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Sumitomo Pharma Co., Ltd.

National Center for Global Health and Medicine

Sumitomo Pharma and National Center for Global Health and Medicine Initiate 2nd Joint International Project on Measures against Antimicrobial Resistance (AMR) and Promoting Proper Use of Antibiotics in Vietnam

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; hereinafter, "Sumitomo Pharma") and National Center for Global Health and Medicine (Head Office: Shinjuku-ku, Tokyo; President: Dr. Norihiro Kokudo; hereinafter, "NCGM") today announced that they had commenced the 2nd Joint Antimicrobial Susceptibility Study (hereinafter, "the 2nd Study") in Vietnam. The study's aims are to contribute to the proper use of antibiotics and measures against antimicrobial resistance (AMR) in Vietnam.

In recent years, AMR has been recognized as a social problem requiring global level action. Especially in Vietnam, it has been reported that resistance to antibiotics for various Gramnegative rods, typically Pseudomonas aeruginosa and Acinetobacter spp., is particularly high. This is a major problem, which needs to be addressed urgently.

In view of this, in the 1st study*1, which was started by the 2 organizations in 2019, a total of over 1,200 strains of four important Gram-negative rods (*Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter* spp.) was collected from ten hospitals in Vietnam in order to measure susceptibility to the main antimicrobials used clinically in the country and investigate the latest status of drug resistance by hospital and by region. In addition to sharing antibiograms*2 based on the obtained data, we have been working on capacity building to encourage individual hospitals to select and use antibiotics based on evidence; for example, through technical training on the use of PK-PD theory*3, which is widely used in developed countries.

It is important to keep epidemiological information up to date by continually conducting antimicrobial susceptibility surveillance studies. Since face-to-face exchanges between Japan and Vietnam are being resumed in the post-COVID-19 era, with the approval of Vietnam's Ministry of Health, it has been decided to conduct a 2nd study. A total of 11 hospitals will be surveyed, including the 10 which have participated since the 1st study. In addition to supplementing the study content based on the results of the 1st study to make it

more compatible with local medical needs, the research in the 2nd study will be conducted according to a new system that emphasizes the future implementation by local communities themselves.

A kick-off ceremony for the 2nd study was held on February 12, 2023 in Hanoi Vietnam, inviting stakeholders both from the two countries including honored guests from Vietnam's Ministry of Health, the Japanese Embassy in Vietnam and other organizations. The ceremony was held as official commemorative events for the 50th anniversary of the establishment of diplomatic relations between Japan and Vietnam as well as the 50th anniversary of friendship and cooperation between Japan and ASEAN, regarding its nature of promoting further exchanges and medical development between Japan and Vietnam.

By continuing its participation in a joint study and sharing the results, Sumitomo Pharma aims to raise awareness of the importance of determining antibiotic susceptibility in routine tests to enable medical institutions to select optimal antibiotics for treatment.

Through participation in industry-academia-government collaborations of this kind, NCGM will actively expand the use of a global clinical research platform for a wide variety of diseases, including infectious diseases, intractable diseases, and neglected diseases that leads to new R&D projects. It aims to conduct international clinical studies that promote the development of pharmaceuticals with the focus on infectious diseases, intractable diseases, and neglected diseases. NCGM also aims to support corporate activities that have a high level of public benefit and contribute to the global expansion of Japanese medical care and advancement of the pharmaceutical industry.



*1 For details of the 1st study, please refer to the press release dated July 9, 2019 - https://www.sumitomo-pharma.com/ir/news/2019/20190709.html

*2 Antibiogram: A list of susceptibility rates (%Susceptible) of bacteria isolated over a certain period of time to various antimicrobial agents at a specific hospital (or aggregated for multiple facilities, by region, country, etc.). Hospitals in developed countries increasingly utilize antibiograms for optimal antimicrobial drug selection in empiric antimicrobial therapy (initial antimicrobial therapy) of bacterial infections as well as in infection control through monitoring of resistant bacteria and assessment of whether antimicrobials are being used properly or not.

*3 PK-PD theory: By combining pharmacokinetics (PK) and Pharmacodynamics (PD) to make connections between them, this theory is used to clarify relationships between dosage and administration, and actions (efficacy, adverse events). Dosage and administration details are set in view of the efficacy and safety of drugs to help ensure their proper use. With both basic and clinical research on antimicrobials progressing, opportunities for the use of such publicized theories as a reference in designing of dosage regimen of antimicrobials are increasing.

Reference

Title of the study

Surveillance study of *in vitro* antibiotic susceptibility and antibiotic resistance mechanism of various Gram-negative bacteria isolated in Vietnam

Sumitomo Pharma's antibiotic business in Vietnam

Via Zuellig Pharma, Sumitomo Pharma has been selling MERONEM® (generic name: meropenem hydrate; brand name in Japan: MEROPEN®), a carbapenem antibiotic preparation discovered in-house, in Vietnam and 4 other Southeast Asian countries as well as Hong Kong, since 2017.

As it is a growth market for pharmaceuticals, the company has been focusing on reinforcing its business in Asia and in 2021 opened a Vietnam representative office in Ho Chi Minh City.

NCGM AMR countermeasures

NCGM has established AMR Clinical Reference Center based on an AMR countermeasures action plan for Japan. The Center has been involved in clinical epidemiology and information provision programs as well as supporting educational activities. It has created a nationwide surveillance system to monitor antibiotic usage based on information collected, and supports measures to prevent outbreaks of AMR-resistant infections in collaboration with local authorities. In addition to compiling guidelines and manuals, the Center creates educational materials for the provision of information to both the public and healthcare professionals.

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