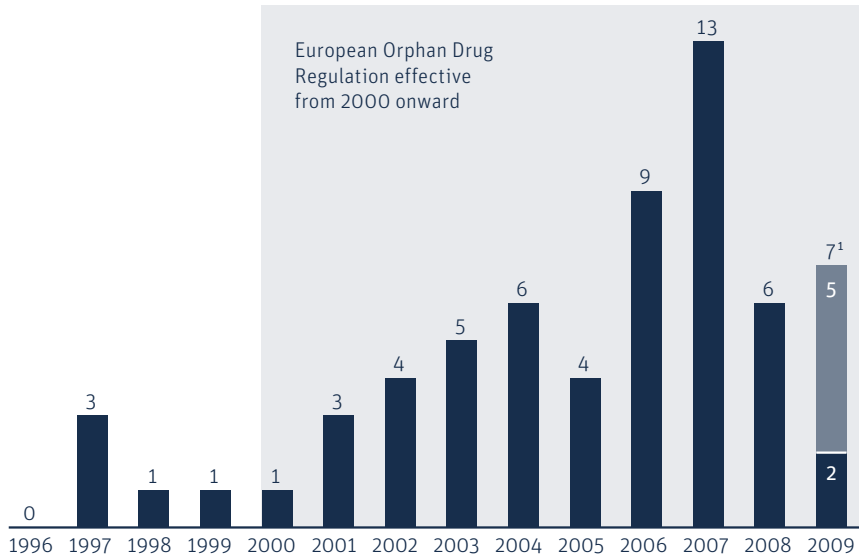


## Marketing Authorizations for Orphan Drugs in the European Union

Number



<sup>1</sup> expected marketing authorizations (as of: June 2009)

Source: vfa

Since the start of 2000, companies have had the opportunity to apply for “orphan drug status” for a pharmaceutical being developed in Europe, if said drug is for a disease that affects no more than one out of 2,000 EU citizens. With this status comes lower marketing authorization fees, free scientific consulting and exclusive marketing rights for a maximum of 10 years, among others. While only one orphan drug on average was approved per year prior to the regulation, this number has increased significantly. A total of 52 orphan drugs have received marketing authorization in the EU since 2000. More than 650 additional ones are being developed (as of June 2009). As a result, the Orphan Drug Regulation is a good example of how meaningful political regulatory activity can increase pharmaceutical research in areas desired by society.