Pentabio Lolos Uji WHO

[:en]BANDUNG— Pentabio vaccine product of PT Bio Farma is ready to enter international market after passing the prequalification stage of the World Health Organization, which is a requirement for a vaccine product to be exported. The President Director of Bio Farma, Iskandar, said that the achievement has added the portfolio of Bio Farma vaccines which are listed to be purchased by the World Health Organization (WHO), UNICEF, PAHO (Pan American Health Organization), and other countries. "We are targeting international market, yet we still prioritize the domestic needs," he stated, Wednesday (31/12). By adding the Pentabio vaccine products as a vaccine which passed the prequalification stage, he said that the total vaccine products of Bio Farma which are listed in WHO is 13 products. "The World Health Organization has the authority to evaluate the quality, safety, and efficacy of vaccine products from all global manufacturers," he continued. He also explained that the important aspects of WHO's prequalification stage include the management commitment, the comprehensive implementation of quality management system, and the quality of Food and Drugs Supervisory Agency (BPOM) in that country. "WHO's prequalification stage is conducted to evaluate the vaccine quality, fulfill the tender specification, and meet the quality standard," as he elaborated. Iskandar also added that the company is very grateful and thank for all of the employees' maximum effort because the PQ WHO process is not something easy. The decision is based on the product review, summary file, evaluation of the consistency of the final product characteristics, audit of the product facility visit, and follow up of the recommendation implementation made by the WHO reviewers during the evaluation. The vaccine product, which is also known as 5 in 1 vaccine as it contains of diphtheria, tetanus, pertusis, hepatitis B, and haemophilus influanzae type b, was certified last year. Head of Corporate Communications of PT Bio Farma, N. Nurlaela, stated that by the certification of WHO prequalification, Pentabio vaccines can be directly market to the developed countries as the targeted market of this red plated company." "During this time, we have only entered the developing market, then Islamic countries. Gradually we are willing to target Pentabio products for Europe," he said. The existence of this type of complete vaccine, according to him, will not replace the other Bio Farma vaccines that have been accepted globally, yet it will complement them. ***(Abdalah Gifar)*** Source : Bisnis Indonesia[:ID]BANDUNG—Produk vaksin Pentabio produksi PT Bio Farma siap memasuki pasar mancanegara setelah lolos prakualifikasi dari Badan Kesehatan Dunia yang merupakan syarat agar produk vaksin dapat diekspor.
Direktur Utama Bio Farma Iskandar mengatakan pencapaian tersebut menambah portofolio vaksin Bio Farma yang listed untuk dibeli oleh Badan Kesehatan Dunia (WHO), UNICEF, PAHO (Pan American Health Organization), dan negara-negara lain.

"Kami sasar pasar luar negeri, selain tentunya kami terlebih dahulu memprioritaskan kebutuhan pasar dalam negeri," katanya, Rabu (31/12). Dengan penambahan produk vaksin Pentabio sebagai vaksin yang lolos prakualifikasi, dia menyatakan total produk vaksin Bio Farma yang terdaftar di WHO menjadi sebanyak 13 produk.

"Lembaga kesehatan dunia atau World Health Organization memiliki kewenangan untuk menilai kualitas, keamanan, dan khasiat produk vaksin dari berbagai produsen dunia," tutumya. Dia menerangkan aspek penting dalam prakualifikasi WHO mencakup komitmen manajemen, penerapan quality management system secara menyeluruh, serta kualitas Badan Pengawas Obat dan Makanan (BPOM) di negara tersebut.

"Pra Kualifikasi WHO dilakukan untuk menilai kualitas vaksin, memenuhi spesifikasi tender, memenuhi standar mutu,"urainya. Iskandar menambahkan perseroannya sangat bersyukur dan mengucapkan terima kasih atas upaya maksimal dari seluruh karyawan Bio Farma karena proses mendapatkan PQ WHO tersebut tidak mudah. Keputusan ini didasarkan pada review product summary file, evaluasi dari konsistensi karakteristik produk akhir, audit visi-tasi ke fasilitas produksi, dan tindak lanjut pelaksanaan rekomendasi yang dibuat oleh reviewer WHO selama evaluasi. Produk vaksin yang juga dikenal dengan vaksin 5 in 1 karena sekaligus mengandung vaksin difteri, tetanus, pertusis, hepatitis B, dan haemophilus influanzae tipe b ini sepanjang tahun lalu dinantikan hasil sertifikasinya. Head of Corporate Communications PT Bio Farma N. Nurlaela menyatakan dengan pemberian sertifikat prakualifikasi WHO, vaksin Pentabio dapat langsung dipasarkan ke negara-negara maju sebagai market yang disasar oleh perusahaan plat merah ini. "Selama ini kami baru masuk pasar negara berkembang, kemudian negara-negara Islam. Secara bertahap kami ingin menyasar Eropa dengan produk Pentabio," ujamya. Keberadaan vaksin yang lebih lengkap ini, menurutnya, tidak akan menggantikan produk vaksin Bio Farma yang selama ini telah diterima pasar global, tetapi justru akan melengkapi. ***(Abdalah Gifar)*** Sumber : Bisnis Indonesia[:]