Evolution of national price negotiations for pharmacy/retail medicines (tri-party negotiations) in Sweden and implications for access

HPR81

Anja Wikström[1], Achmet Ali Tsaous[2], Thomas Johansson[1], Ebba Gregory[1]

1 Bristol Myers Squibb (BMS), Solna, Sweden; 2 Bristol Myers Squibb (BMS), Helsinki, Finland

Introduction

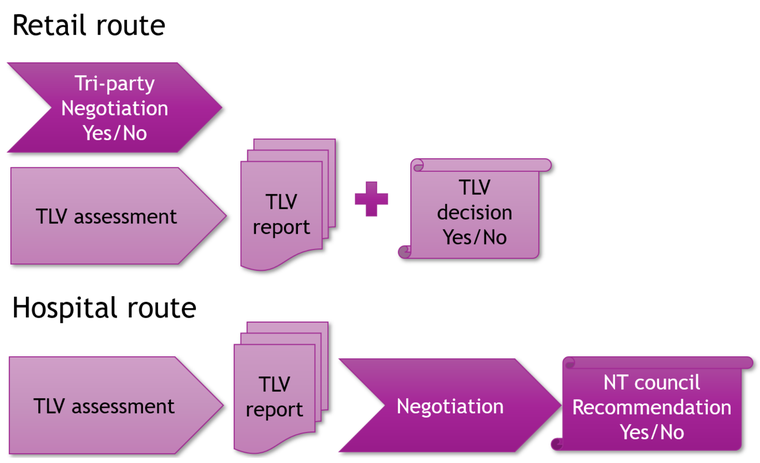
Sweden has two routes to reimbursement relying on a health economic assessment by TLV (The Dental and Pharmaceutical Benefits Agency), one for retail medicines and another for hospital medicines selected for joint national introduction (figure 1).

For hospital medicines the regions negotiate for a net price based on the TLV assessment report and the NT council (representing the regions) decide if the treatment should be recommended for use or not.

For retail medicines, negotiations with the regions (tri-party negotiations) would instead need to happen in parallel to the TLV assessment and be finalised before TLV reaches a decision.

The first tri-party negotiations were initiated over a decade ago, in 2014, with the introduction of hepatitis C treatments. The negotiations aimed at reducing budgetary constraints and at the same time facilitated a rapid introduction of new treatments. To date (September 30, 2025) 99 products have had a tri-party agreement.

Figure 1. Routes to reimbursement (retail) or recommendation (hospital)



Objectives

The aim is to describe how tri-party negotiations have evolved during 2014-2025, which products or therapeutic areas have been the focus of such negotiations, and to investigate how the access to tri-party negotiations might impact the possibility to gain reimbursement.

Methods

Aggregated information on number of agreements, number of assessments, type of decisions (reimbursement or rejection) for new products (including new indications) and number of withdrawals (new products, indications or formulations) was extracted from annual and prognostic reports from TLV (2014-2024). The numbers were cross-checked against individual assessments. Information on disease severity was retrieved from individual assessment reports.

For medicines with marketing authorization 2021-2023, and a positive TLV decision by January 2025, time to reimbursement was compared between treatments with and without a tri-party agreement and disease severity was compared between rejections and approvals with and without agreements.

Results

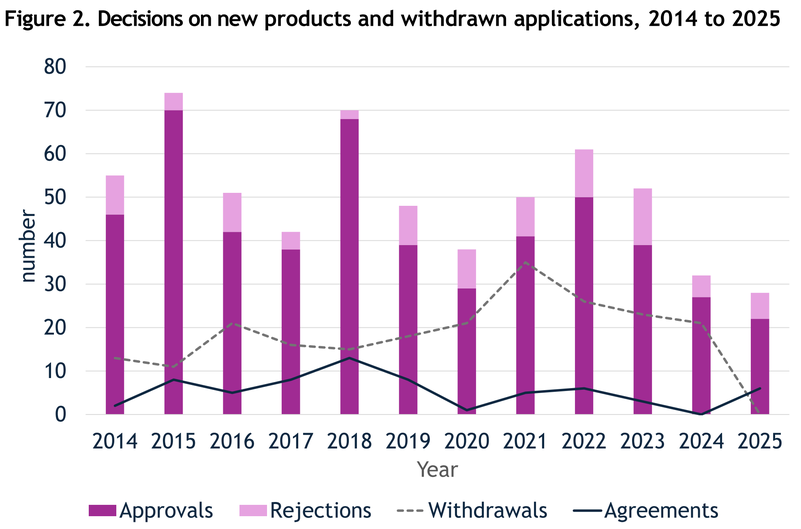
61 products have been introduced with agreements

During 2014 to 2024, 61 new products were introduced with a tri-party agreement, with the largest number in 2018, when 13 new products were introduced with an agreement (figure 2). In 2025 (September 30), 9 products have been introduced with an agreement.

