HPR8

An analysis of Risk Sharing Arrangements (RSAs) between 2013 and 2021 in Australia

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1) Objectives

Achieving market access in the Australian pharmaceutical market is challenging, as payers request greater certainty relating to clinical and cost effectiveness, as well as for budgetary constraints. Risk Sharing Arrangements (RSAs) are one method used by payers to increase certainty. The aim of this study was to analyse the use of RSAs in Australia between 2013 and 2021.

2) Background

- The Pharmaceutical Benefits Advisory Committee (PBAC) considers a range of factors when deciding to recommend the listing of a drug on the Pharmaceutical Benefits Scheme (PBS), including clinical effectiveness, cost-effectiveness.
- The PBAC may require a pharmaceutical company to enter into a RSA to manage uncertainty that exists around these factors.
- RSAs include four types of arrangements: Special Pricing Arrangements (SPAs); Subsidisation cap and reimbursement arrangements; “Shared” deeds of agreement and; Data provision arrangements.
- To date no extensive analyses has identified the use of RSA within the decision-making capability of the PBAC and the implementation after reimbursement decisions.

3) Methods

- The Market Access One Stop Shop (MAOSS) database contains PBS schedule item data from 2007 and is released monthly in .txt format.
- Public Summary Documents (PSDs) were searched from 2013 to 2021 using terms to identify where pharmaceutical companies proposed the use of an RSA, or where a RSA was recommended by the PBAC.
- PSDs requesting minor changes to the listing of the PBS drug (ie minor submissions) were removed from the analysis, along with rejected or deferred submissions.
- PSDs were ordered by drug (defined by the generic name) and date, and the first occurring PSD was included. This method was used to avoid double counting of drugs which have multiple RSAs across indications (but same therapeutic area).
- Identified drugs were then linked with their respective Anatomical Therapeutic Chemical (ATC) code, obtained through the PBS and MAOSS databases, and the first level of ATC code was used to group drugs with RSAs by therapeutic area.

4) Results

The number of PBS listed drugs with a requested or proposed RSA, as reported within the PSDs grew from 3 in 2013 to 18 in 2021 (Figure 1)

There was significant growth in the expected use of RSAs between 2013 and 2016, reaching 21 in 2016.

The use of RSAs for immunological or oncology products has remained stable at 8 to 9 per year between 2016 and 2021.

Since 2017, the proportion of new drugs with RSAs constituted approximately 1 in 3 recommended new drugs listed on the PBS (Figure 2).

From 2017 onwards, the expected use of RSAs has stabilised dropping to 12 in 2017 and slowly growing to 18 in 2021.

Oncology and Immunology products with RSAs increased to 64% until 2017, this trend has diminished between 2018 and 2021, with the requirement of RSAs constituting 26.7% of new oncology/immunology products listed on the PBS in 2021.

