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LONDON, UK (GlobalData), 9 March 2016 - The UK Department of Health's <u>rejection of an</u> 800,000-signature public petition

to expand the routine administration of the only approved vaccine to offer protection against invasive meningococcal disease (IMD) caused by serogroup B (MenB), may lead to parents and physicians to consider purchasing the vaccine themselves, according to an analyst with research and consulting firm GlobalData.

The decision to keep free access to GlaxoSmithKline's MenB vaccine, Bexsero, limited to infants rather than vaccinating children up to 11 years of age, as requested in the petition, is a significant setback for the advocacy groups and parents aiming for expanded vaccine administration.

Mirco Junker, Ph.D., GlobalData's Analyst covering Infectious Diseases, explains: "Even though IMD cases caused by serogroups B and C are most prevalent, the majority of European countries only routinely administer meningococcal vaccines against serogroup C, which provide excellent safety and efficacy profiles in combination with relatively low price points. MenB vaccines, on the other hand, are relatively new and expensive, and there is only limited clinical data demonstrating their long-term effectiveness.

"This uncertainty regarding the long-term efficacy - together with studies indicating low cost-effectiveness of MenB vaccines - also highlights the general conflicts rare diseases like IMD bring up when medical needs are pitted against the commercial viability of vaccines. Indeed, vaccinating entire populations against rare diseases can be extremely challenging to rationalize from a pharmacoeconomic perspective."

In fact, in 2014, a study using the analysis of quality-adjusted life-years indicated that the new MenB vaccine would not be cost-effective even if provided to the National Health Service (NHS) for less than £1 per dose. However, cost-effectiveness should not be viewed as the main determining factor for the broad application of a vaccine against a rare disease, as many

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vaccines might not pass this threshold, given low enough disease prevalence.

Junker continues: "While the Department of Health's decision is a disappointment for parents worried about their children developing IMD, GlobalData believes it is understandable from the perspective of the NHS, as healthcare costs continue to rise and governmental agencies have to balance the restraints of a limited budget with society's medical needs.

"A reasonable compromise could be to provide individual families concerned about IMD to purchase vaccines out-of-pocket without having to face the list price of the vaccine. As such, it might be in the interest of the pharmaceutical industry to provide incentives to make the vaccine available to individuals not covered under the NHS guidelines."