WHO Prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Overview of prequalification processes & product-specific updates

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WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
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Conclusion
• **WHO-PQ contributed to the Millennium Development Goals (MDGs):**

• Eight international development goals that 192 United Nations member states and at least 23 international organizations have agreed to achieve by the year 2015

4. **Reduce child mortality**
5. **Improve maternal Health**
6. **Combat HIV/AIDS, Malaria and other diseases**
WHO-PQ contributes to the achievement of Sustainable Development Goals (SDGs)

WHO-PQ by making safe quality priority health products available through efficient and scientifically solid assessment contributes to achieving SDGs and UHC. SDG 3 targets by 2030 include:

- reduce the global **maternal mortality**
- end preventable deaths of newborns and children under 5 years of age,
- end the epidemics of **AIDS, tuberculosis, malaria and neglected tropical diseases** and combat **hepatitis**, water-borne diseases and other communicable diseases
- ensure universal access to sexual and **reproductive health-care** services, including for **family planning**
- Achieve **universal health coverage**, including access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
- Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries and provide access to medicines for all
Structure of the Prequalification Team

Prequalification Team

Coordinator’s office

Vaccines Assessment

Medicines Assessment

Diagnostics Assessment

Inspections

Vector control

Administrative team
The prequalification team is responsible for the quality-assurance of IVDs, MCDs, FPPs, APIs, QCLs, vaccines, immunization devices, VCPs and VCIs.

<table>
<thead>
<tr>
<th>Diagnostics (Dx) assessment of in-vitro diagnostics (IVD) &amp; male circumcision devices (MCD)</th>
<th>Medicines (Mx) assessment of finished pharmaceutical products (FPP) &amp; active pharmaceutical ingredients (API)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines (Vx) assessment of vaccines &amp; immunization devices (ImD)</td>
<td>Vector control (VCx) assessment of vector control products (VCP) &amp; vector control active ingredients (VCAI)</td>
</tr>
<tr>
<td>Inspections of manufacturing sites</td>
<td></td>
</tr>
<tr>
<td>Laboratory evaluation &amp; testing of Dx, Mx &amp; Vx</td>
<td>Laboratory prequalification of Mx quality control laboratories (QCL)</td>
</tr>
<tr>
<td>Technical assistance to manufacturers, NRAs and other stakeholders</td>
<td></td>
</tr>
<tr>
<td>Facilitation of National regulatory approval for Dx, Mx &amp; Vx</td>
<td></td>
</tr>
</tbody>
</table>
The prequalification team is responsible for the quality-assurance of IVDs, MCDs, FPPs, APIs, QCLs, vaccines, immunization devices, VCPs and VCI.

A pilot WHO prequalification process for similar biotherapeutic products to be launched on 1 September 2017.

WHO will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: rituximab and trastuzumab.
Through the prequalification process, WHO has made available numerous quality-assured products to WHO Member State markets.

At the close of 2016, PQT’s list of prequalified products included:

- **Medicines**
  - 416 FPPs
  - 100 APIs
  - 41 QCLs

- **Diagnostics**
  - 64 IVDs
  - 2 MCDs

- **Vaccines**
  - 147 Vx
  - 310 ImDs

- **Vector control**
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

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1. Introduction
2. Prequalification role
3. Prequalification process
4. Product-specific updates
5. Conclusion
The mission of WHO prequalification is to ensure timely availability of quality-assured medical products for the prevention, diagnosis and treatment of priority diseases in LMICs

**Goal**
- Make quality priority products available in a consistent and timely manner
- Ensure sustainable supply of quality-assured products
- Create national capacity to evaluate and monitor the ongoing quality of products

**Strategy**
- Apply and promote unified quality, safety and efficacy/performance standards, for a comprehensive evaluation of medical products
- Build the capacity of staff from NRAs, QC labs, manufacturers or CROs

**Key outputs**
- List of prequalified products and QCLs
- WHO public reports
- Accelerated national registration of prequalified products
- Increased regulatory capacity at national level
- Improved GMP and QMS
WHO prequalification has also raised awareness of the importance of quality-assurance of medical products in resource-limited settings, made available and facilitated the uptake of new products.

**Common achievements**

- Creation of awareness of **quality issues** to regulators, manufacturers and procurers
- Building of **NRA capacity** and regulatory **harmonization**
- Improvement of manufacturers **GMP status and QMS**
- Development and implementation of **quality policies** with procurement agencies
- Development of a **robust mechanism** applicable to different types of products and diseases
- Adaptation to the **needs of stakeholders**
- Creation of a **sustainable and affordable market** of quality-assured products
WHO prequalification assesses the quality, safety and efficacy/performance of medical products, while focusing on the specific needs in resource-limited settings.

