Daiichi Sankyo Announcement Regarding Vaccine Quality Testing Methods

Tokyo, Japan (April 26, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) has found that there has been no prior verification* on a part of the quality test methods (hereafter, sterility test) of the added solutions to the bulk of vaccine regarding Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine “Daiichi Sankyo” (hereafter, this vaccine) which is manufactured and sold by Daiichi Sankyo, and consequently the company sincerly apologizes for this oversight.

Once discovered, Daiichi Sankyo immediately reported the matter to the Ministry of Health, Labour and Welfare (hereafter, MHLW) and has been studying remedial measures.

From the results of quality testing for other quality control processes and final products, Daiichi Sankyo has confirmed that there are no problems with the quality, efficacy or safety of this vaccine. Daiichi Sankyo has also verified the quality testing procedure for the added solutions concerned and it has reported to the MHLW that there is no problem.

Daiichi Sankyo sincerely apologizes to the public, medical professionals and other parties involved for any concern they may have had regarding the quality of this vaccine, a pharmaceutical product essential to public health.

Daiichi Sankyo will take thorough measures to prevent recurrence and make efforts toward further improvements.

*Prior confirmation that the added solution contains no substance that inhibits bacterial growth when conducting a sterility test