# Regulatory convergence
# WHO's perspective

*IMDRF meeting*
20 March 2013, Nice, France
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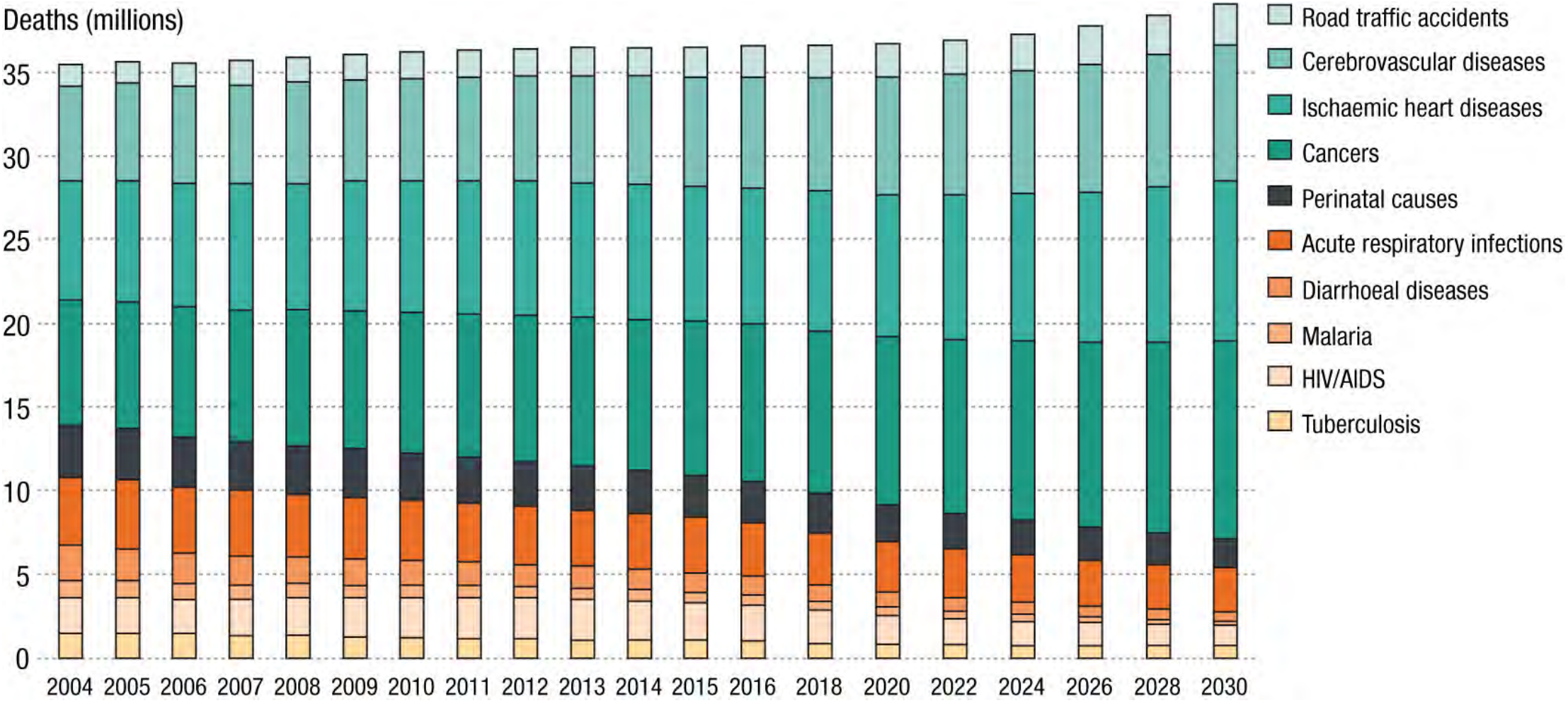
# Epidemiological Changes: increasing NCDs



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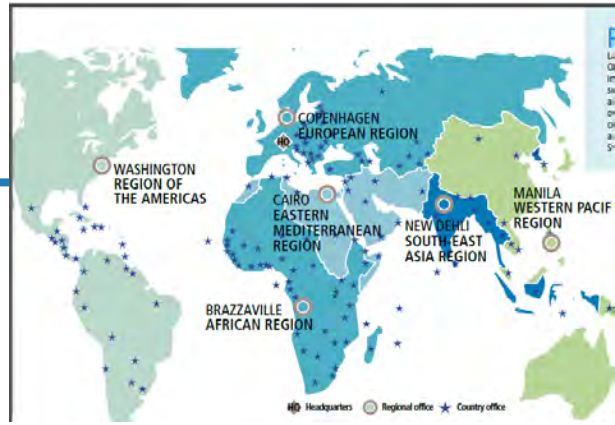


