

Annual Report of DA-EWG Activity

It has been 5 years since APAC DA-EWG activities started in 2012. During this period, in order to realize the mission of activities aimed at the “Promotion of open innovation in Asia to achieve drug discovery originating in Asia”, we have strengthened alliances with pharmaceutical companies and research institutions in each economy and have conducted a great number of talks and events. The most important progress was in setting up three pillars for the platform - the base of promotion of innovation - and in taking concrete action. Until last year, we revised concept papers for DA-EWG before the APAC general meeting; however, this year we have summarized the progress of activities over the past year and future prospects as an annual report focusing on the three pillars defined in the previous concept paper of 2015.

1. Sharing information at the research stage (Pillar 1)

In recent trends in technological innovation, global drug companies including Japanese companies now emphasize open innovation rather than in-house completion. APAC DA-EWG aims for drug discovery considering the promotion of open innovation at the research stage in the Asian area determines its success and failure; however, the level of drug discovery in Asia other than in Japan is rather lower compared to that of advanced economies. Meanwhile various Asian economies are actively promoting growth in life sciences and development policies and human resource development. In order to strongly promote drug discovery capabilities, it is considered important to build up close ties between academic researchers who carry out basic research leading to drug discovery seeds, and drug companies which create prospective compounds from drug discovery seeds and perform clinical development/application for approval/sales; and further working together with the governmental institutions of various economies, which aim to promote the advancement of science, industrial development, and academic-industrial alliances. In the near future, we anticipate open innovation making full use of geographical advantages in addition to the merits of research leading to new drug discoveries originating in Asia. However, it is not easy to achieve completion in one economy alone, so carrying out joint research and academic-industrial alliances through cross-border open innovation is considered to be the most effective promotion measure. Therefore, we set the building up information sharing systems in Asia, which is necessary for advancing alliances, as Pillar 1 for APAC’s drug discovery platform.

In order to advance cross-border innovation in a concrete way on a trial basis, we have been working on setting up a bilateral system between Japan with its abundant

experience in drug discovery and Taiwan, which has most actively responded to APAC's call. We see the DSANJ (Drug Seeds Alliance Network Japan) system as a candidate for the platform that has a record of performance and is hosted by the Osaka Chamber of Commerce and Industry considering expansion towards other Asian economies. In 2014 cooperation between Taiwan and Japan began with transactions between people in charge of research alliances in drug companies and Taiwan's research institutions at the time of BioTaiwan. Then the Taiwan-side promoter and DSANJ officials together selected academic research seeds in Taiwan, and invited Taiwan's academic researchers to a DSANJ business meeting (held in January 2015 in Osaka) and they had business talks with staff in charge of research alliances in Japanese companies. In July 2015, a business meeting was held to introduce Taiwan's academic research seeds compiled based on the DSAN system to officials responsible for research alliances in Japanese companies as a pilot trial in Taipei which aimed to build up the DSANA (Drug Seeds Alliance Network Asia), an expanded Asian version of the DSANJ. Through this pilot trial, there were both successes and problems, and we are working on solutions for these problems. In terms of successes, we can point to the fact that understanding the detailed needs of companies by academic researchers was promoted through compilations based on the DSAN system and business meetings. On the other hand, one issue was the handling of intellectual property, which is always a problem in the case of academic-industrial alliances. Different stances between academic researcher and drug company strategies concerning economies, timing, and the content of patent applications may offer a hindrance to later joint research. Circumstances differ on a case-by-case basis, and these are issues of agreement between academia and companies, so APAC rules can't be unconditionally set. However, we think that it is important to show a certain direction by preparing guidelines to lead to more successful cases.

We also have the objective of expanding knowledge obtained through bilateral trials in multilateral systems. This year we are going to promote partnering between Taiwan's academia and persons in charge of research alliances in drug companies, making use of the meeting of BioTaiwan. It is absolutely necessary to call out many economies to participate in those projects to achieve APAC's goals. Of those measures, if joint research contracts are to be concluded and drug discovery research to be initiated, this would be a very important milestone of drug discovery originating in Asia. Promoting the conclusion of contracts and follow-up methods of research are also important tasks to think about.