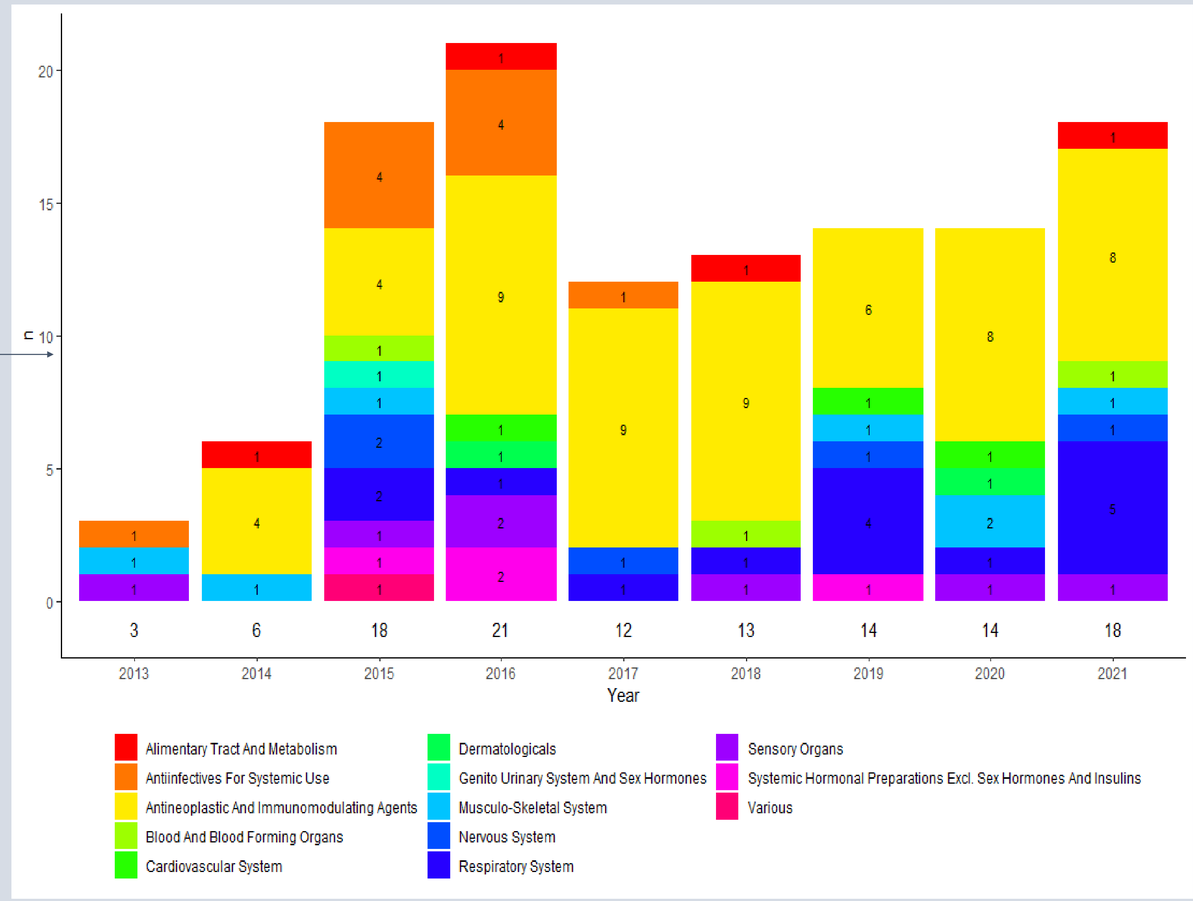

Figure 1: Number of PBAC positive recommendations with RSAs (2013-2021) by Therapeutic Area

Table 1: Proportion of Oncology & Immunology Products Recommended on the PBS with Risk Sharing Arrangements between 2013 and 2021

2013	2014	2015	2016	2017	2018	2019	2020	2021
0% (0/11)	20% (4/20)	36.4% (4/11)	47.4% (9/19)	64.3% (9/14)	60.0% (9/15)	40.0% (6/15)	42.1% (8/19)	26.7% (8/30)

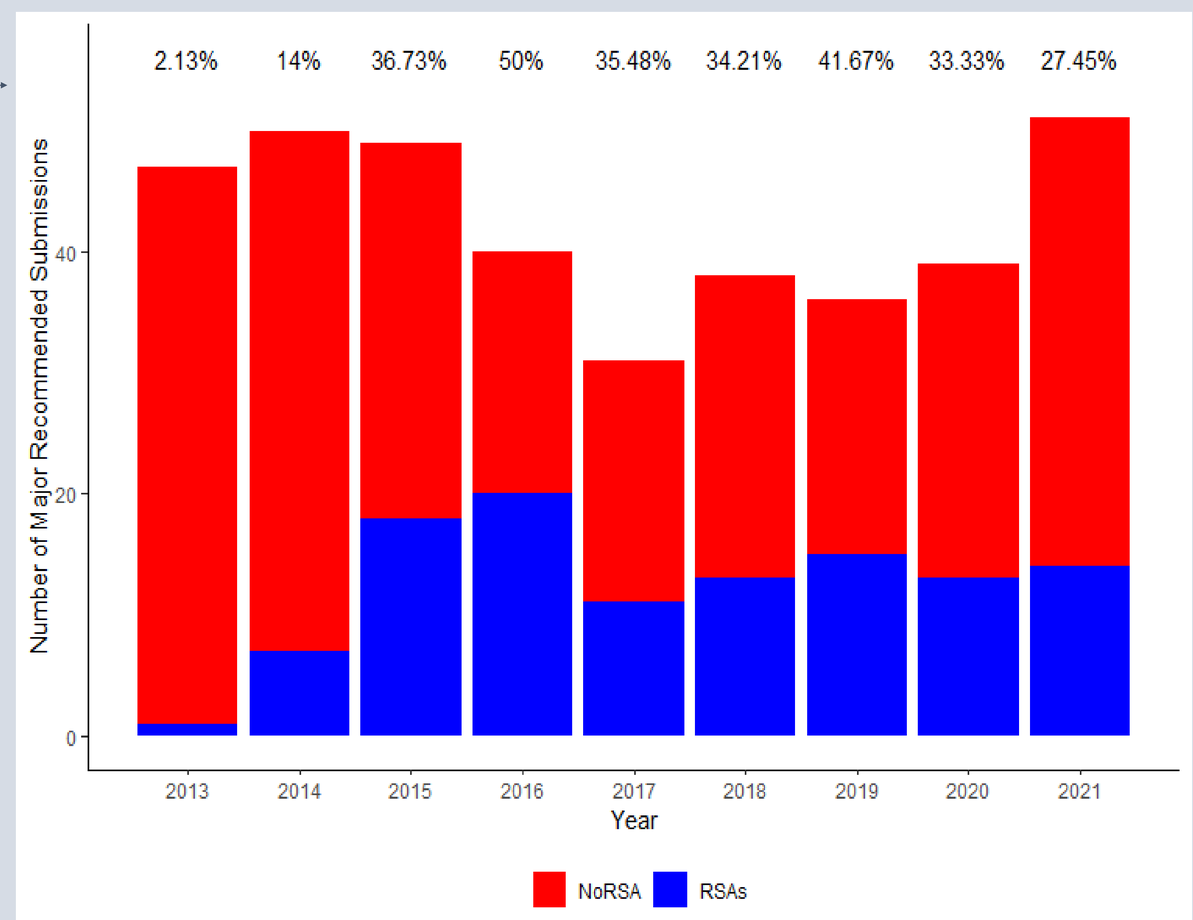

Figure 2: Risk Sharing Arrangements between 2013 and 2021 as a proportion of all Recommended Major PBAC Submissions

5) Discussion

- This analysis provides insight into the distribution of the use of RSAs across recommended PBS listed drugs, with a focus on oncology and immunology products.
- While there appeared to be a growing dependence on RSAs, especially with oncology/immunology products, the impact of this dependence appears to waned in recent years.
- This may be due to better, or more familiar, trial design, greater certainty in the targeted patient population, or more realistic pricing negotiations.
- However with the growth in the use of SPAs with oncology products (see HPR75), there appears to be greater uncertainty in the cost-effectiveness price presented in PBAC oncology submissions.

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