Editorial

ABCG Collaboration as Interdisciplinary Collaboration Model to Formulate Regulation on Production and Marketing of Medical Devices in Indonesia

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Ministry of health policy number 17/2017; 20/2017; 60/2017; 62/2017; and 63/2017 define health devices as instruments, apparatus, machine, and/or implants that do not contain drugs used to prevent, diagnose, treat, and alleviate diseases, treating sick individuals and restoring their health, and/or form structures and restore body functions. Health devices are categorised into 4 classes:

1. Class I
Class I health devices do not cause significant effect for their failure. Assessment for this class medical device focuses on the quality of the product.

2. Class IIa
Class IIahealth devicemay give significant effect for its failure, however no serious effects would be found. Requirements need to be fulfilled before being distributed andclinical trials are not required.

3. Class IIb
Class IIb device is health device that has the potential to cause very significant effects to the user, but no serious effects should be found for its failure. A more thorough requirement need to be fulfilled before being distributed including risk and safety analysis, but do not require clinical trial.

4. Class III
The failure or misuse of class III medical devices does cause any significant consequences to the patients and operator. These devices need to fulfill requirements such as risk analysis, and prove of safety before being distributed, and clinical trials are required for this class of devices.

Independence of medical devices in Indonesia, especially class III medical devices such as bone implants are still constrained.There has been no domestic industry that is capable of producing bone implants, meanwhile there is an increasing demand of bone implants as the number of traffic accident rises.

Indonesian Health Ministry hasonly published 966 (8%) distribution permits for local medical devices, on the other side there are 10,893 (92%) distribution permit issued by the Indonesian Ministry of Health for imported medical devices. There are only 87% of the total local company that are certified to distribute medical devices (CDAKB). The total value allocated for medical devices reaches 17 trillion rupiah per year based on national annual financial statement. The cost is greater than the total of regional annual financial statement (2,080 trillion rupiah).

Why does it stop at prototype-pre clinical trial phase?

Indonesia has the potential to develop implants through research. Some researchers from higher institutions such as Fakultas Teknik Universitas Indonesia (FTUI), LIPI, and BPPT have done studies on bone implants and have produced some prototypes and have been through pre-clinical trials. Unfortunately the majority of studies are originated from sense of curiosity of the researchers and not based on market demand, therefore they are not able to meet the demand. Moreover, opinions on clinicians whether they are reluctant to use local implants hinder the potential to develop local implants. Other factors that aggravate such condition is government policy number 63, 2017 under the ministry of health on how class III medical devices have to undergo clinical trials, although such policy is still unclear and not specific, and there are no standardised facilities available for clinical trials to be conducted.

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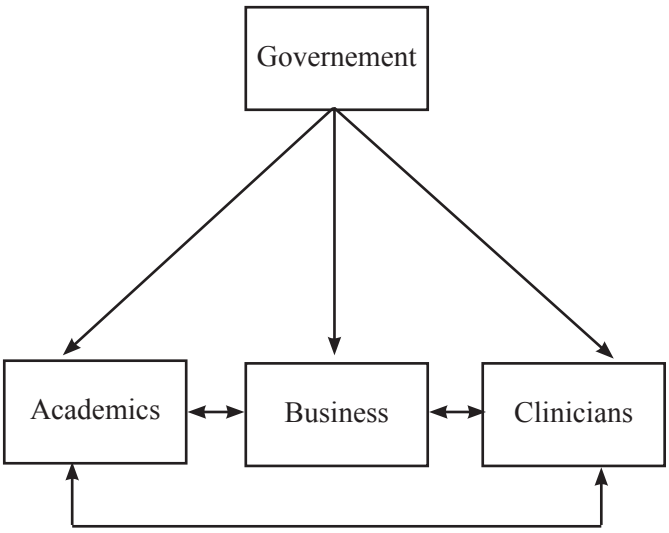
This condition is different from FDA rules that divide agreement process based on risk classification of the devices in a form of FDA product registration for class I, pre-market notification for class II, and pre-market agreement (pre-market approval / PMA) for class III medical devices. PMA is a process of scientific and regulation review for safety and effectiveness evaluation of class III medical devices. PMA does not rely on randomised controlled clinical trials and use other similar medical devices safety and effectiveness records as control. Therefore, scientific explanation on side effects can be used as a guide without having to undergo randomised controlled clinical trials.

Is there a solution to resolve this condition?

To resolve this issue, collaboration between scientific disciplines and strategic contributions among institutions including academics, business, clinicians, and the government (ABCG) are needed. Those institutions play a major role in maintaining the continuity between usage, regulation, production, and distribution build upon the following scheme:



Each institution has its own duties and roles in this collaboration.Clinicians act as the final user (target market) and decision holder that are required to have the ability to apply the implant product, as well as to teach and train other medical doctors. Clinicians also play a role in connecting their needs as a user with academicians (researchers) by giving inputs and becoming reviewers starting from the design and materials being used until implant trial. Clinicians involved ideally are medical staff of Educational Hospitals working alongside Faculty of Medicine so that there will be doctors as users, patients as subjects, as well as the availability of Health Research Ethics Committee as supervisors in any clinical trials.

Academicians, in this case academic institution, act in developing supporting equipment and preclinical trial laboratories, providing reliable human resources (researchers) and preparing learning modules or curriculum. With this condition researchers are expected to create implant design, design installation tool as well as developing basic materials required and allow continuous education/training process.
Business, in this case thegovernment-owned enterprise (BUMN) industry and private sector act as active partners that support the course of research and government programs by providing funding, identifying markets, conducting mass production and developing a profit oriented marketing strategy, where some of the profits can be allocated to researchers to support the continuity of the research to generate research products in the form of new prototypes.

The government acts as a regulator that create budgeting and incentive programs that support the acceleration of national implant independence by opening marketing opportunities, setting low taxes so that implant prices become competitive and obligate hospitals and doctors to prioritize the use of local implants. In addition, the government is also expected to facilitate and support interdisciplinary collaboration by providing incentives to universities and minimizing research administration process with output-oriented assessments. Another important role of the government is to facilitate ABCG collaboration.

Among the four roles, the government is important in maintaining the continuity between usage, regulation, production and distribution.

This kind of interdisciplinary collaboration is expected to prevent overlap between each research and prototype production, therefore time allocated for research and refining implant production technology can be immediately implemented. This is important to create effective and efficient conditions in producing health equipment policies, products and marketing systems that are oriented towards the best results for its users. (RAJ)