Interview with Dra Lucky Slamet , Deputy Minister, BPOM

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How has the increasing international integration of the Indonesian economy influenced the challenges and transformations the BPOM went through in the past 9 years since its reorganization?

The constant changes and upgrades in international standards in the last decade posed strategic choices to our agency. Since then, BPOM chose to engage in strong efforts to improve our technical regulations and harmonize it with the international standards.In the year 2001 our Agency updated its regulatory code in order to harmonize it with GMPâ??s new standards. However, in only five years the GMP went through important upgrades, leading us to renew our regulation already in 2006. The same harmonization has been made with the pre-market evaluations and bioequivalence. BPOM is mandated to ensure that all products comply with high standards of quality safety and efficacy; thanks to our rapid responses, we have been able to be up the challenge.

Will Indonesia follow Singapore and Malaysia and join the PICS anytime soon?

Indonesia already submitted the application in 2008 and at the moment the institution is evaluating our submission. We are looking forward to have PICSâ?? inspection already next year.The transformation the Indonesian pharmaceutical industry in going through is remarkable and Iâ??m confident the international community will soon realize that. The number of pharmaceutical industries in Indonesia has been very dynamic, from 204 in 2004 to 196 in 2008, in a context of continuous and remarkable growth. This trend is in part a consequence of consolidation efforts that only companies complying with our high quality standards to continue in the market, incentivizing companies that arenâ??t capable of adapting to the new standards to migrate to other activities like traditional medicine.

How is BPOM trying to make the drug registration procedure more effective and efficient?

Companies need to constantly release new products to hold and improve their competitiveness in the market. Nevertheless, itâ??s BPOM role to guarantee the efficacy, safety and quality of these new products. The agency is aware of the need to make the registration more efficient and we are working hard on this direction. In this regards, BPOM is also engaged in improving the electronic documentation consultation so companies can preempt problems with their documentation. We would also like to assist companies in their compliance with the GMP regarding specially issues from documentation and pre-market evaluation.Our aim is to implement more online tools for the market products needed to be monitored closely. Besides, last month we just inaugurated our new building in which all procedures for product registration is being conducted (one roof services). We hope this will provide our service bemore transparent and efficient Our aim is to deliver transparency, open

communication and information and incentivize every company to comply with our standards.The Minister of Health decree no.1010/2008has made many international headlines.

Whatâ??s your perspective over the real impact of this decree on the Indonesian pharmaceutical market?

The decree reinforces some important points from the previous regulation. Its main goal is to protect public health by ensuring overall safety, efficacy and quality of medicine marketed in Indonesia. Indirectly, it also aimed at making the manufacturer entirely responsible for the application, making it more accountable for any fault in the process. Therefore, I have reason to believe that the impact for the industry or especially for the Indonesian population will be positive.The pharmaceutical industry needs to realize that our function is, above all, to guarantee the quality, safety and efficacy of all product produced and consumed in Indonesia;. Besides, the decree also enforces the responsibilities of the distributors, who didnâ??t have a clear legal framework regarding their obligations over the products they were distributing. Finally, the decree clarifies some important points such as categories of imported products, sanction of those violates the regulation etc.In the wake of some critics, as you mentioned, we are preparing a series of documents such as Q&A documents as well as a forum for communication to clarify the changes that were introduced by the decree. Hopefully it will clear any doubt that might still exist. However, even with all our efforts to clarify the approval system, there will always be those who wonâ??t be able to comply and will complain.

Are there special procedures for the state owned companies compared to other private ones?

There are no differences on the procedures on drug registration between state owned and private companies, either multi-national or locals.BPOM is making sure they will comply with our rules, benefitting our industry and population.

How BPOM manages to control more then 2000 drug distributors in such a geographically fragmented country?

It is a great challenge and our Agency is working hard to tackle it. In the year of 2003 BPOM released the Good Distribution Practices in order to gradually select the distributors that were capable and willing to comply with our standards, giving the opportunity for the rest to migrate to other activities.This year we have already classified all the distributors between those who distribute more high risk products and those who donâ??t. The first ones will be under an in-depth evaluation and according to it we will provide them with the GDP (Good Distribution Practice) certification.

What is the BPOM making in order to contain the counterfeits in Indonesia?

The main constraint BPOM faces is how to enforce deterent sanctions and properly punish those who produce, distribute and sell counterfeits. The Agency works by ourselves or together with the industry in order to identify the products that are being threatened by counterfeits and to protect our population; but in many cases once we find the criminals, proper punishments or sanction could not be enforced.To solve this issue we are working closely with the law enforcement agency, the national police and the general custom attorney to identify, judge and execute the penalties of the offenders. The agency has two different fronts to combat counterfeits: the supply and the demand. From the supply front, twice a year we have a simultaneous control operation in 33 provinces to combat the illegal market. We managed to find many offenders, where the law needs to be enforced.From the demand side we have to make the population more aware of the dangers of buying counterfeits and how to avoid it. However, with the current economic crisis, people are more inclined to go for the cheapest prices no matter the risks. Our duty is to raise awareness on the risk while making counterfeits less accessible. Last but not least, BPOM has established a post-market

alert system as part of ASEAN harmonization scheme and collaborates with the WHO including IMPACT program in order to tackle this challenge that goes far beyond our borders.

How do you see the current harmonization taking place in the ASEAN evolving? There could be a unified regional regulatory agency in the future?

The harmonization process is indeed moving in this direction. Naturally, once you have the system completely harmonized you will find, in practice, only one system. However, the existence of a supranational agency like in the European Union still looks far on the horizon.What really matters is that we keep caring the principles of one big Asian family aiming the same goal â?? long and sustainable regional development. This is why BPOM strongly agrees and supports the regional efforts for harmonization, facilitating the free flow of goods without compromizing of its safety, efficacy and quality while guarantying that our populations will have access to the best products available in the market.

How do you see Indonesian companies taking advantage of this increased integration with ASEAN nations and beyond?

Indonesia has taken the regional lead in the development of guideline on Quality aspects of ACTR (ASEAN Common Technical Requirements) and active role in process lead to MRA of ASEAN GMP inspection; this provides our companies an important advantage in the region. Besides, the capacity of the Indonesian local industry must not be overlooked; it is big, competitive and it is growing rapidly. What our industry need is a clear market strategy and a focus on the products that present the biggest opportunities on our markets, such as make use of Bolar provision for drugs that will expire soon.BPOMâ??s role in this scenario is to make sure that there is no infringe of existing law and no discrimination on the enforcement of the standards and regulation.

In your opinion, being a woman leading one of big division in the BPOM has posed you bigger challenges?

Regardless of gender, to be the head of my division in the BPOM is very challenging, since it involves issues of great importance, such as public health. However, I must say that being regulator of pharmaceutical matters I need to tackle each little detail in order to have our work done and I believe a woman can do it much better then a man. In my division, 80% of the staff is woman and I believe this is one of our keys for success.That said, I must acknowledge that the main challenges of being in my position and of working in BPOM is to constantly prove our technical abilities, that are daily putted to the test due to the challenging environment that we work at. Therefore, Iâ??m very proud of the men and women that have made BPOM the much respected agency it is today.

Do you have a final message to our readers?

BPOM is trying its best to enforce its mandate by ensuring that all pharmaceutical products are of assured quality, safety and efficacy and are in accordance with the higher international standards. We are doing our part in order to improve the Indonesian pharmaceutical market; I hope our industry can maintain its performance nationally and be able to successfully compete in international markets providing cutting-edge quality products for our population.

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