

of breakage. If used in the designed way the Onkoprotektor® is effective to prevent contamination.

The TopLoad® is relatively space-saving and produces little extra volume. Due to the grooves on the bottom part, the TopLoad® has a very good grip and is transparent. The snap-off cover cup allows easy and fast opening. The glass vial is locked and cannot be removed; the protection is safeguarded.

The TopLoad® is disinfected in one step and there is no thread. The TopLoad® is a protective container with the most effective prevention of breakage and contamination.

Onco-Safe®/NeoSafe®: EBEWE

Pharma, a Sandoz company

Onko-Guard®: Actavis Deutschland

Onkoprotektor®: Cell Pharm / STADA

TopLoad®: LOGENEX Pharm

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HEALTH DATA

Orphan drugs – a successful EU policy but also a ‘back door’ to profits?

Since 2000, companies have been able to apply for ‘orphan drug status’ for a drug being developed in Europe, if it is for a disease that affects no more than one in 2,000 EU citizens. With this status come many financial incentives. The figure shows how the number approved per year has increased significantly. A total of 52 orphan drugs have received marketing authorisation in the EU since 2000, see Figure 1. More than 650 additional ones are being developed (as of June 2009). This is hailed by the industry as meaningful political regulatory activity increasing pharmaceutical research in areas desired by society.

However it is argued that exclusivity has been granted to numerous orphan drugs that would have been produced anyway, because of how orphan status is defined. These orphan drugs are extremely expensive.

Given their lack of cost-effectiveness, the funding of orphan drugs can only be justified if the public is willing to give up some of the overall health gain produced by the healthcare system, because access to treatments for orphan diseases is perceived to be a socially valuable objective. The policy argument usually is, that the budget impact for one orphan drug is relatively low. However, given the total number of orphan diseases (see the special feature on orphan diseases in upcoming issues of *EJHP Practice* in 2010), the total budget impact may become significant.

Figure 1: Number of marketing authorisations for orphan drugs in the EU per year

