

## Comprehensive Study on BUSINESS IN BA-BE LABORATORY TOWARD HARMONIZATION OF ASEAN MARKET June 2008

In line with the agreement between the member countries of the *Association South East Asia Nation* (ASEAN), harmonization of Asean pharmaceutical market will start in 2008. There are two substances of the agreement. First, all Asean products of pharmaceutical are required to have the same standards as *Asean Common Technical Dossier* (ACTD) for administration data and information products, quality and efficacy of medicines. Second, all Asean products of pharmaceutical having the quality standard are free to enter the southeast Asian regional market.

The Asean market harmonization is widely seen as both a threat and an opportunity. It is a threat to pharmaceutical companies producing low quality products (not up to the standard), but it is a big opportunity for producers, which have fully met the standard, to expand sales and make bigger profit.

Therefore, all Indonesian pharmaceutical producers not yet meeting the standard, have to improve their quality if they want to gain from the regional agreement. All pharmaceutical products of Asean are required to have the same **Ba-Be** (*Bioavailability* and *Bioequivalence*) standard. That means that all products must show that they have passed a Ba-Be test.

The Ba-Be test could only be made at a Ba-Be Laboratory, which has met the criteria of the best tests nationally and internationally. A Ba-Be laboratory must perform *Good Laboratory Practice* (GLP) and *Good Clinical Practice* (GCP). A Ba-Be laboratory must have an accreditation from the National Committee of Accreditation (KAN) and is in line with ISO/IEC 17025-2005.

For large pharmaceutical companies which make up 60% of 122 pharmaceutical companies in the country it might be a small matter to meet the standard, but for small companies it would be a big problem that could signal their death.

Analysts said there are two big opportunities coming with the Asean Market Harmonization scheme -- first, market expansion and second, new business in offering Ba-Be laboratory service.

An estimate puts the cost of starting business in Ba-Be laboratory at around Rp6 billion-Rp7 billion to build and operate the laboratory. The costs of testing a pharmaceutical product range from Rp100 million to Rp800 million. It would not be easy for small pharmaceutical producers to spend that much money only for testing. Small companies may cope with the problem through contract manufacturing in cooperation with large producers having a Ba-Be laboratory.

So far, Indonesia has only 9 Ba-Be laboratories for 10,000-15,000 items of pharmaceuticals needing Ba-Be tests. It is most likely pharmaceutical companies from advanced countries like the United States and Europe will want to do the testing in this region as the costs of Ba-Be tests in their countries are much more expensive.

The new business is quite promising . With the lowest testing cost of Rp100 million per item the Ba-Be testing market could reach more than Rp1 trillion a year. The market value could be much larger if operation is expanded to other countries in Asean.

PT Media Data Riset has carried out a study of various aspects related to the Ba-Be laboratory business and government policy related to the implementation of Asean Market Harmonization scheme. The results of the study are compiled in a 350-page report that should be useful for the decision makers in pharmaceutical industry and other related industries in Indonesia.

For detail of the report, please find enclosed the Report Outline and its ORDER FORM or please contact us anytime PT Media Data Riset through telephone number 021-8093140, mobile phone: 085217061945 or through e-mail: [info@mediadata.co.id](mailto:info@mediadata.co.id) / [mediadatariset@yahoo.com](mailto:mediadatariset@yahoo.com) for other enquiries.

*Yours faithfully*

**Mansur S**  
Marketing Manager

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**June 2008**

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