medicines patent pool

March 2025

PEMBROLIZUMAB

ONCOLOGY
LUNG CANCER

Merck

DISEASE BURDEN

In 2022, globally, lung cancer was responsible for 2.48 million new cases and 1.8 million deaths. 80% are classified as non-small cell cancers (NSCLC).

CLINICAL RELEVANCE

Pembrolizumab as a single agent reduces the risk of death in non-small cell lung cancer patients by 40%, significantly extending survival by more than a year with fewer side effects compared to traditional chemotherapy. Pembrolizumab is also indicated against several other cancers.

INTELLECTUAL PROPERTY LANDSCAPE

MSD holds the exclusive patent rights on pembrolizumab until 2028 with patents filed or granted in at least 15 LMICs.

SERVICE DELIVERY ENABLERS

Access to pembrolizumab and other immune checkpoint inhibitors is reported to be extremely low and challenging in LMICs.

REGULATORY

Pembrolizumab is approved by stringent regulatory authorities. Potential sublicensees of pembrolizumab could rely on mechanisms like Swissmedic MAGHP or EU-M4all for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Clinical trial waivers would not be an option.

MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. No challenges with respect to excipients or final packaging. Shelf life is two years under refrigeration.

MARKET

Pembrolizumab is registered in only a limited number of LMICs and is unaffordable in most of them, being costlier than standard of care.

EU-M4all: The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'; NSCLC: non-small cell lung cancer; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; Swissmedic MAGHP: Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products