- 194 member countries
- WHO mandate:
  - Norms and standards for medical products
  - To promote improved access to safe and quality medical products
- World Health Assembly:
  - maximum governing body
  - 60TH World Health Assembly , 23 May, 2007 approved resolution WHA60.29:

***WHA60.29 " to draw up Regional guidelines for GMP and regulatory practices to ensure quality , safety and efficacy of medical devices… and participate in international harmonization".***



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# To promote improved access to safe and quality medical products

## Medicines

- Policies, access, pricing
- Essential Medical List (EML)
- Norms and standards ( INN)
- Regulation and safety monitoring
- Prequalification
- SSFFC medicines

## Vaccines

- Quality
- Safety
- Prequalification

## Medical Devices

- Prequalification of IVD
- Medical devices and IVD regulations
- Health technology management
  Safe use
- Policies for medical devices and HTA

# Regulatory convergence in medicines and vaccines

- Nomenclature : INNs
- WHO Expert Committees guidelines + norms/standards
- ICH guidelines
- ICDRA
- (sub-)regional collaboration initiatives : EU, PANDRH, ASEAN; ARMH; APEC, …..
- Global Safety Monitoring, Uppsala Center

# To promote improved access to safe and quality medical products

## Prequalification of priority diagnostics

- Dossier review
- Laboratory evaluation
- Inspection
- Using GHTF guidance

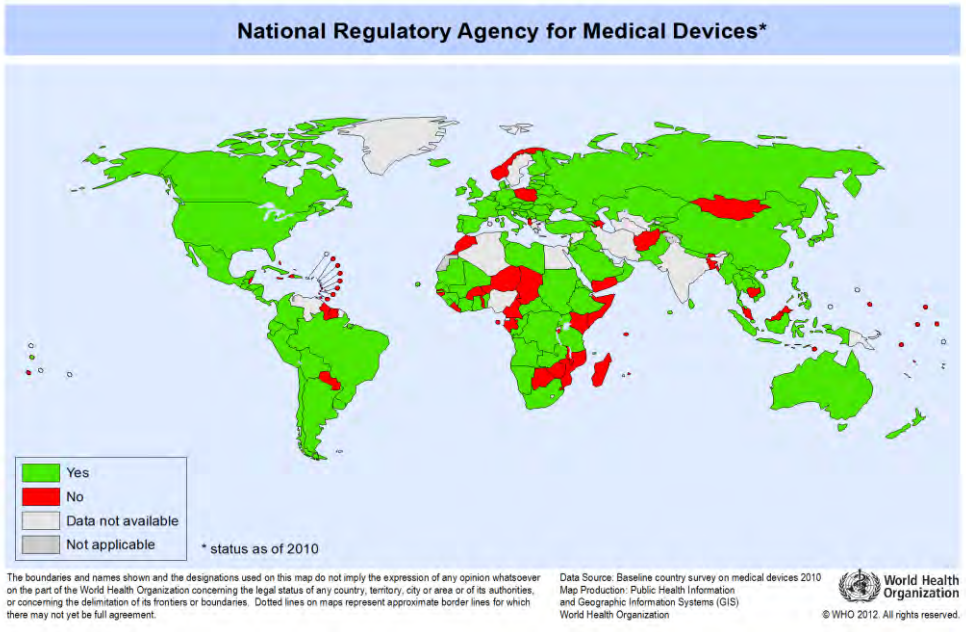
# Regulatory problems with prequalification of diagnostics

- Multiple regulatory versions for the "same" product
- Variable stringency of regulatory review by NRAs
  - depends on risk classification
  - if product is for export-only, minimal review
- Variable stringency of conformity assessment bodies/inspection agencies
  - Some inspections may be outsourced to in-country agencies
  - Differences in QC lot release procedures for different regulatory agencies/ notified bodies

# Strengthening Regulatory Capacity for prequalifing diagnostics

- Provide tailor-made technical support to Member States
  - Legislative framework
  - Registration, processes and procedures, PMS
- Learning by doing
  - Dossier assessments
  - Inspections
  - Lot testing
- Promote global harmonization (GHTF) and networking
  - Fast track procedures
  - Sharing information

