

Data exclusivity

Data exclusivity refers to the period during which the data of the original marketing authorisation holder is protected. It is the time during which another company cannot use the originator's data in support of another marketing authorisation application, i.e.: generics, hybrids, biosimilars. Therefore, competent authorities may not accept such an application during this period of time. In Europe, this protection period lasts for a minimum of eight years and is intended to incentivise innovation.