IMS Health & Quintiles are now IQVIA™

First edition, May 2019

EvidANZ

A data driven review of Market Access trends in Australia

We are living in a transformational era defined by the increasing availability and accessibility of data

It touches every aspect of our lives, from how we socialise, to where we eat, when we exercise and how we shop. The transformational impact of data on our healthcare system is no exception.

Today, real world evidence is being used to accelerate drug discovery, improve commercial decision-making, define the framework for health technology assessments and influence clinical guidelines. So it stands to reason that data can, and in fact should inform Market Access strategy as well.

With this, **IQVIA** and **Lucid Health Consulting** are working to **reimagine the way our industry thinks about Market Access.**

IQVIA's breadth of data, advanced analytics and real world evidence generation capabilities, combined with contributions of deep local Market Access expertise from Lucid Health Consulting, have enabled us to build a **first-in-class evidence, value and outcomes strategic advisory offering.**

In the first edition of the **EvidANZ** newsletter, we provide a sneak peak into how we can help you harness the power of data to enhance your Market Access strategy.

More specifically, this newsletter introduces **IQVIA's** proprietary Health Technology Assessment (HTA) Accelerator tool, details key outcomes from a data-driven review of 2018 Market Access outcomes in Australia, and considers implications for 2019 and beyond.

In future editions, we will continue to monitor and communicate how Market Access trends are tracking over time, so stay tuned.

Introducing the HTA Accelerator

> 25,000
HTA publications in **250 diseases** from **39 countries** and **100 agencies**

> 4,200
Price records in EU5+US

An IQVIA proprietary database with **one stop shop**' access to historical payer decision-making information

> 1,400
Regulatory records from FDA and EMA

> 2,300
Clinical records

The Year in Review

2018 Market Access in Australia – at a glance

Submission by Type

In 2018, **175 standard** and **13 NIP** submissions were assessed by PBAC

This consisted of...

43% **Major** submissions

54% **Minor** submissions
+ 3% other

57% new listings
+
42% change listings
+ 2% other

72% new submissions
+
27% re-submissions
+ 1% other

PBAC = Pharmaceutical Benefits Advisory Committee
NIP = National Immunisation Program

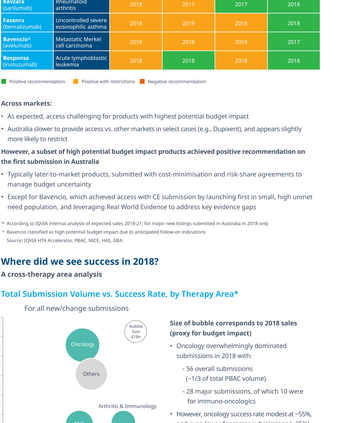
Submission Outcomes*

* For major & minor standard submissions; excludes NIP and "other" submissions

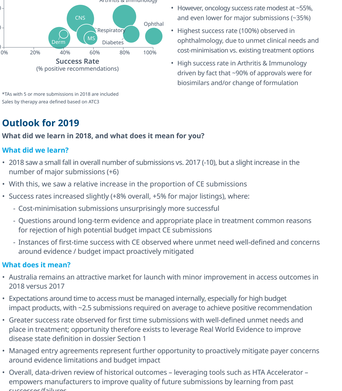
How does 2018 stack up?

A historical benchmarking exercise

A Two Year Comparison of PBAC Outcomes



Cost-Minimisation (CM) vs. Cost-Effectiveness (CE)



Only submissions with an economic evaluation were included; one submission may include more than one type of economic evaluation, so double counting may exist.

How does Australia compare globally?