**Unique PQ characteristics**

- **Programmatic suitability**: specific emphasis on issues of particular relevance to resource-limited settings, such as:
  - Stability of products (heat conditions)
  - Adapted specimen type (Dx)/ formulation (Rx)/ presentation (Vx)
  - Labelling of products
  - Ease of use (in terms of training and material)

- Efficacy/performance evaluated in the **global population**
- **Life cycle management** of products
- **Strengthening** manufacturers and NRAs capacity
The prequalification team interacts with a number of public and private stakeholders within the global public health environment.
**WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise.**

### Patients
- Access to quality-assured products, adapted to their specific needs
- Accurate prevention, diagnosis, and treatment

### WHO Member States & NRAs
- Reduced burden for regulatory approval
- Increased regulatory capacity & harmonization of regulatory practices in WHO MS
- Implementation of specifically developed and road-tested international guidelines
- Access to quality-assured products

### Donors, procurers and UN agencies
- List of prequalified products
- Increased availability of quality-assured products
- Monitoring quality of prequalified products
- Healthy market: diversity and affordability of products
WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise.

**Benefits for stakeholders**

- Access to donor-sponsored tenders
- Faster regulatory approval
- Timely assessment of variations and changes
- International quality-assured product status (improved image)
- Recognition of GMP status, beyond prequalified products
- Increased capacity in quality management systems
- Target Product Profiles
- Harmonization of regulatory practices within WHO Member States
- Reduced operating and manufacturing costs

**Manufacturers**

- International recognition of prequalified QCLs
- Technical assistance and scientific advice

**QC labs**
Outline

1. WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

   - Introduction
   - Prequalification role
   - Prequalification process
   - Product-specific updates
   - Conclusion
WHO-PQm process

Expression of Interest

Product dossier
SMF

Assessment
Additional information and data

Acceptable

Inspections
Corrective actions

Compliance

Prequalification

Maintenance and monitoring
Collaborative registration

Variations
Requalification

Routine inspections
Special inspections
Handling complaints

FPP: GMP
API: GMP
CRO/BE: GCP/GLP

Follow-up NOC
Closing letter WHOPIR
For each type of product, prequalification includes a comprehensive dossier assessment and a manufacturing site inspection, as well as other product-specific elements of evaluation…
… such as the pre-submission form and laboratory evaluation for in vitro diagnostics
… or NRA functionality and programmatic suitability for vaccines

Prequalification workflow

Dossier submission

Screening

NRA functionality

Programmatic suitability

Assessment

CAPA

Prequalification decision

Inspection

Follow-up inspection

CAPA
In addition, SRA-approved products are evaluated according to the abridged prequalification procedure.
→ In addition, SRA-approved products are evaluated according to the abridged prequalification procedure

**Eligibility criteria for abridged assessment**

**Diagnostics**
- IVDs only
- Stringently assessed SRA-approved products & their RoW version if no substantial difference

**Medicines**
- FPPs only
- SRA-approved

**Vaccines**
- Vaccines only
- SRA-approved

Prequalification workflow
WHO prequalification seeks to add value and never duplicate the work already performed by stringent regulatory authorities, while encouraging NRAs to rely on the work of WHO prequalification.

Example of WHO PQ reliance on other SRAs:

- Development of **guidelines** only where gaps exist
- **Abridged assessment** for prequalification of SRA approved products
- Recognition of manufacturing site **inspections** performed by SRAs (Mx only)
- On request from the manufacturer, **listing** of products evaluated under EU art. 58, USFDA tentative approval, PEPFAR and Health Canada approval
- Use of **EDQM CEPs** in FPP and API application

Example of NRAs reliance on WHO PQ:

- **Collaborative procedure** for national registration
- **API prequalification** recognized by NRAs
Ensuring the ongoing quality of prequalified products is an equally important responsibility of the prequalification team.

