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Objective	Methods
<ul style="list-style-type: none"> To assess the authorization status of reimbursement applications rejected by the Swedish Dental and Pharmaceutical Benefits Agency (TLV) during the last five years. To identify trends among these rejections in terms of authorization status. To examine if the medical products that were rejected for reimbursement are nevertheless used by Swedish patients. 	<ul style="list-style-type: none"> All TLV reimbursement rejections published during the years 2019 to 2023 were identified through the Nordic Market Access proprietary database NMAi, using built-in filters¹. Information on authorisation status have been collected using European Medicines Agency (EMA)² and Swedish Medical Products Agency (Läkemedelsverket)³ webpages. Dispensation data for 2023 have been collected using National Board of Health and Welfare (Socialstyrelsen)⁴ webpage. Prices have been collected using one of Swedish community pharmacies webpage⁵
Results	

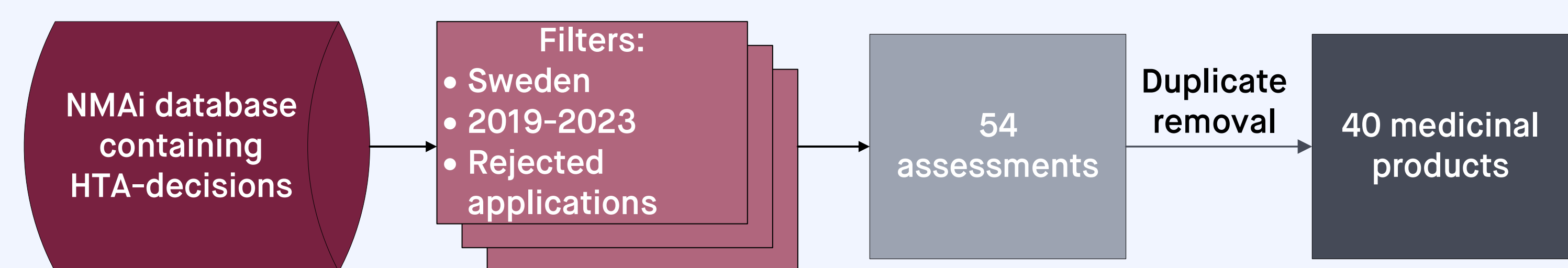


Figure 1. Selection process, criterion: authorization status

A total of 54 TLV rejections, concerning 40 medical products, were identified for the time period January 2019 and December 2023. 30 underwent a centralised authorisation procedure and ut of those, 18 had been granted orphan designation status.

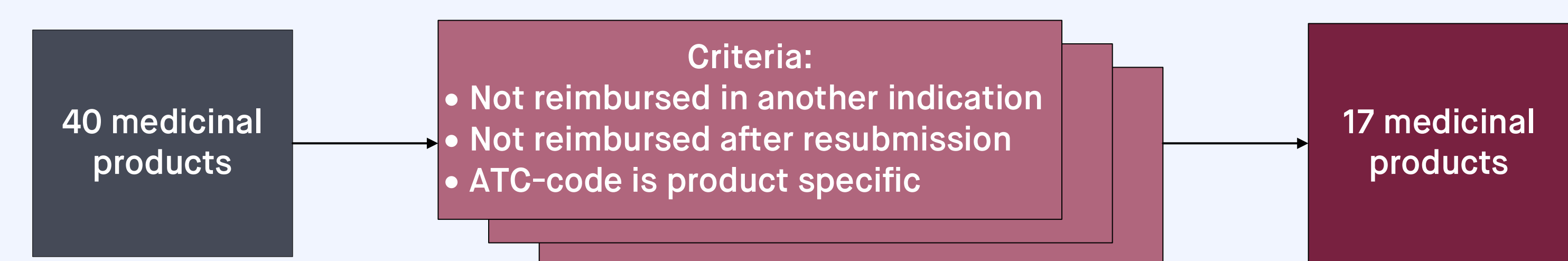


Figure 3. Selection process, criterion: prescription despite lack of reimbursement

Out of those 40, following medicinal products were excluded from the analysis:

- Products having received reimbursement at the time of the analysis either after resubmission or for another indication
- Products with ATC-code being not product specific.

