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Societal Vaccinology. The Netherlands Public Sector Vaccine Development, Production and Technology Transfer in the Context of Global Health.
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Summary

Global health has improved remarkably through the introduction of a multitude of vaccines in childhood vaccination programmes since the 50s of the previous century. The successful global eradication of smallpox and the imminent global eradication of the polio virus are but two examples of global public goods which only became a reality through widely available safe and effective vaccines against these viruses. New vaccines that are now increasingly becoming available result from the science and technology field commonly called "vaccinology". Recent global introductions include vaccines against hepatitis B, *H. influenzae* type B, rotavirus, pneumococcus and human papillomavirus. While early classical vaccines against diphtheria, pertussis, tetanus, polio and measles were made mainly in state owned laboratories and institutions under a national mission to provide these goods for the population, nowadays the manufacture and supply of new vaccines and combination vaccines have in the Western world become the domain of only a handful of multinational companies. This "privatisation" of the vaccinology science field has been accompanied with the gradual erosion of public sector vaccine development and production. As regards vaccine provision in low and middle income countries, non-state actors and public-private-partnerships such as the Bill and Melinda Gates Foundation and the GAVI Alliance have become dominant in agenda setting and prioritisation, once the remit of WHO and countries themselves. Within this "global vaccine system", counterbalancing developments are also noticeable. These include the growing importance of public and private vaccine suppliers in developing countries themselves and is associated with an increase in innovative capacity within these countries.

This thesis describes the specific case of public sector vaccine development and manufacturing in Bilthoven, the Netherlands. After successes from the 1960s onwards, there followed a period of institutional transformations and gradual decline. This culminated in the eventual partial take-over by the private sector in 2012. For nearly three decades until the 90s, the National Institute of Public Health was successful in producing and supplying all the vaccines required for the national immunisation programme. Production technologies and quality control assay techniques for diphtheria, pertussis, tetanus and polio vaccines that had been developed largely in-house were widely shared in the public domain with various developing countries through extended practical training courses under WHO auspices but also on a bilateral basis. From the 90s onwards, when it became progressively more challenging to meet the national demand for newer or better vaccines, the institute increasingly engaged in several vaccine development and technology transfer activities and projects focused on the developing world. The dynamics described in this thesis illustrate the effects of globalisation upon a public health driven vaccinology expertise centre with a semi-industrial infrastructure that over the period of study disintegrated into three legally separated parts. The sale of the national production capacity to the private sector in 2012 was accompanied by the re-integration of public advisory tasks on vaccination schedules and vaccine procurement into the National Institute of Public Health and the Environment (RIVM), whereas the privatisation of the national vaccine development and technology transfer capacity, the Institute for Translational Vaccinology (Intravacc), is imminent. From a global perspective, this case of privatisation is of particular interest because the buyer, the Serum Institute of India Ltd. (SIIL), is one of the world's largest private vaccine manufacturers playing a key role in the supply of affordable vaccines for developing countries made available through the global United Nations vaccine procurement systems. Since the mid-1960s, SIIL had also been benefitting from vaccine know-how and technology transfer programmes from the Netherlands' public domain. The main finding of this

thesis is that national public sector vaccinology institutions, in particular the Netherlands public health institute, have over the past decennia had a hitherto hardly acknowledged but profoundly positive impact on the global vaccine system that aims to increase access to vaccines in developing countries. This impact is the result not of supply of vaccines, but through enabling vaccine manufacturing entities (public or private) in developing countries to set up or improve their capacity. From a participant observer perspective, I conclude that this larger societal value for global health has received too little attention in the privatisation process of vaccinology in the Netherlands. This is remarkable, because in the overseas development assistance arena, the Netherlands always supported the goal of providing access to vaccines for all children. From a societal and horizontal angle this study illustrates that in the current global vaccine system a divergence between policies and practices between different ministries within the same government may lead to missed opportunities for global health. It is to be hoped that the conditions set by the government for the pending privatisation of Intravacc, planned for 2017, will ensure at least the partial continuation of global public good creation from Bilthoven as has been done so successfully in the past decades.