TLV made decisions for 573 new products (or indications) 2014-2024. Most decisions were approvals (figure 2). However, 220 applications (for products, indications or formulations) were withdrawn before a decision was made (figure 2).

Assuming all withdrawals relate to new products or indications, 62 percent of the applications were approved (489 of 793), 28 percent withdrawn (220 of 793), 11 percent rejected (84 of 793), and tri-party agreements were achieved in 8 percent of the assessments (61 of 793).

Figure 2. Decisions on new products and withdrawn applications, 2014 to 2025



99 products have had an agreement

In addition to agreements for new treatments, several treatments already reimbursed have been subject to reviews, resulting in tri-party agreements. To date (Sep 30, 2025), 99 retail medicines have been associated with a tri-party agreement, and 66 currently have an agreement which has not expired.

Figure 3 illustrates the initial rapid increase in agreements both for new (purple) and already reimbursed treatments (turquoise) from 2014 to 2025 (September 30). The figure omits renegotiations outside of reviews.

Figure 3. Tri-party agreements, 2014 to 2025

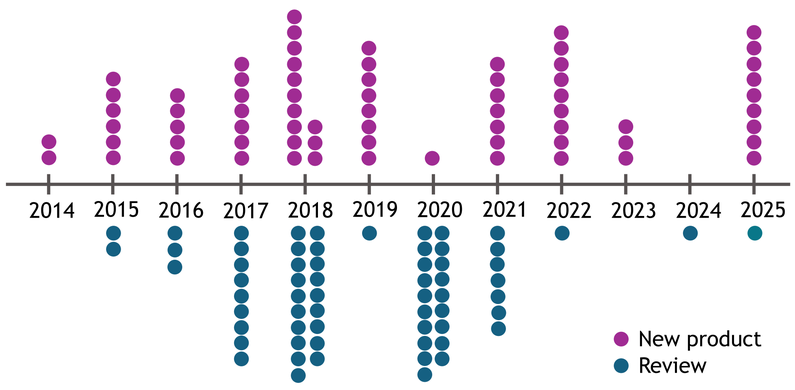
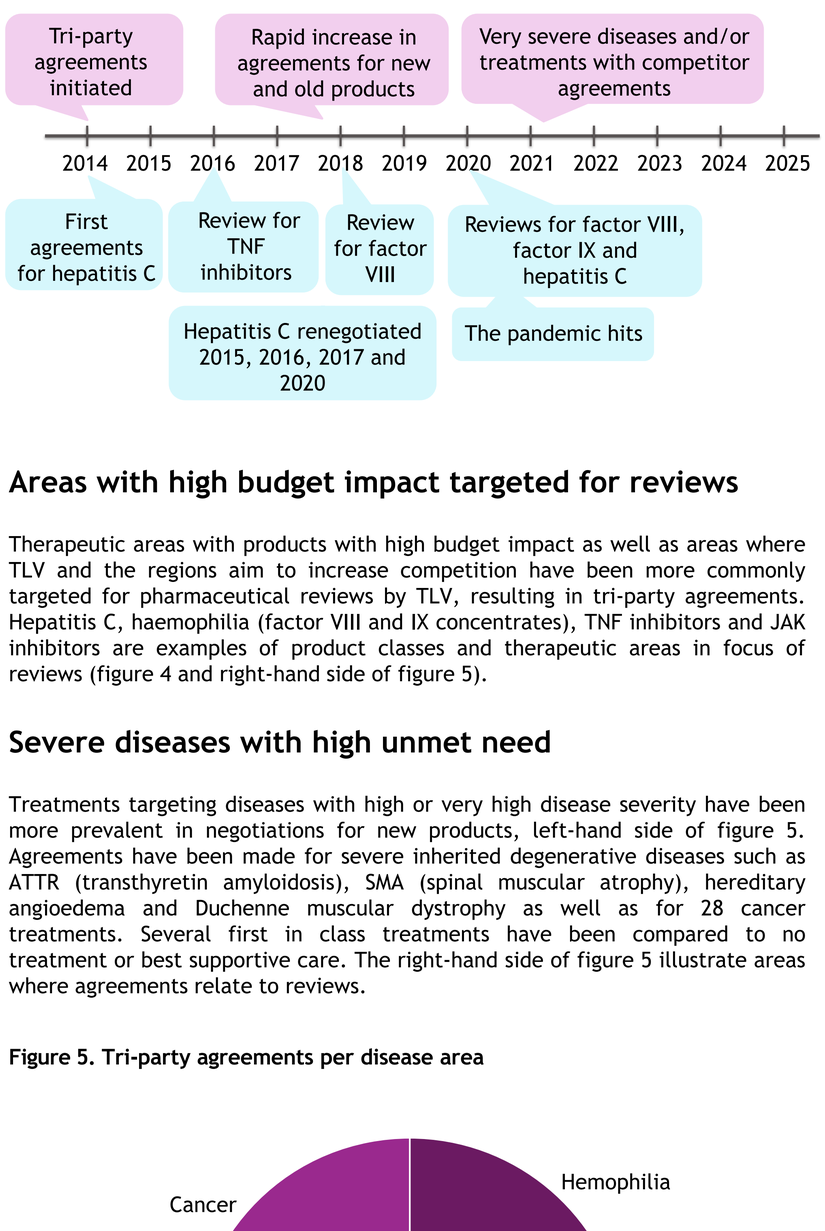