**Post-PQ validation**
- Annual report review
- Reinspection
- Requalification

**Post-marketing surveillance**
- Sampling & testing
- Adverse event monitoring

**Systematic**
- Variations/changes assessment

**Triggered**
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NEW PQTm WEBSITE
https://extranet.who.int/prequal/

Essential Medicines and Health Products: Prequalification of medicines

- DOCUMENTS A-Z
  - PREQUALIFIED LISTS
    - Medicines/finished pharmaceutical products
    - Active pharmaceutical ingredients
    - Medicines quality control laboratories
  - PREQUALIFICATION PIPELINE
    - Summary: FPPs & APIs invited/prequalified/under assessment
    - FPPs under assessment
  - FPPs and APIs Eligible for Prequalification (EOIS)

- PROCEDURES & FEES FOR WHO PREQUALIFICATION
  - Medicines / FPPs
  - Active pharmaceutical ingredients
  - Medicines quality control laboratories

- POST-PREQUALIFICATION PROCEDURES
  - Amendments to API MFs
  - Variations to FPPs
  - Requalification of FPPs
  - Quality monitoring
  - Notices of concern/suspension
  - Monitoring QCL performance

- PREQUALIFICATION REPORTS
  - WHO Public Assessment Reports
  - WHO Public Inspection Reports

- GUIDANCE DOCUMENTS
  - WHO Technical Report Series
  - WHO medicines prequalification guidance
  - International Pharmacopoeia

- COLLABORATIVE PROCEDURES FOR ACCELERATED REGISTRATION
  - Accelerated registration of prequalified FPPs
  - Accelerated registration of FPPs approved by SRAs

- SUPPORT TO MANUFACTURERS, CROS AND QCLS
  - Technical advice
  - Technical assistance

- MARKET INFORMATION

- WHO response to the USFDA import alert issued for Qinhuangdao Zizhu Pharmaceutical Co Ltd, Active Pharmaceutical Ingredient (API) manufacturing site
  - 11 APRIL 2017

- 9th Annual PQT Medicines Quality Assessment Training
  - Copenhagen K, Denmark
  - 15 - 19 MAY 2017

- • Prequalified Lists:
  - finished pharmaceutical products
    - International Classification of Medicines (ICM 2007)
New Funding Structure for PQ

• **Background and process:**
  – Fees to WHO in place – vaccine since 1999, In-Vitro Diagnostics since 2010 and **medicines since 2013**
  – following a year of discussions between WHO, Industrial groups and key partners
  – **The new fee structure for vaccines and medicines was effective 01 January 2017**, and in early 2018 for diagnostics.

• **Objectives:**
  – ensure the **financial sustainability** of WHO’s PQ
  – to make PQ **better equipped** to address current global quality challenges,
  – to lay the ground for **strengthening and expanding services provided**, and
  – to **improve financial predictability and transparency**

• **Fees structure:**
  – Designed to **ensure equity** among manufacturers
  – **modelled on the practice of NRAs** around the world,
### New Funding Structure for PQ

#### Fees principles and structure:

- product nature: active pharmaceutical ingredient (API) or finished pharmaceutical product (FPP);
- type of assessment: full or abridged assessment of new application, or assessment of major variation;
- an annual maintenance fee tailored to whether the initial assessment was full or abridged.

<table>
<thead>
<tr>
<th>Assessment fee</th>
<th>Annual Fee per product</th>
<th>Variations</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Full</td>
<td>Abridged</td>
<td>Major</td>
</tr>
<tr>
<td>FPP</td>
<td>$25,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>API</td>
<td>$20,000</td>
<td>$3,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td>$6,000</td>
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<tr>
<td></td>
<td>$8,000</td>
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</tbody>
</table>
### Table 1: Fees for FPP and API prequalification applications (effective 1 January 2017)

<table>
<thead>
<tr>
<th></th>
<th>Single Registration Fee Per Product</th>
<th>Annual Fee Per Product</th>
<th>Post-PQ Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application Fee</td>
<td>Annual Fee</td>
<td>Major variation</td>
</tr>
<tr>
<td>FPP – Full assessment</td>
<td>$25,000</td>
<td>$20,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>FPP – Abridged assessment¹</td>
<td>$6,000</td>
<td>$5,000</td>
<td>NA</td>
</tr>
<tr>
<td>API</td>
<td>$20,000</td>
<td>$8,000</td>
<td>$3,000</td>
</tr>
</tbody>
</table>

¹ Refer to SRA-Approved Multisource (Generic) or Innovator FPPs procedure - https://extranet.who.int/prequal/content/abbreviated-assessment-multisource-generic-or-innovator-product-0

### Table 2: Fees for Vaccine prequalification applications (effective 1 January 2017)

<table>
<thead>
<tr>
<th></th>
<th>Single Registration Fee Per Product</th>
<th>Annual Fee Per Product</th>
<th>Site Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application Screening Fee</td>
<td>Abridged assessment procedure²</td>
<td>Full assessment procedure</td>
</tr>
<tr>
<td>Simple / Traditional Vaccines</td>
<td>$2,500</td>
<td>$25,000</td>
<td>$100,000</td>
</tr>
<tr>
<td>Combinations or Novel Vaccines</td>
<td>$5,000</td>
<td>$55,500</td>
<td>$232,750</td>
</tr>
</tbody>
</table>

PQT – revised fee model

• The fees are structured to consider the type of product, complexity, assessment procedure, and manufacturer sales (vaccines only)

• The model includes both an application fee and annual fee.