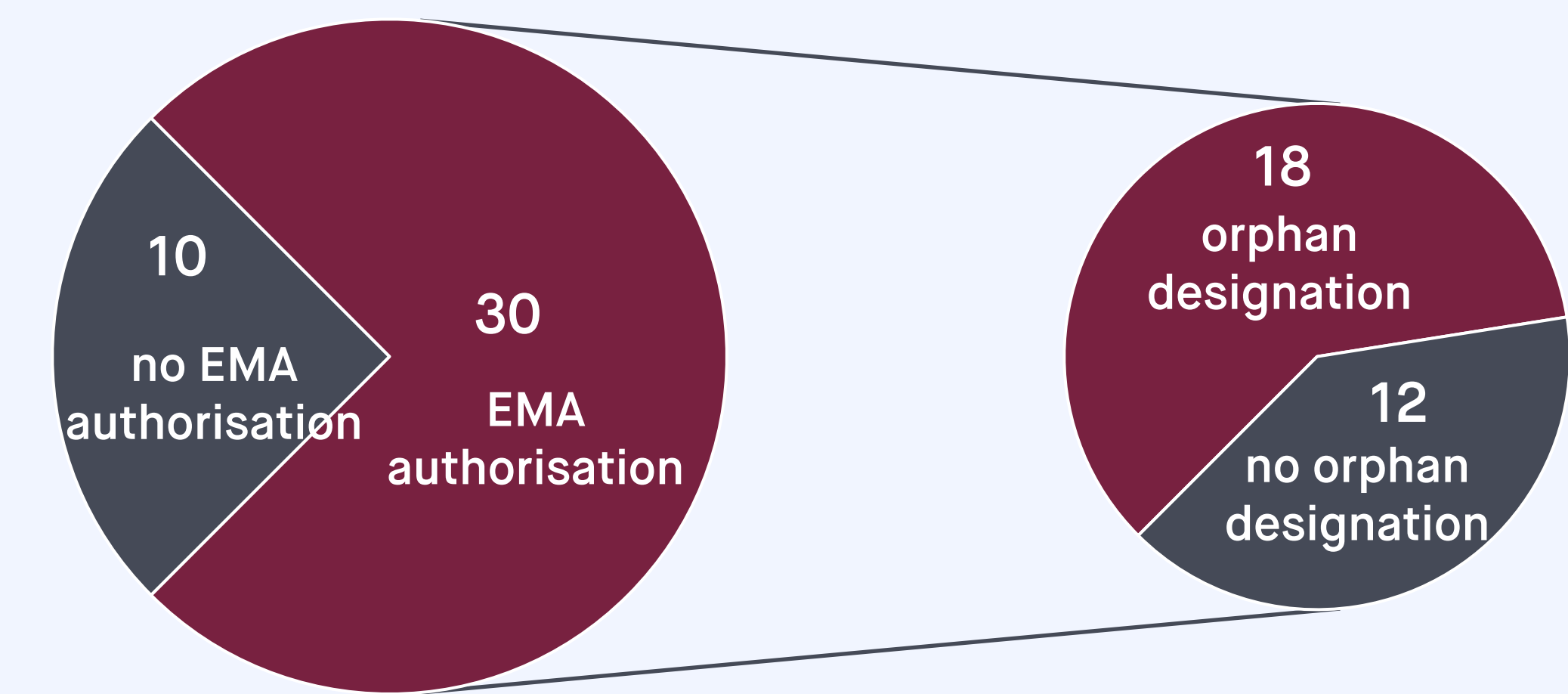


Figure 2. Authorisation status for non reimbursed products

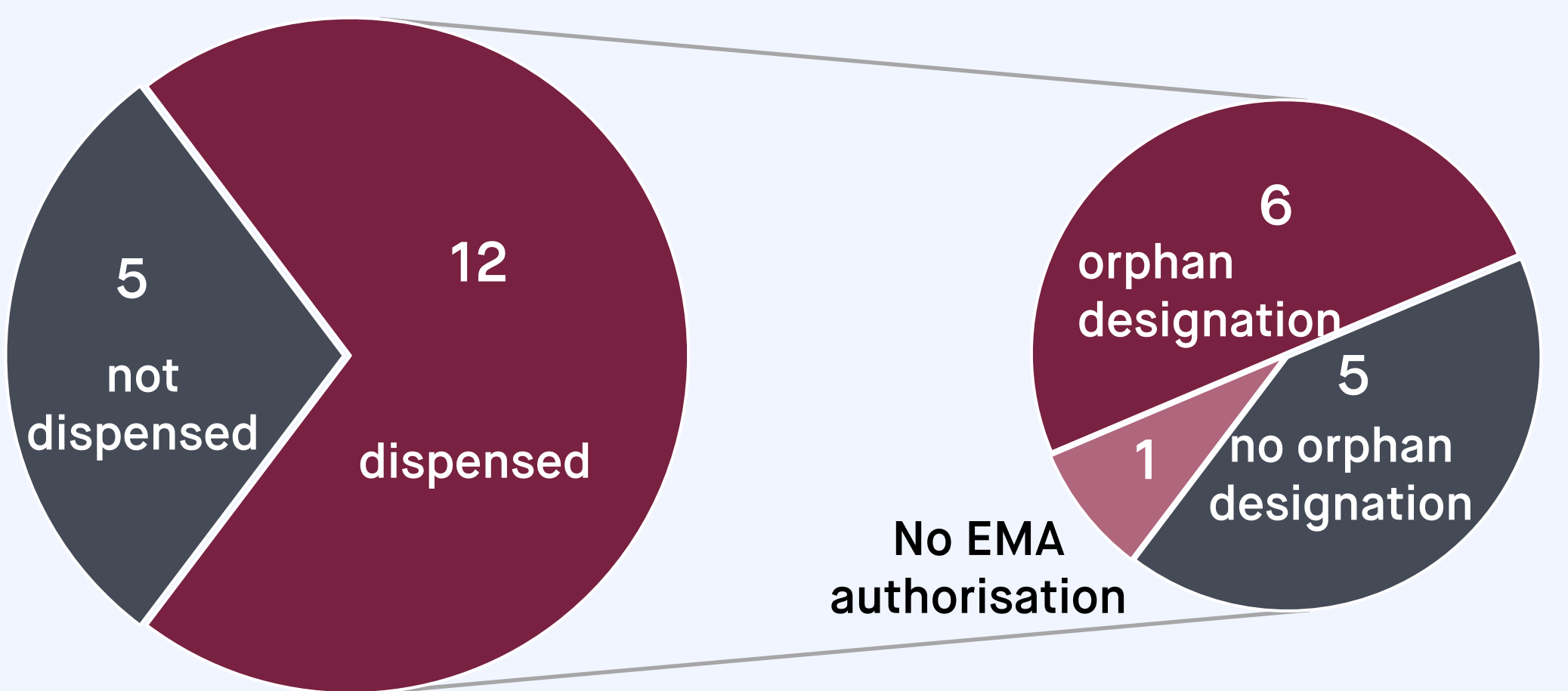


Figure 4. Prescription of products without reimbursement

12 out of 17 non-reimbursed medicinal products that were suitable for the analysis, were dispensed in Sweden at least once.

Table 1. Medicinal products that were at least once prescribed to a patient despite lack of reimbursement in Sweden

Indication ⁶	Patients ⁷	Price ^{8,9}	Indication ⁶	Patients ⁷	Price ^{8,9}
Vulvar and vaginal atrophy in postmenopausal women	5804	26 €	Distal renal tubular acidosis (drta) in adults, adolescents and children aged one year and older	14	129 €
Management of weight in adult patients	4141	102 €	5q spinal muscular atrophy (SMA) in patients with a clinical diagnosis of SMA	4	7 752 €
Mild gastrointestinal cramps, stomach gas and abdominal pain in patients with irritable bowel syndrome (IBS)	3 081	15 €	Progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older	2	N/A
Narcolepsy with or without cataplexy	61	320 €	Gaucher disease type 1 (GD1)	2	20 569 €
Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), tuberous sclerosis complex (TSC)	30	1 282 €	Symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above	2	N/A
Locally advanced basal cell carcinoma (BCC), not amenable to curative surgery or radiation therapy	14	3 897 €	Cytomegalovirus (CMV) infection (...) in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT)	1	11 329 €

Discussion & Conclusion

Out of the 17 medicinal products for analysis, at least 12 were prescribed and dispensed in pharmacies. The prices of the products were available for 10 out of 12 reveling a broad price range from approximately € 15 to € 20 000. For certain cases, e.g. weight control, it may be the patient, paying out of pocket. The more expensive medicinal products may be reimbursed based on an individual decision and funded by the regions. This analysis shows, that the negative TLV reimbursement decision does not necessarily prevent a product from being used and prescribed in Sweden. No clear connection between the authorization status and prescription patterns was observed.

References

1. NMAi database
2. https://sdb.socialstyrelsen.se/if_lak/val.aspx
3. <https://www.ema.europa.eu/en/medicines>
4. <https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta?activeTab=1>
5. <https://www.kronansapotek.se/>
6. The indications were sourced from the SmPC. Due to space constraints certain passages were omitted.

7. Number of patients in 2023
8. In case of different pack sizes, the smallest one was taken for the analysis
9. The original prices in Swedish krona (SEK) were converted to EUR; 1 SEK = 0,086 EUR