Figure 4. The evolution of tri-party agreements



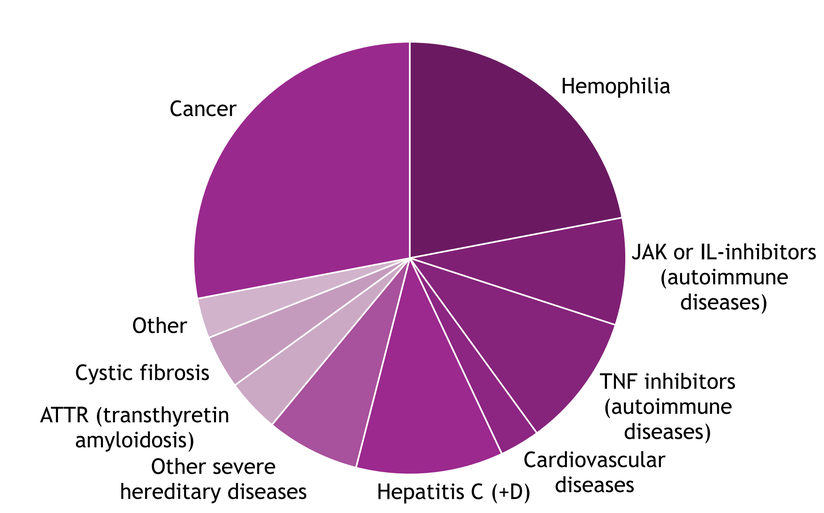
Areas with high budget impact targeted for reviews

Therapeutic areas with products with high budget impact as well as areas where TLV and the regions aim to increase competition have been more commonly targeted for pharmaceutical reviews by TLV, resulting in tri-party agreements. Hepatitis C, haemophilia (factor VIII and IX concentrates), TNF inhibitors and JAK inhibitors are examples of product classes and therapeutic areas in focus of reviews (figure 4 and right-hand side of figure 5).

Severe diseases with high unmet need

Treatments targeting diseases with high or very high disease severity have been more prevalent in negotiations for new products, left-hand side of figure 5. Agreements have been made for severe inherited degenerative diseases such as ATTR (transthyretin amyloidosis), SMA (spinal muscular atrophy), hereditary angioedema and Duchenne muscular dystrophy as well as for 28 cancer treatments. Several first in class treatments have been compared to no treatment or best supportive care. The right-hand side of figure 5 illustrate areas where agreements relate to reviews.