An international benchmarking exercise

HTA outcomes by market

For major new submissions with highest potential budget impact*

PRODUCT	INDICATION	REVIEW OUTCOMES			
Dupixent (dupilumab)	Severe atopic dermatitis	2018	2018	2018	2018
Imfinzi (durvalumab)	Non-small cell lung cancer	2018	Ongoing	Ongoing	Ongoing
Staquis (crisaborole)	Atopic dermatitis	2018	Ongoing	Not submitted	Not submitted
Aimovig (erenumab)	Chronic migraine	2018	Draft rec.	Not submitted	Ongoing
Kevzara (sarilumab)	Rheumatoid arthritis	2018	2017	2017	2018
Fasenra (benralizumab)	Uncontrolled severe eosinophilic asthma	2018	2019	2018	2018
Bavencio^ (avelumab)	Metastatic Merkel cell carcinoma	2018	2018	2018	2017
Besponsa (inotuzumab)	Acute lymphoblastic leukemia	2018	2018	2018	2018

Positive recommendation | Positive with restrictions | Negative recommendation

Across markets:

- As expected, access challenging for products with highest potential budget impact
- Australia slower to provide access vs. other markets in select cases (e.g., Dupixent), and appears slightly more likely to restrict

However, a subset of high potential budget impact products achieved positive recommendation on the first submission in Australia

- Typically later-to-market products, submitted with cost-minimisation and risk-share agreements to manage budget uncertainty
- Except for Bavencio, which achieved access with CE submission by launching first in small, high unmet need population, and leveraging Real World Evidence to address key evidence gaps

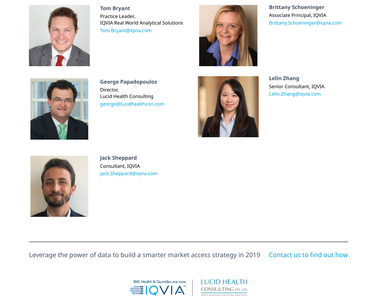
* According to IQVIA internal analysis of expected sales 2018-21; for major new listings submitted in Australia in 2018 only
^ Bavencio classified as high potential budget impact due to anticipated follow-on indications
Source: IQVIA HTA Accelerator, PBAC, NICE, HAS, GBA

Where did we see success in 2018?

A cross-therapy area analysis

Total Submission Volume vs. Success Rate, by Therapy Area*

For all new/change submissions



*TAs with 5 or more submissions in 2018 are included
Sales by therapy area defined based on ATC3

Size of bubble corresponds to 2018 sales (proxy for budget impact)

- Oncology overwhelmingly dominated submissions in 2018 with:
  - 56 overall submissions (~1/3 of total PBAC volume)
  - 28 major submissions, of which 10 were for immuno-oncologics
- However, oncology success rate modest at ~55%, and even lower for major submissions (~35%)
- Highest success rate (100%) observed in ophthalmology, due to unmet clinical needs and cost-minimisation vs. existing treatment options
- High success rate in Arthritis & Immunology driven by fact that ~90% of approvals were for biosimilars and/or change of formulation

Outlook for 2019

What did we learn in 2018, and what does it mean for you?

What did we learn?

- 2018 saw a small fall in overall number of submissions vs. 2017 (-10), but a slight increase in the number of major submissions (+6)
- With this, we saw a relative increase in the proportion of CE submissions
- Success rates increased slightly (+8% overall, +5% for major listings), where:
  - Cost-minimisation submissions unsurprisingly more successful
  - Questions around long-term evidence and appropriate place in treatment common reasons for rejection of high potential budget impact CE submissions
  - Instances of first-time success with CE observed where unmet need well-defined and concerns around evidence / budget impact proactively mitigated

What does it mean?

- Australia remains an attractive market for launch with minor improvement in access outcomes in 2018 versus 2017
- Expectations around time to access must be managed internally, especially for high budget impact products, with ~2.5 submissions required on average to achieve positive recommendation
- Greater success rate observed for first time submissions with well-defined unmet needs and place in treatment; opportunity therefore exists to leverage Real World Evidence to improve disease state definition in dossier Section 1
- Managed entry agreements represent further opportunity to proactively mitigate payer concerns around evidence limitations and budget impact
- Overall, data-driven review of historical outcomes – leveraging tools such as HTA Accelerator – empowers manufacturers to improve quality of future submissions by learning from past successes/failures

We're excited to hear from you

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Leverage the power of data to build a smarter market access strategy in 2019 Contact us to find out how