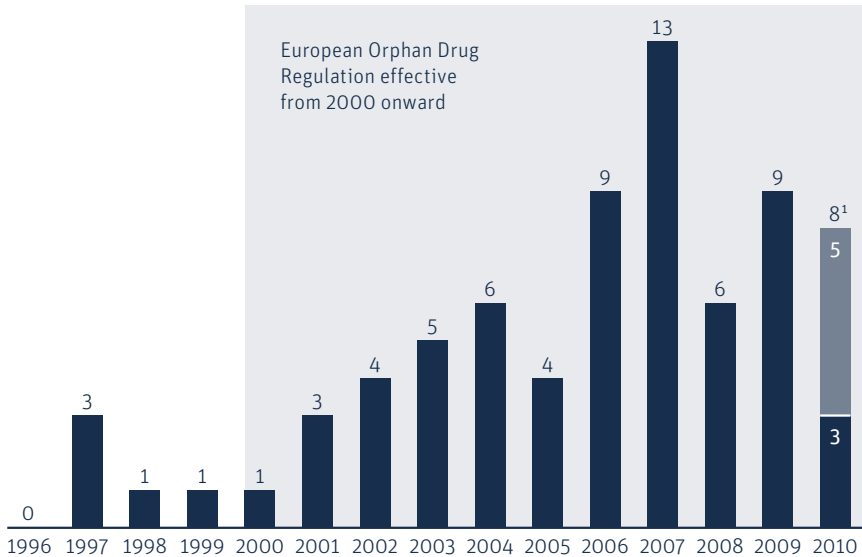


Marketing Authorizations for Orphan Drugs in the European Union

Number



Source: vfa

Since the start of 2000, companies have been able to apply for “Orphan Drug” status for a drug being developed in Europe if it is for treating a disease affecting no more than one in 2,000 EU citizens. With this status comes lower marketing authorization fees, free scientific consulting and exclusive marketing rights, usually for ten years.

Whereas on average only one drug for treating a rare disease (Orphan Drug) received marketing authorization every year before the regulation came into force, the figure is now much higher. A total of 60 Orphan Drugs have now received marketing authorization in the EU and over 700 more are being developed (as of July 2010). The Orphan Drug Regulation is therefore a good example of how meaningful political regulatory activity can boost pharmaceutical research in areas society deems important.