Even if chronic studies have been performed e.g. during the market authorisation of new drugs, the results are often confined to the authorisation dossiers, i.e. the information is not available for independent review or a meta-analysis. This resembles the pre-REACH situation for industrial chemicals, which were divided into so-called “existing chemicals” (on the market prior to 1981, for which no risk assessment was required) and “new chemicals” (for which a risk assessment was mandatory).

The complexity of the issue and the need for specific, case-by-case judgements is highlighted by the recent analysis by Bergmann et al. (2011), who calculated risk quotients (MECmax/PNEC ratios) for medicinal products for the aquatic environment. The risk quotient range from almost 10 000 for EE2 to less than 0.00001 for Cyclophosphamid, an anti-cancer drug, i.e. the values span over 9 orders of magnitude (Figure 6). That assessment factors of up to 25 000 had to be used indicates the enormous uncertainty and data gaps in the data on environmental hazards, which were often limited to one value on the acute toxicity to one species (16 out of 70 analysed compounds).

**Figure**

