Drug registration in emerging countries: Opportunities and Challenges in BRICS countries

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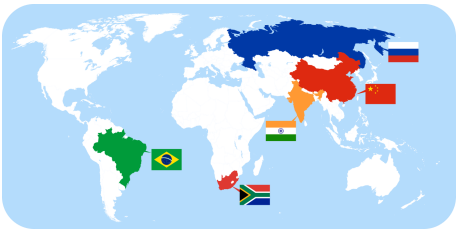
BRICS (Brazil, Russia, India, China and South Africa) are promising emerging markets based on their size, demographics, level of economic growth, and desire to improve health care and life expectancy. Together, they represent 41% of the global population and 22% of the world's gross product.



Therefore, early access of new medicinal products in the BRICS countries is of great interest for pharmaceutical companies.

Aims

To describe the possible strategies for a global submission of new pharmaceuticals.
More specifically:

- what are the regulatory requirements in the BRICS countries; and
- how can these be integrated into one global submission

Methods

Several local guidelines were used to examine the clinical and regulatory framework for clinical trial applications (CTA) and marketing authorization applications (MAA).

Results

Challenges to integrate BRICS countries into one global submission are:

- translation to local language;
- need of local representatives;
- lack of scientific meetings;
- changing regulatory environment, and
- requirement of local clinical trials

The need of and approval times for clinical trials differ per country as demonstrated in Figure 1. In China and Russia local clinical trials are required, while in Brazil and South Africa no local clinical trials need to be performed. In general, India does not require local clinical trials but this can differ per type of product and changes in guidelines. When applying for a clinical trial in China the approval can take up to 22 months. However, this could be reduced in the future as major reforms are presently taking place. After global submission it is also a challenge to achieve simultaneous marketing approval because the average approval time is around 1,5 years (Figure 2). In Russia and China it can even take 2 years and in South Africa 4 years due to huge back logs at the health authorities. In addition, for MA approval in Brazil a certificate of pharmaceutical product (CPP) from the country of origin is needed.

Figure 1: Approval times for clinical trials

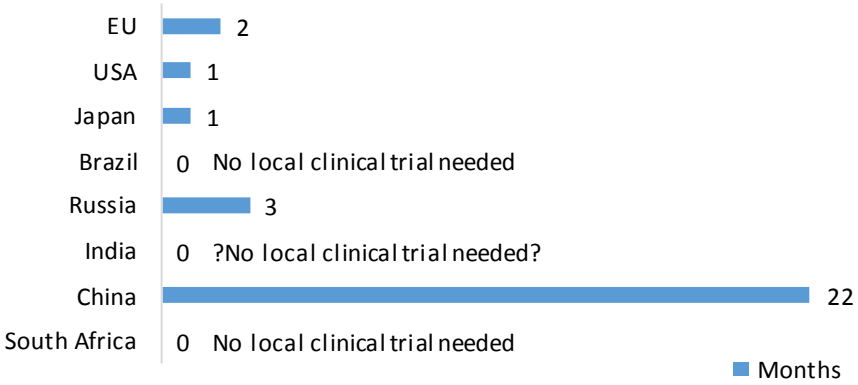
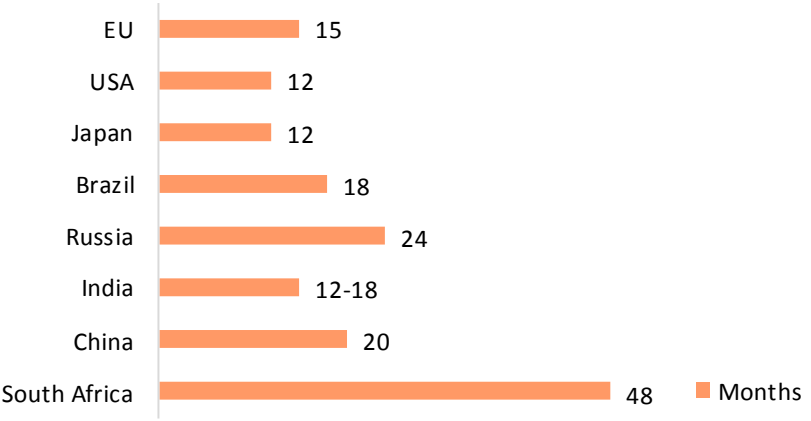


Figure 2: Approval times for marketing approval



Conclusion

When aiming for a global submission of new pharmaceuticals, companies should take into account:

- to include Russia and China as clinical sites for Phase III studies in addition to studies performed in Europe, Japan and the USA;
- that the big challenges are changes in timelines due to delays in the start of studies and the ever changing local regulatory environment. Especially in Russia and China which might delay or improve CTA approval times, respectively;
- that Brazil, India and South Africa do not require local clinical trials; the marketing authorization application can be submitted at the same time as in Europe, Japan and the USA