G.N. (E.) 899 of 2022

PREVENTION AND CONTROL OF DISEASE (USE OF VACCINES) REGULATION (Chapter 599 sub. leg. K)

It is hereby notified that, in exercise of the power conferred on the Secretary for Health by section 3(1) of the Prevention and Control of Disease (Use of Vaccines) Regulation (Chapter 599 sub. leg. K), the Secretary for Health authorized the following vaccine with effect from 30 September 2022:—

Name of the vaccine authorized

Comirnaty 3 micrograms/dose Concentrate for Dispersion for Injection
COVID-19 mRNA Vaccine (nucleoside modified)

Name and address of the authorization applicant

Fosun Industrial Co., Limited
Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong

Name and address of the manufacturer of the vaccine

BioNTech Manufacturing GmbH
Kupferbergterrasse 17-19, Mainz, Rheinland-Pfalz, 55116, Germany

Conditions attached to the authorization

(a) the authorization applicant is required to report to the Department of Health ("DH") as soon as possible, and in any event no later than 72 hours after receipt of information, of any actions taken by overseas drug regulatory authorities on the authorized vaccine as a consequence of any safety concern of the authorized vaccine. Such overseas actions include, but are not limited to, the following actions arising from the safety concern of the authorized vaccine:—

(i) recall, suspension or withdrawal of the authorized vaccine; or

(ii) addition or modification for safety reasons of a contraindication, warning or precaution statement in the product information;

(b) the authorization applicant is required to submit the final reports of all planned, on-going or future clinical studies of the authorized vaccine to the DH for reassessment at the same time when the said reports are submitted to Canada, European Union ("EU"), the United Kingdom ("UK") or the United States ("US") drug regulatory authorities as part of its post-marketing commitments. A summary of the conclusion of the clinical studies and the proposed follow-up actions also have to be provided. If there are any regulatory actions taken by Canada, EU, UK or US drug regulatory authorities in view of the results of the clinical studies of the authorized vaccine, the authorization applicant is required to inform the DH of the actions as soon as possible, and in any event no later than 72 hours after the actions have been taken;

(c) the authorization applicant is required to submit periodic safety update reports, or their equivalents, of the authorized vaccine to the DH every six months or at an interval as may be notified by the Secretary for Health; and to submit summary safety reports to the DH at the same time when the said reports are submitted to other overseas drug regulatory authorities until notified by the Secretary for Health;

(d) the authorization applicant is required to report all serious or unexpected adverse events following immunization of the authorized vaccine occurring in Hong Kong to the DH in accordance with available guidance for COVID-19 vaccines;

(e) the authorization applicant is required to implement the Risk Management Plan ("RMP") for the authorized vaccine in Hong Kong as it has proposed. The authorization applicant is also required to update the local RMP in accordance with the EU RMP when it is modified and implement accordingly;

(f) the authorization applicant is required to report to the DH any significant changes or any conditions relating to the manufacturer or to the manufacture of the vaccine which may affect the quality, safety or efficacy of the authorized vaccine without undue delay;

(g) upon commencement of recall of the authorized vaccine, the authorization applicant is required to report the recall and submit pertinent product information relating to that recall to the DH and to comply with available guidance for pharmaceutical products,

including the current Pharmaceutical Products Recall Guidelines issued by the Drug Office of the DH;

(h) the authorization applicant is required to document any defect impacting the quality of the authorized vaccine released for sale or distribution;

(i) the authorization applicant is required to submit further quality data to the DH at the same time when the said quality data or relevant quality documents reports are submitted to Canada, EU, UK or US drug regulatory authorities as part of its post-authorization commitments, and to update the relevant quality documents of the authorized vaccine, if applicable, in order to continue to assure the quality of the authorized vaccine;

(j) the authorization applicant is required to ensure the authorized vaccine is distributed in accordance with the logistic plan as it has proposed;

(k) the authorization applicant must provide the certificate of analysis issued by the manufacturer for each batch of the vaccine supplied to Hong Kong;

(l) the authorization applicant should provide a lot release certificate issued by national regulatory authority ("NRA") or batch release certificate issued by accredited laboratory authorized by NRA or certificate of analysis issued by an independent accredited laboratory for the batch of the vaccine supplied to Hong Kong as directed by the DH; and

(m) the authorization applicant is required to submit relevant information and justifications/ supporting evidence to the DH for any changes related to the authorized vaccine, including but not limited to the content of package insert, label, or any quality attributes. The changes should only be implemented after endorsement by the Secretary for Health is obtained.

Effective period of authorization

The effective period of authorization is a period of 12 months after the date on which the authorization takes effect.