(Attachment)

Partial amendment to the Public Notice on National Release Testing

1 According to Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the pharmaceuticals subject to National Release Testing which are designated by Minister of Health, Labour and Welfare (the Public Notice No. 279 of MHW, 1963) has been notified in order to stipulate the pharmaceuticals subject to National Release Testing, fees, criteria and quantities for the testing.

2 The Public Notice on National Release Testing shall be amended as follows ;

・ Fee and quantity for testing

- To amend the provisions for fee and quantity in the "Recombinant adsorbed hepatitis B vaccine (prepared from yeast)".

・ Criterion for testing

- To delete the provision for MPL content test in "Recombinant adsorbed bivalent Human papillomavirus-like particle Vaccine (derived from Trichoplusia ni cells)".
- To delete a part of the provision for potency test in "Human prothrombin complex" and "Freeze-dried activated human blood coagulation factor VII concentrate containing factor X."
- To delete the provision for rabbit pyrogen test in "Freeze-dried ion-exchange-resin treated human normal immunoglobulin" and "Human anti-thrombin III."

- This amendment will be promulgated on November 2021.