# Regulations of medical devices

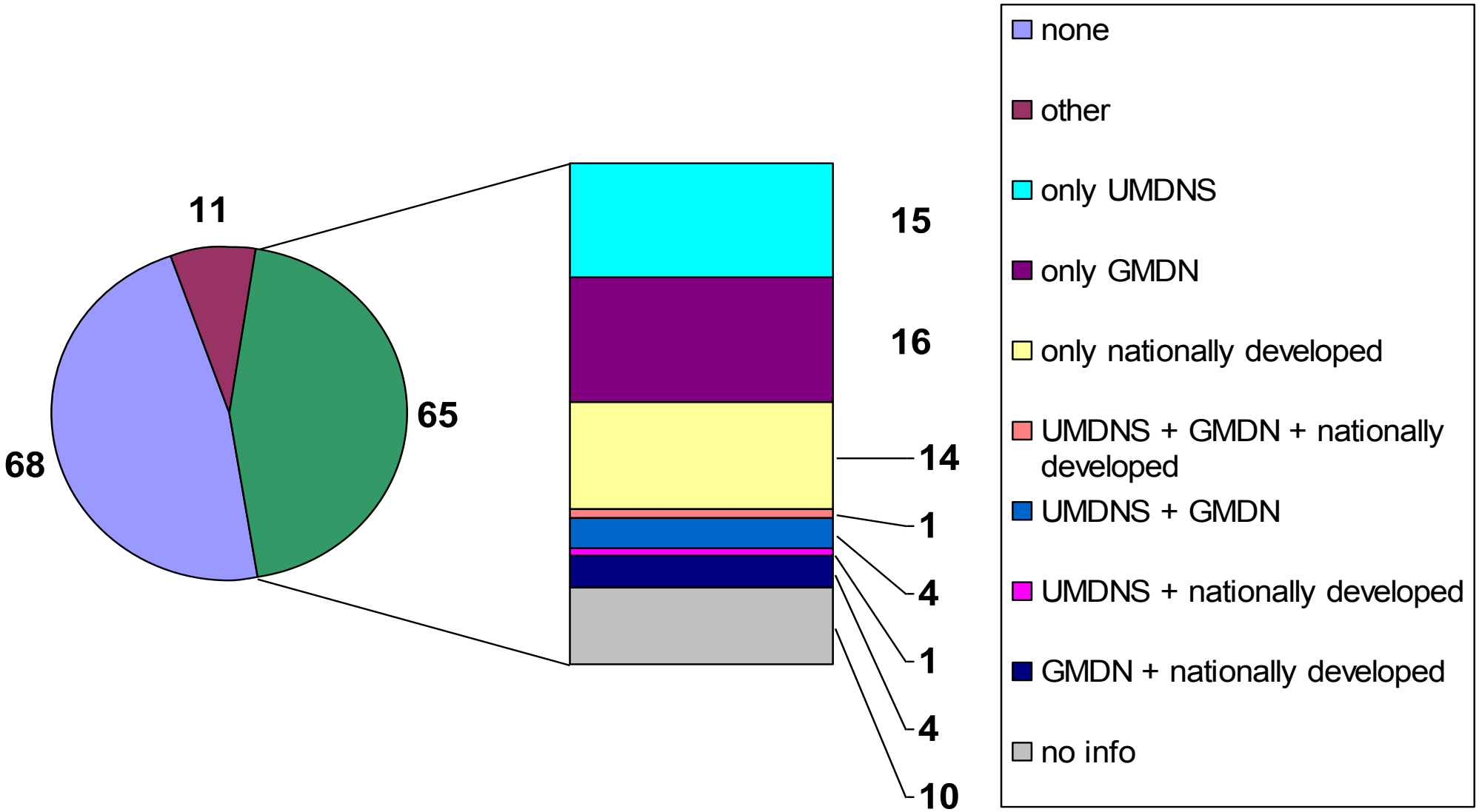



Only 65% of member states have any form of medical devices regulation

Approximately only 33% have IVD regulation

- **In LMIC:**
  - lack of specialized knowledge, staff and resources to perform medical devices regulations.
  - Very weak post market surveillance
  - Lack of regulation, identified as a barrier to safe and effective medical devices

# Status of Nomenclature Systems in 144 MS



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# Importance of a nomenclature system