• The annual fee:
  – for medicines and APIs is fixed, whereas for vaccines the annual levy is linked to sales from PQ’d vaccines (PQ enabled sales).
  – The annual fee will be invoiced on the 1 October each year for all products that have been present on the list of prequalified APIs, or FPPs for 12 months or greater as of the 1 September of that year.

• The Medicine and API fee covers both assessment and inspection activities, whereas for vaccines assessment and inspection activities are charged separately.

Key performance Indicators (KPIs)  
- Reasons & Advantages -

Reasons for introducing new performance metrics

- Encouragement from the Gates Foundation for developing indicators measuring performance (as opposed to project-related indicators)
- Increased transparency for manufacturers and other stakeholders following the introduction of the new fee model

Advantages of those new performance indicators

- Following up the progress of applications throughout the PQ pipeline (as opposed to only measuring timeline at the end of the PQ assessment)
- Monitoring performance of the different components of the PQ assessment
- Measuring performance of processes controlled by WHO PQ (limited external influence on performance)
Key performance Indicators (KPIs) - Approach & Development -

First, the harmonization initiative…

- Harmonization of terminology across product streams, for PQ and PQ-related product and processes
- Alignment of phases and steps of PQ processes across product streams, including PQ assessment and post-PQ processes
- New algorithm for calculating WHO and manufacturer time, now identical for all types of products

... then, the new performance indicators

- Development finalized, but full implementation pending the new IT system launch

... and finally the KPIs

- KPIs are a subset of the application-based performance indicators to be reported publicly
# Key performance Indicators (KPIs)

## Annual PQ cohort (products *prequalified* in a calendar year)

<table>
<thead>
<tr>
<th>KPI</th>
<th>Description</th>
<th>70% (30% for APIs)</th>
<th>Full assessment:</th>
<th>Abridged assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Number of products PQed</td>
<td>-</td>
<td>270 calendar days, 350 calendar days for IVDs PQed</td>
<td>100 calendar days, 180 calendar days for IVDs PQed</td>
</tr>
<tr>
<td>110</td>
<td>Median WHO PQ time</td>
<td>-</td>
<td>without the alternative laboratory mechanism</td>
<td>without the alternative laboratory mechanism</td>
</tr>
<tr>
<td>111</td>
<td>Median manufacturer PQ time</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>112</td>
<td>Median total PQ time</td>
<td>-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Submission cohort (PQ applications *submitted for PQ assessment* in a calendar year)

<table>
<thead>
<tr>
<th>KPI</th>
<th>Description</th>
<th>80%</th>
<th>30 calendar days</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>Number of PQ applications submitted</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>210</td>
<td>Number of ‘screening first actions’</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>211</td>
<td>% of 'screening first actions' taken at or below target time</td>
<td>80%</td>
<td></td>
</tr>
</tbody>
</table>
# Key performance Indicators (KPIs)

## Assessment cohort (PQ applications accepted for PQ assessment in a calendar year)

### Time to 'first action'

<table>
<thead>
<tr>
<th>KPI</th>
<th>Description</th>
<th>Target Time</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>Number of PQ applications accepted</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>310</td>
<td>Number of ‘dossier first actions’</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>KPI 3.1</strong></td>
<td>% of ‘dossier first actions’ taken at or below target time</td>
<td>80%</td>
<td>90 calendar days, 120 calendar days for FPPs &amp; APIs (due to fixed assessment sessions)</td>
</tr>
<tr>
<td>320</td>
<td>Number of ‘inspection first actions’</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>KPI 3.2</strong></td>
<td>% of ‘inspection first actions’ taken at or below target time</td>
<td>80%</td>
<td>210 calendar days</td>
</tr>
<tr>
<td>330</td>
<td>Number of 'laboratory first actions’</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>KPI 3.3</strong></td>
<td>% of 'laboratory first actions’ taken at or below target time</td>
<td>80%</td>
<td>180 calendar days</td>
</tr>
</tbody>
</table>

## Change cohort (post-PQ change applications accepted for change assessment in a calendar year)

### Time to 'post-PQ change first action'

<table>
<thead>
<tr>
<th>KPI</th>
<th>Description</th>
<th>Target Time</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>400</td>
<td>Number of post-PQ change applications assessed</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>410</td>
<td>Number of ‘post-PQ change first actions’</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
| **KPI 4** | % of 'post-PQ change first actions' taken at or below target time | 80%         | APIMF | major (minor) amendment: 90 (60) calendar days  
APIMF | immediate notification: 45 calendar days  
FPP | major (minor) variation: 90 (60) calendar days  
FPP | immediate notification: 45 calendar days  
IVD | reportable change: 90 calendar days  
Vx | major variation, type A: 90 calendar days |

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**Assessment cohort** includes PQ applications accepted for PQ assessment in a calendar year.

