# Prequalification Timeline Key Performance Indicators (KPIs)
## — Summary Table —

This document is a summary table of **PREQUALIFICATION TIMELINE KPIs**, containing details of indicators and targets. Targets have been set for 2018 and may be revised one year after implementation, to include new targets from 2019 onwards, once preliminary results have been collected and reviewed. This should be read in conjunction with the full background information relating to prequalification (PQ) timeline indicators.

| # | Indicator | % Target | Target time |
|---|---|---|---|
| **APPLICATION-BASED PERFORMANCE INDICATORS** | | | |
| **Annual PQ cohort (products *prequalified* in a calendar year)** | | | |
| **Products prequalified → for applications accepted after 1 January 2015, 2016 for APIs (i.e. the annual PQ cohort)** | | | |
| 100 | Number of products prequalified | - | - |
| 101 | Median number of dossier review cycles | - | - |
| 102 | % of products prequalified for which the number of dossier review cycles is at or below target | 70% | Target number of dossier review cycles: 3 |
| **Time to prequalification (from acceptance for assessment to prequalification) → for applications accepted after 1 January 2015, 2016 for APIs** | | | |
| 110 | Median WHO PQ time | - | N/A |
| 111 | Median manufacturer PQ time | - | N/A |
| 112 | Median total PQ time | - | N/A |
| **KPI 1** | **% of products prequalified at or below target WHO PQ time** | **70% (30% for APIs)** | **Full assessment:** 270 calendar days, 350 calendar days for IVDs prequalified without the alternative laboratory mechanism <br> **Abridged assessment:** 100 calendar days, 180 calendar days for IVDs prequalified without the alternative laboratory mechanism |
| **Submission cohort (PQ applications *submitted for PQ assessment* in a calendar year)** | | | |
| **PQ applications submitted for PQ assessment (i.e. the submission cohort)** | | | |
| 200 | Number of PQ applications submitted for PQ assessment | - | - |
| **Time to *screening first action*** | | | |
| 210 | Number of *screening first actions* | - | - |
| **KPI 2** | **% of *screening first actions* taken at or below target time** | **80%** | **30 calendar days** |
| **Assessment cohort (PQ applications *accepted for PQ assessment* in a calendar year)** | | | |
| **PQ applications accepted for PQ assessment (i.e. the assessment cohort)** | | | |
| 300 | Number of PQ applications accepted for PQ assessment | - | - |
| **Time to *dossier first action*** | | | |
| 310 | Number of *dossier first actions* | - | - |
| **KPI 3.1** | **% of *dossier first actions* taken at or below target time** | **80%** | **90 calendar days, 120 calendar days for FPPs & APIs (due to fixed assessment sessions)** |
| **Time to *inspection first action*** | | | |
| 320 | Number of *inspection first actions* | - | - |
| **KPI 3.2** | **% of *inspection first actions* taken at or below target time** | **80%** | **210 days** |
| **Time to *laboratory first action*** | | | |
| 330 | Number of *laboratory first actions* | - | - |
| **KPI 3.3** | **% of *laboratory first actions* taken at or below target time** | **80%** | **180 days** |

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| # | Indicator | % Target | Target time |
|---|-----------|----------|-------------|

**Products prequalified**

| # | Indicator | % Target | Target time |
|---|-----------|----------|-------------|
| 340 | Number of products prequalified | - | - |
| 341 | Median number of dossier review cycles | - | - |
| 342 | % of products prequalified for which the number of dossier review cycles is at or below target | 70% | Target number of dossier review cycles: 3 |

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

**Post-PQ change applications accepted for change assessment (i.e. the change assessment cohort)**

| # | Indicator | % Target | Target time |
|---|-----------|----------|-------------|
| 400 | Number of post-PQ change applications accepted for post-PQ change assessment | - | - |

**Time to *post-PQ change first action***

| # | Indicator | % Target | Target time |
|---|-----------|----------|-------------|
| 410 | Number of *post-PQ change first actions* | - | - |
| KPI 4 | % of *post-PQ change first actions* taken at or below target time | 80% | **APIMF\|major amendment: 90 days**<br>**APIMF\|minor amendment: 60 days**<br>**APIMF\|immediate notification: 45 days**<br>**FPP\|major variation: 90 days**<br>**FPP\|minor variation: 60 days**<br>**FPP\|immediate notification: 45 days**<br>**IVD\|reportable change: 90 days**<br>**Vx\|major variation, type A: 90 days** |

**PQ list cohort (all prequalified products *on the PQ lists* at the beginning of a calendar year)**

**Prequalified products on the PQ lists (i.e. PQ list cohort)**

| # | Indicator | % Target | Target time |
|---|-----------|----------|-------------|
| 500 | Number of products on the PQ list | - | - |
| 501 | Number of products withdrawn after prequalification | - | - |