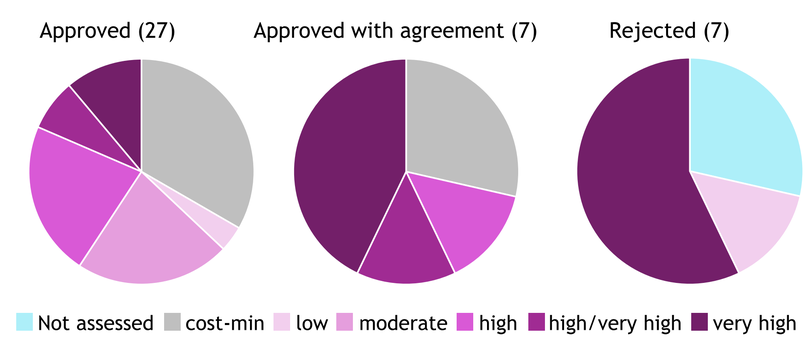
Figure 5. Tri-party agreements per disease area



The cohort with marketing authorization 2021-2023

For medicines with marketing authorization between Jan 2021 and Dec 2023, by January 2025, 34 had received a positive TLV decision, 7 a negative decision, 1 was withdrawn and 3 pending. In addition, there may also be undisclosed cases where companies choose to withdraw their application before a formal negative decision is issued. Among the 7 treatments with marketing authorization 2021-2023 that were introduced with tri-party agreements, 2 target very severe cancer, 3 severe/very severe inherited diseases and 2 were JAK/IL inhibitors where competitors have agreements (assessed by cost minimisation). Figure 6 shows the similarity in disease severity between the products rejected (n=7) and introduced with agreements (n=7) and how products introduced without agreements (n=27) were typically used in less severe diseases.

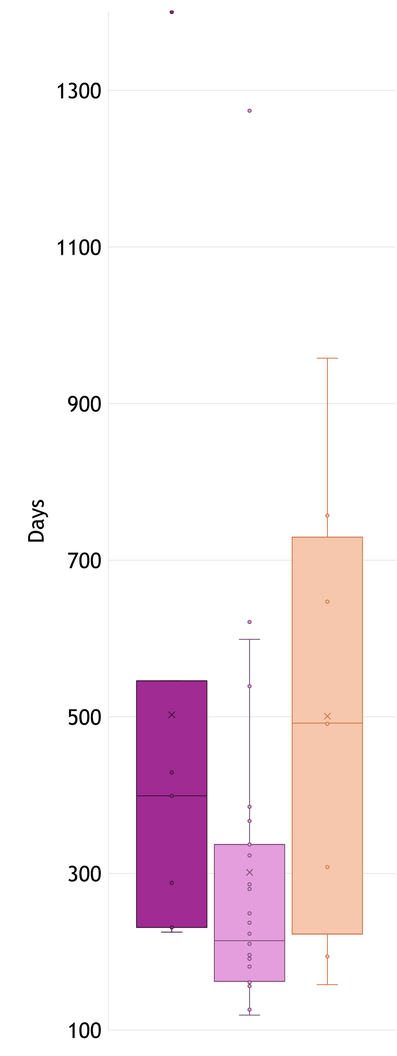
Figure 6. Comparison of disease severity in rejections and approvals



Time to reimbursement

Treatments introduced with a tri-party agreement (7 of 34) took longer to reach a positive TLV decision than those without (27 of 34), with a *median* delay of 6 months (*average* delay of 7 months) after marketing authorization (figure 7). All products introduced with tri-party agreement received a restricted reimbursement. For products introduced without an agreement, 15 of 27 received a restricted reimbursement.

Figure 7. Time to decision for products with and without agreements



The products with the longest access time between marketing authorization and positive TLV reimbursement decision are used for the treatment of SMA and bile duct cancer. One was introduced with and the other without a tri-party agreement.

Two products initially received a negative reimbursement decision, and four products were licensed for individual patients with special needs prior to marketing authorization. Therefore, during the time that TLV was investigating the reimbursement application, the product was granted a so-called temporary subsidy. All these six treatments later received general or restricted reimbursement.

Conclusion

Since 2014, tri-party negotiations have been used to

- facilitate the introduction of new treatments for very severe diseases where patients have limited alternative treatment options
- achieve cost savings in therapeutic areas with high budget impact products

Treatments which do not fall into either of these categories have often not been selected for negotiations.

In the cohort with marketing authorization 2021-2023, products approved with tri-party agreements and rejections often targeted areas with very high disease severity where the willingness to pay is highest (increases with severity), but agreements might be needed to reduce uncertainties and meet cost-effectiveness thresholds.

The possibility to offer confidential discounts is becoming increasingly important in the current global landscape. Initiatives by TLV, the regions and LIF to facilitate the process are ongoing.

References

Annual, prognostic and assessment reports from TLV (www.tlv.se)

Presented at ISPOR Europe 2025; November 9-12, 2025; Glasgow, Scotland, UK

Email: <anja.wikstrom@bms.com>