Facilitate access to technology through partnerships; e.g. WHO/EGA/KEMRI/NIPRD etc.

Access to funding & incentives

Key objective:

Assist African companies to access affordable capital, and advise governments on conducive incentives

Key interventions:

- ❑ Advisory and technical assistance to governments on development of policies including incentive programmes that are supportive of the growth of the pharma industry
- ❑ Mobilise enthusiasm for pharma sector and lobby for review of funding /and investment criteria (e.g. local banks and international finance organisations)

Regulatory systems strengthening

Key interventions:

Key objective:

Assist NMRAs to develop the capacity to fulfil their mandate – ensuring that the products on the market are safe, efficacious and of good quality

- Offer technical assistance to
 - Develop legislative framework for the NMRA
 - produce organisational development plans, policies and procedures
 - NMRA's and partnership with AMRH for regulatory harmonisation
- Establish a "GMP road map" & an audit tool to establish baseline for industry & Enhance capacity of NMRA's to enforce

Facilitating partnerships & business linkages

Key objective:

Promote business linkages and partnerships to facilitate access to products, finance, and skills & know how

Key interventions:

- Create a web portal with corporate profiles and a B2B facilitation platform
- Facilitate bi-annual matchmaking meetings and fairs with global counterparts
- Strengthen linkages with ANDI and other CoE's
- Strengthen industry associations & partner with them to foster internal partnerships (e.g. Pooled procurement of products and services)
- Monitor and track deal flow & and the aspirations of global and African pharma

Enhancing market data collection & access

Key objective:

facilitate the collection of market data

Key interventions:

- Identify & partner with reputable research organisations to collect market data and intelligence
- TA to government procurement agencies to develop forecasting and data collection abilities

Facilitating access to market

Key objective:

Assist companies to improve product quality & portfolio thereby strengthening their access to local & funded markets

Key interventions:

- Facilitate acquisition of international GMP standards, product and technology to supply funded markets
- Promote regulatory harmonization and intra-regional trade
- Exploit TRIPS flexibilities

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Conclusion

End

thank you...

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