

## Guaranteeing Security and Quality, BPOM Supervised MR Vaccine Strictly From Pre-Marketing to Post-Marketing



JAKARTA - BPOM carried out a long process related to drug and food supervision, including the Measles Rubella (MR) vaccine. Supervision of either pre-marketing or post-marketing was carried out very tightly, related to security and quality.

Thus what was elaborated from the information given by the Plt Deputy of Drug Supervision and NAPPZA BPOM, Reri Indriani, Dallas Media Discussion of the Forum Merdeka Barat (FMB) 9 with the theme "The Long Way of MR Vaccine MUI Fatwa", held in the Multifunction Hall of the Ministry of Communication and Information, Jakarta, Tuesday (09/18/2018).

"The role of BPOM in terms of the circulation of MR vaccines in Indonesia suitable with the mandate given. Namely, monitoring drugs and food produced and circulated, so as to achieve the state's vision, which includes improving drug safety, quality and competitiveness of the nation," he said.

Supervision, according to Reri, was carried out both in the pre-marketing stage and post-marketing of MR vaccine. In general, he continued, there are a number of general requirements that must be met by drugs and food, including vaccines. "Quality standards must be met, which refer to national and international standards," he said.

Then also, Reri added, supervision of raw materials, production processes, additives, and stability. Including, he continued, towards complete and objective product information in order to guarantee rational drug use.

"In this case, including information on the label of medicine and food," she said.

On that occasion, Reri also said, MR vaccine has also been registered and had a marketing permit since 2017. The monitoring carried out, she continued, related to the efficacy of security and quality, distribution and production facilities, "So it can be concluded, BPOM has the authority to provide quality and safety guarantees of a drug and food product including vaccines. And for monitoring the MR vaccine, it has been carried out comprehensively," she said.

One quality control system, according to Reri, was a release batch. This means, she continued, imported products already had gotten through certificates.

In addition, Reri said, BPOM also monitored pharmacovigilance or checked drug side effects. "BPOM also continues to commit to producing halal vaccines, by assisting the drug industry to produce halal products," she said.

Meanwhile, related to availability, Reri explained, BPOM encouraged the commitment of vaccine availability by conducting fasttrack or quick registration.

Minister of Health Nila F Moeloek, President Director of PT Bio Farma M Rahman Roestan, and General Chairman of MUI KH Ma'ruf Amin also attended as resource person in FMB 9 this time.

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