**Drug lag and approval time metrics - are they good markers to assess the global regulatory environment?**

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**Introduction**

The global development plans for registration of medicines in order to make them available to patients worldwide in a timely manner is a critical part of global healthcare. The release of new medicines is a complex process involving many stakeholders and requiring a range of regulatory and approval processes. One of the key challenges is to ensure that new medicines are made available to patients in a timely manner across multiple jurisdictions.

**Objectives**

- Evaluate time to submission and approval of new active substances (NASs) in 2009 in EM and MM countries.
- Identify the influencing factors on the drug lag and approval time metrics.
- Discuss the usage of drug lag and approval time metrics as markers for assessing the global regulatory environment.

**Methodology**

- Study was conducted for submission and approval period 2009-2013.
- Study included 36 organisations in 40 EM and MM countries.
- Companies were asked to provide data on approval and submission.
- Data were collected through a web-based survey.

**Results**

- For 2009-2013, the overall median approval time by the Scientific Assessment Model was 268 days for USA, 343 days for EU, 414 days for Switzerland, 400 days for Australia, 464 days for Canada, 644 days for Japan.
- An evaluation by country showed that regulatory approval times could be linked to the type of submission route within a country. Approval time for full assessment route was 2.1x faster than Brazil which does a full review, but both require a CPP.
- For full assessment route, overall median approval time for all EM countries studied was 414 days for Latin America, 464 days for Asia Pacific and 780 days for Europe, Middle East and Latin America.
- The overall median approval time for all EM countries combined was 462 days for USA, 209 days for Canada, 353 days for Canada, 367 days for Japan, 412 days for Australia, 468 days for Europe, 533 days for Switzerland.

**Definitions**

- **EM countries:** grouping acronym that refers to Brazil, Russia, India, China, South Korea, Turkey, Mexico.
- **MM countries:** grouping acronym that refers to USA, EU, Canada, Switzerland, Australia.
- **EM countries:** includes Saudi Arabia, India, Malaysia, South Korea and Taiwan.

**Conclusions**

- Drug lag and approval time metrics can be used to assess the regulatory environment across a number of countries, and in a diverse set of regulatory frameworks. The time from FDA approval to market launch for EM countries may vary from 90 days to 2 years, whereas the differences between country processes is not clear. Indeed, MM countries apply different review routes based on product type and supporting data, which may influence approval time.
- Companies are now including these countries in their global development strategies.

**Figure 1:** Time to Approval in the PMR/EMR countries (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 2:** Time between the first world approval and submission to the particular authority of the new medicine at the local country (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 3:** Time between the approval in the CPP issuing country and submission to the local country (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 4:** Time between the approval in the CPP issuing country and submission to the local country for 15 NASs approved in the EMR/PMR countries in 2009-2013, by country (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 5:** Time between the approval in the CPP issuing country and submission to the local country for 15 NASs approved in the EMR/PMR countries in 2009-2013, by route (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 6:** Time between the approval in the CPP issuing country and submission to the local country for 15 NASs approved in the EMR/PMR countries in 2009-2013, by competent authority (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 7:** Approval timing for 15 NASs approved in the EMR/PMR countries in 2009-2013, approved route identification (source: CIRS, London UK, 2015, 2013, 2011).

**Figure 8:** Approval timing for 15 NASs approved in the EMR/PMR countries in 2009-2013, approved route determination (source: CIRS, London UK, 2015, 2013, 2011).