Access to Orphan Drugs in Hungary

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Objective

Orphan drugs are usually more expensive than the non-orphan medicines[1]. Thus, the general access to these pharmaceuticals is often limited[2]. The aim of this research is to evaluate the accessibility of orphan drugs in Hungary in 2022.

Methods

We have collected all the pharmaceuticals that had been listed as orphan drug by the European Medicines Agency (EMA) on 30 June 2022. Then we analyzed the accessibility and reimbursement status of these pharmaceuticals in the official database of the National Health Insurance Fund.

We identified two major reimbursement technics. If a general reimbursement decision is granted by the Government, there is no further patient-level decision-making is needed. While in case of the individual reimbursement the decision is made case by case. This technic puts significant administrative pressure on the system.

Results

The EMA has granted marketing authorizations for 131 orphan medicines until 30 June 2022. Of these 131 medicines, 55 (42%) were available to Hungarian patients with any type of reimbursement.

45 medicines were available with individual reimbursement (82%)[4] and 10 with general reimbursement (18%)[5,6].

The three most common therapeutic areas in which these orphan-drugs were available were haematology (n=16, 29%), metabolism disorders (n=10, 18%) and neurology (n=7, 13%).

The average time from EMA approval to the start of the general reimbursement was 1,245 days.

Figure 1: The status of orphan medicines in Hungary

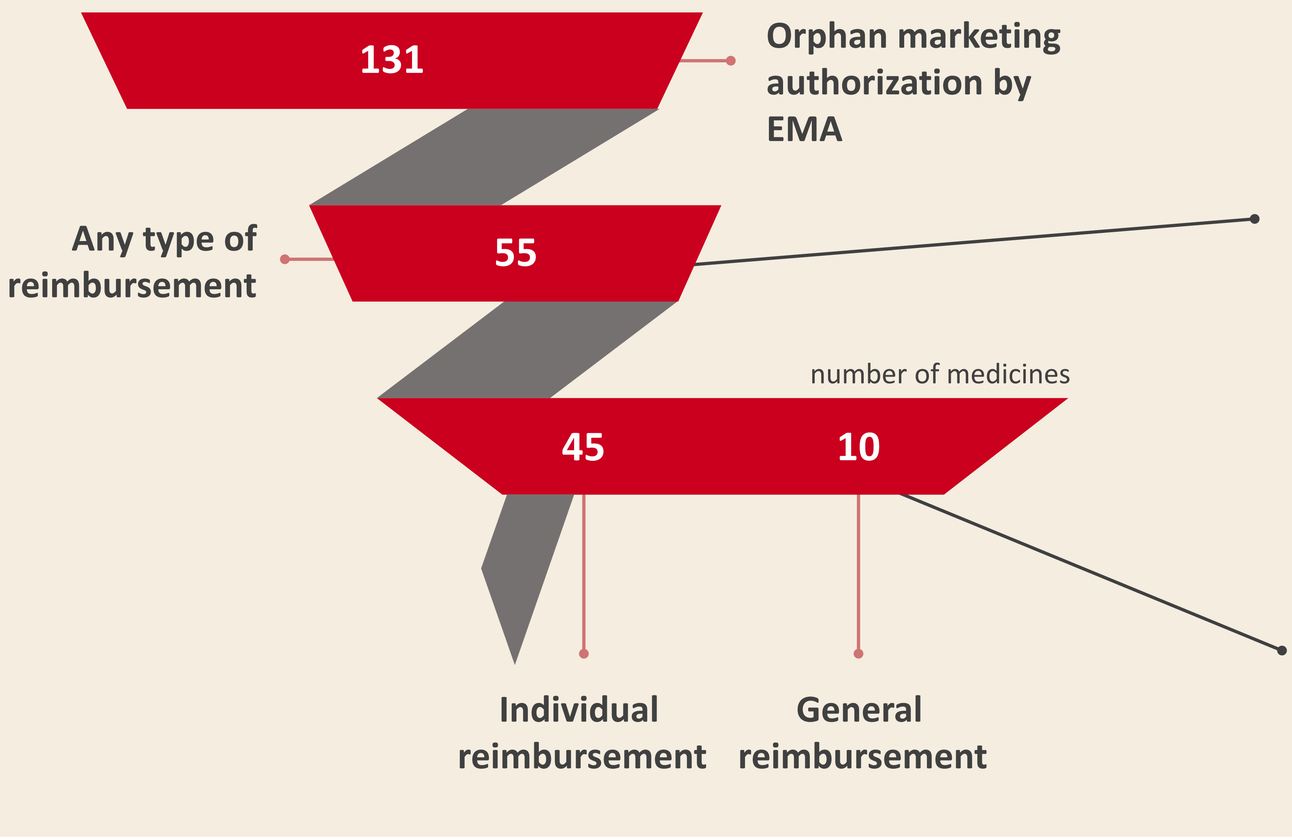

Figure 2: The most common therapeutic areas

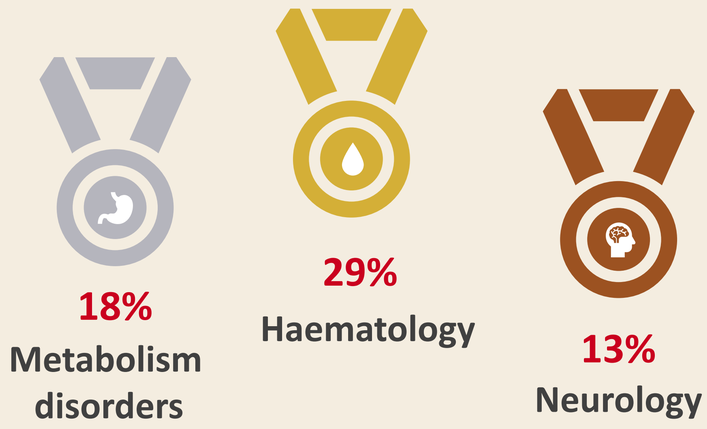

Figure 3: Time from EMA approval to general reimbursement

Conclusions

The general access to orphan drugs seems to be limited in Hungary, while throughout the individual reimbursement thousands of Hungarians get access to these innovative pharmaceuticals. From the Payer's point of view the individual reimbursement can guarantee stricter control on the spendings, but on the other hand it puts enormous administrative pressure on the system. It is worth considering that some of these individually reimbursed pharmaceuticals should be reimbursed generally.

Sources

[1]Chambers JD, Silver MC, Berklein FC, Cohen JT, Neumann PJ. Orphan Drugs Offer Larger Health Gains but Less Favorable Cost-effectiveness than Non-orphan Drugs. J Gen Intern Med. 2020 Sep;35(9):2629-2636. doi: 10.1007/s11606-020-05805-2. Epub 2020 Apr 13. PMID: 32291711; PMCID: PMC7458970.

[2]Gammie T, Lu CY, Babar ZU. Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries. PLoS One. 2015 Oct 9;10(10):e0140002. doi: 10.1371/journal.pone.0140002. PMID: 26451948; PMCID: PMC4599885.

[3]European Medicines Agency (https://www.ema.europa.eu/en)

[4]National Health Insurance Fund (http://www.neak.gov.hu/)

[5]Decree 9/1993. (IV. 2.) of the Hungarian Ministry of Public Welfare

[6]Decree 32/2004. (IV. 26.) of the Hungarian Ministry of Health, Social and Family Affairs