2. Networking at the development stage (Pillar 2)

The next step of information sharing after the research stage is the networking development stage. It is an action closer to marketing than that of Pillar 1; therefore, if a license contract is settled, the marketing of the new drug is directly routed. There are a lot of events for networking at the development stage such as the BIO International Convention. However, we focus on Asia and we have already set the stage for this Pillar 2 at BioJapan, where a great number of Asian academia and companies participate. In order to lead to the conclusion of licensing contracts by increasing opportunities for networking, it is important to gather as many Asia academia and venture companies with compounds under development as possible. As a result of our continuing efforts at promotion over the past two years through DA-EWG, the number of participants at matching events hosted by us has been steadily increasing. In 2014, the first year, 20 researchers from 6 Asian economies and 24 people in charge of BD from 13 drug companies participated. In 2015, the second year, 50 researchers from 5 Asian economies and 24 officials from 10 drug companies participated. Actually 28 proposals were individually presented, and then active interviews were carried out. Currently, research from Asian venture companies and the importing side are composed of major drug companies doing research and development in Japan. However, given that this is a project for all Asian economies, we widely call on drug companies in Asia and venture companies in Japan and hope to further promote networking which lead to the conclusion of license contracts.

3. Capacity building for drug discovery (Pillar 3)

The above-mentioned two pillars are short term measures, while capacity building is a mid-to-long term measure. Capacity building for new innovative drug discovery means not only the development of drug discovery researchers but also grand projects including system building and capacity building for whole organizations such as government, administration, academia, and companies where all persons concerned are involved. Therefore, such projects are not completed overnight, and yet capacity building is indispensable and the most effective way for each Asian economy to steadily acquire drug discovery capabilities. In dealing with Pillar 3 we have been working on carrying out seminars, and panel discussions focused on the themes of capacity building and human resource development at BioJapan for two consecutive years. At the 5th APAC this year, we took up capacity building as the theme for the special lecture and the panel discussion in the DA-EWG session. All of the following factors are important; methods for making use of government innovation promotion plans, cases of

developing drug discovery researchers at universities, and advancing joint research sharing common perceptions concerning intellectual property problems and problem solving methods in academic-industry alliances. DA-EWG aims to advance drug discovery through the promotion of open innovation. Sharing each other's knowledge, experience, and wisdom through open innovation based on cross-border joint-research such as academic-industry alliances, we see, is the most effective for capacity building and human resource development. Although we only picked up capacity building in Pillar 3, it is closely related with the other pillars as well.

4. Other actions

At the 4th APAC last year, Asia-specific disorders and natural products were taken up as Pillars 4 and 5 respectively. Particularly regarding Pillar 5, this was taken up as an agenda for the full meeting of members when BioJapan was held. Information concerning undertakings and future directions of economies which see natural product resources as their advantages such as Taiwan, Thailand, and Malaysia was shared in this meeting. APAC deals with all of Asia, so everyone believes that the drug discovery alliance handles research which utilizes the advantages of each economy in Asia. If there are probabilities that drug discovery based on natural products can create a new innovative drug(s), it is necessary to actively work on this, which is one of the advantages of Asian economies. By carrying out discussions as much as we can, we would like to know how natural products lead to new innovative drug discoveries through cross-border open innovation, while taking into consideration a biological diversity treaty concerning Asian specific natural things.

5. Increase of DA-EWG members

One of the biggest achievements this year was the actual participation of China. In November 2015, we were able to visit companies and research institutions in Beijing and Shanghai by organizing a delegation with the full support of PhIRDA. It was significant that we made advancements toward a total Asian alliance; we planned the DA-EWG session of the 5th APAC including China. We also received an announcement of the active participation of Indonesia, which so far shared information concerning DA-EWG's activities, so we are delighted to see the advancement of major drug companies participating in the 5th APAC. On the other hand, some economies have not taken concrete action to participate. Several countries practically suspended their activities. These are the points we need to reconsider the EWG operation. In order to make these activities more productive, we look forward to active proposals from

participating economies other than Japan, improving transparency through the sharing of activities and progress through the APAC homepage opened at the end of March 2016.

6. Summary

APAC's undertaking is to take action aimed at creating new innovative drugs to meet patients' needs in Asia, completing all drug discovery cycles refining each economy's fields of advantage in a mutually complementary manner even though all drug discovery cycles are not completed in a single economy.

As it stands now, costs of research and development are increasing and the success rate of drug discovery is sharply decreasing, and the creation of new innovative medicines through open innovation has been highly anticipated. Our mission is to deliver drugs to meet the needs of people who live in Asia through the promotion of open innovation in Asia starting at APAC. We would like to advance our activities step by step in the future and speak with many people in Asia who agree with our vision.