**Change cohort** includes post-PQ change applications accepted for change assessment in a calendar year.
The collaborative procedure enables NRAs to accelerate the registration of prequalified products so that they can enter local markets more quickly.

**Principles**
- WHO PQ shares the reports that served as the basis for the prequalification decision, so that NRAs do not conduct assessment and inspections.
- National registration based on PQT evaluation.

**Diagnostics**
- Procedure in development.
- Ongoing discussions with NRAs.

**Medicines**
- Started in 2012.
- **As of December 2016:**
  - 30 countries participating.
  - 183 registrations in 20 countries for 73 different products.

**Vaccines**
- **In 2015:**
  - Adopted by expert committee (ECBS).
### Participating NMRAs

1. Armenia
2. Botswana
3. Burkina Faso
4. Burundi
5. Cameroon
6. *Caribbean Community (CARICOM)*
7. Cote d'Ivoire
9. Eritrea
10. Georgia
11. Ghana
12. Kenya
13. Kyrgyzstan
14. Lao PDR
   * CARICOM

   **Member States:** Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago

   **Associate Member States:** Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

15. Madagascar
16. Malawi
17. Mali
18. Mozambique
19. Namibia
20. Nigeria
21. Philippines
22. Senegal
23. Sierra Leone
24. South Africa
25. Tanzania
26. Uganda
27. Ukraine
28. Zambia
29. Zanzibar
30. Zimbabwe

*As at 12 May 2017*
Country registrations & therapeutic area

Total registrations: 215
(As at 12 May 2017)
No products registered or under review yet: Georgia, Lao PDR, Sierra Leone, Zanzibar

As at 12 May 2017
### Pipeline of applications, by company

<table>
<thead>
<tr>
<th>Company (when started)</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
<th>100</th>
<th>120</th>
<th>140</th>
<th>160</th>
<th>180</th>
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<tbody>
<tr>
<td>Macleods Pharmaceuticals</td>
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<td>Strides Shasun Limited</td>
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<td>Cipla Ltd (Jan-14)</td>
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<td>Hetero Labs Limited (May-...)</td>
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<td>Jai Pharma (formerly:...)</td>
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<td>Mylan Laboratories Ltd</td>
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<td>Lupin Ltd (Jun-16)</td>
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<tr>
<td>China Resources Zizhu</td>
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<td>Strides Pharma Global Pte...</td>
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- **Registered**
- **Under review**
- **Dossier awaited**

As at 12 May 2017
Time to registration
(2013 – 2017 to date, n=215)
Including regulatory time and applicant time

As at 12 May 2017
Median time to registration

*Including regulatory time and applicant time

As at 12 May 2017

Days*

Days

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<td>All (n=215)</td>
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</table>
The same pharmaceutical product...

1. Product (technical content) dossier,
2. Manufacturing chain, processes and control of materials,
3. API and FPP specifications
4. Bioequivalence information and
5. Essential elements of product information.
PQT IT System: management expectations

- Harmonization of business processes
- Consolidation of disparate IT systems
- Capability for automated reporting across product streams
- Stakeholder access to dashboard reporting
- Applicant access to application status tracking
Key Business Requirements and Functionalities

- Authorized Access and Verification
- Portal for web based submissions
- Database for entry, storage and retrieval of Records and Attributes
- Workflow
- Reports/Dashboard
- Document Management
- Integrated Web Publication
- Accounting
Project Scope

- **Business units**: all current PQT units and applicable RSS units
- **Data**: Pre-qualification findings, vendors, products, sites, authorities, external and internal assessment and inspection documents, migration from current solutions
- **Processes**: All PQT activities and technical assistance that support PQT are considered to be in scope
- **Location**: Global Access
- **Users**: WHO/PQT staff, external consultants (inspectors and assessors), manufacturers submitting applications for assessment, national regulatory authorities and procurement agencies
- **Training**: On site training for internal users; remote or access to training materials for all the others