## Nomenclature and product name

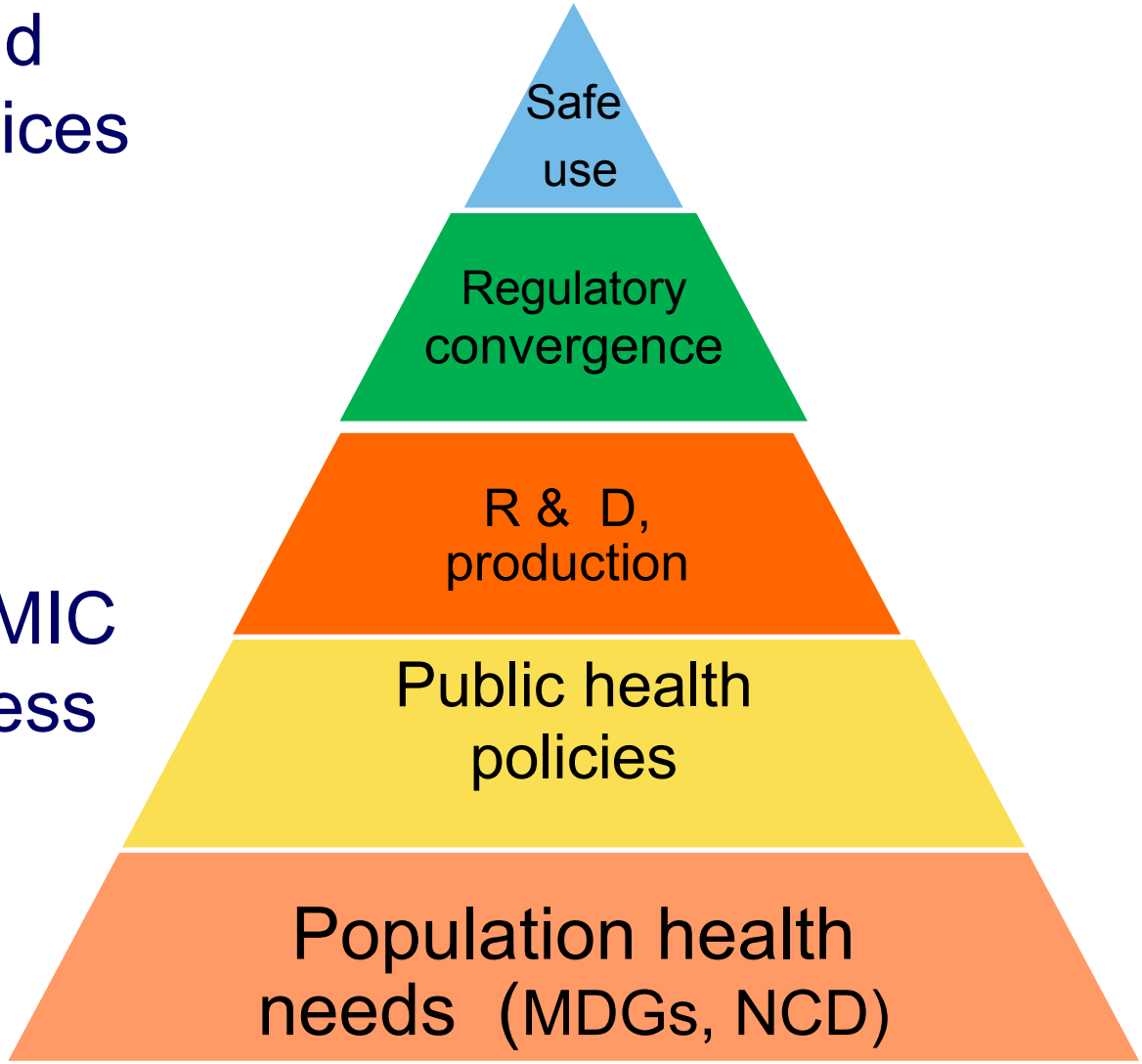
| | | |
|---|---|---|
| Transparent code designation for new / innovative products<br>UDI manufacturer | For regulatory authorities:<br>registration, RSP, post market surveillance. | In health services delivery,<br>patients and health professionals:<br>Access : from selection to safe use,<br>tracking user problems |

# Lack of regulatory convergence affects patients

- Hinders access to medical products
- Increases final cost of medical devices
- Slows  access to innovative products
- Decreases responsiveness to post-market problems
- Increases possibilities of counterfeit devices
- Quality and safety cannot be assured in an equitable manner.

# WHO challenges and next steps: promote access to safe medical devices of good quality

- Need for global norms and standards for medical devices
- Promote regulatory strengthening and convergence
- Capacity building
- Balance participation of LMIC in global regulatory process of medical devices.



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# Thanks
# www.who.int/ medical devices/ en


**WHO Medical Devices Reports (2008-2012)**


**WHO Regions**

## Country Publications




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