The Expert Committee recommended the inclusion of cladribine, glatiramer acetate and rituximab as individual medicines on the complementary list of the EML for the treatment of multiple sclerosis. The Committee did not recommend the inclusion of ocrelizumab for this indication, either as an individual medicine, or as a therapeutic alternative to rituximab under a square-box listing. The Committee noted that multiple sclerosis is the most common non-traumatic cause of neurological disability in young adults, with approximately 2.8 million people living with multiple sclerosis worldwide. Until now, the EML has not included any medicines for the treatment of multiple sclerosis. The Committee considered that the inclusion of effective and safe treatments for multiple sclerosis on the EML would address an important public health need and support global advocacy efforts to reduce the global burden of multiple sclerosis, especially in low and middle-income countries. The Committee acknowledged the availability of a large number of disease-modifying medicines for multiple sclerosis (particularly for the treatment of relapsing and remitting forms of the disease) and the need to prioritize the most effective, tolerable, and affordable options. The Committee considered that the approach taken in the application submitted by MSIF to identify which medicines to prioritize for EML listing from among the many available was comprehensive, up-to-date, transparent, robust and evidence based. The Committee recognized the value of involving different organizations and stakeholders at the global level, including consultation with people living with multiple sclerosis. The Committee considered that the application's selection of cladribine, glatiramer acetate and rituximab as priority medicines for EML inclusion was well justified and supported by evidence of clinical benefit and safety across different settings, as well as suitability for use in different patient populations (e.g. pregnant women) and feasibility. The inclusion on the EML of three medicines, with different routes of administration, different prices (including the availability of generics and biosimilars) and different recommended uses, would provide valuable options for patients and national selection decisions and could facilitate improved access to treatment for people living with multiple sclerosis. The Committee acknowledged that rituximab does not have
market authorization by regulatory authorities for treatment of multiple sclerosis and is thus used “off-label” for this indication. The Committee reiterated that the Model List can play an important role identifying those medicines for which off-label use is supported by convincing evidence, complementing the assessment and labeling by jurisdictional authorities. The Committee acknowledged the benefits of ocrelizumab in the management of relapsing and primary progressive forms of multiple sclerosis. However, there was no compelling evidence of its superiority over other alternatives, specifically rituximab, which has the same target (CD20) and a similar peptide sequence, is widely used, more affordable and reimbursed for use in multiple sclerosis in several countries. The Committee considered the option of listing ocrelizumab as alternative to rituximab, but also recognized the large difference in current prices of the two products which decreases ocrelizumab competitiveness. The Committee concluded that including ocrelizumab as a therapeutic alternative to rituximab could result in considerable additional expenditure at country level for patients and health systems, without offering additional clinical benefit.