# Oncology combination therapies in Asia-Pacific markets: what are the current access challenges?

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## 1. Background and Objectives

- Combination therapies (CT) are increasingly being developed in oncology and have clinical benefits over and above monotherapies. However, challenges in their assessment and pricing can delay or prevent access for patients, especially when CTs consist of multiple on-patent constituents with different manufacturers[1].
- We conducted a study in two stages (desk research and expert interviews) with the aim to:
  - describe the regulatory and reimbursement landscape of CTs in oncology in five Asia-Pacific (AP) markets: Hong Kong (HK), New Zealand (NZ), Singapore (SG), South Korea (SK) and Taiwan (TW);
  - identify challenges and barriers with value assessment and reimbursement of CTs with ≥2 on-patent drugs.

## 2. Methods

- 14 free-dose CTs that received EMA marketing authorisation between 2015 and June 2020 were selected. All CTs included a constituent therapy that is licensed in another indication or CT.
- We conducted a literature search to extract regulatory and reimbursement status of the 14 CTs, as of November 2021 in each market. Australia (AU) was included in this stage of the study only as a benchmark in the AP region.
- We developed an interview guide to inform a series of semi-structured interviews with local HTA and regulatory experts from each market. The interviews were conducted and transcribed by an external agency with local language expertise.
- The purpose of the interviews was to understand the evaluation process for CTs, factors considered in pricing the individual therapies and overall CT, barriers to access and openness to innovative pricing mechanisms.
- We analysed the translated interview transcripts and developed key messages and learnings for each market.

## 3.1 Results: regulatory and access landscape

- The market with largest number of reimbursed CT was SG (36%), which is comparable to the AU benchmark, while the market with lowest was NZ, where none were reimbursed (Figure 1).
  - **Only 6 out of 14 CTs of interest achieved access in any of the five AP markets.**
- CTs are more likely to be reimbursed if they consist of **off-patent constituents and/or are produced by a single manufacturer**. The former is a result of relatively lower costs of generic brands while the latter indicates greater flexibility for the manufacturer to negotiate a mutually acceptable price with the payer/decision-maker and secure access.
  - The CTs that were not reimbursed did not share either of these characteristics.
- **CTs produced by multiple manufacturers face a longer time to availability than those produced by a single manufacturer** (Figure 2).
- The CTs that were produced by multiple manufacturers were reimbursed after loss of exclusivity of two of the three molecules. This could imply the following:
  - i. Reimbursement processes and pricing negotiations are less time-consuming when only one molecule is on-patent, and/or
  - ii. Payers opt to delay listing until less costly generic products are available in their market.
- Time to access for CTs (Figure 2) is longer compared to the average of 15.4 months in Europe and AU[2].
- Nonetheless, in Europe and AU, time to access for CTs produced by multiple manufacturers was 105 days longer compared to the average across all oncology medicines.

Figure 1: regulatory and reimbursement status of 14 free-dose CTs in AP markets

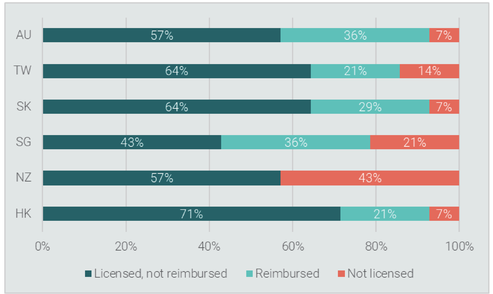
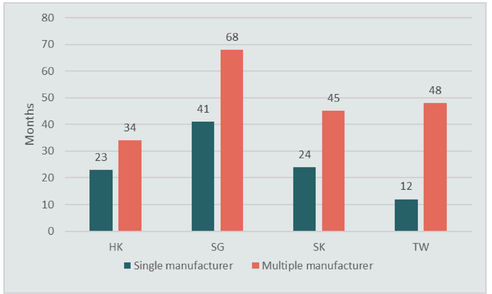



Figure 2: average timeline (months) between regulatory approval and reimbursement for reimbursed CTs produced by a single manufacturer versus multiple manufacturers




## 3.2 Results: challenges and barriers to reimbursement

- Barriers that were common across AP markets include **impact of anti-trust law** on impeding pricing negotiations between multiple manufacturers; **monotherapy-centric focus of regulatory and reimbursement processes; inability or reluctance of health systems to track usage** by indications to facilitate indication-based pricing (IBP); and a **focus on budget impact** to drive pricing and listing decisions that tend not to fully recognise and reflect the value of therapies.
- Payers are not willing to pay more for CTs compared to other therapies and typically do not engage with matters of competition law and splitting CT value amongst constituent therapies.There are no specific legislation or dedicated policies for CTs; this is not unique to AP and many of these challenges are similar to those observed elsewhere, e.g. Europe.

## 4. Discussion

- Environment shaping is needed to shift and allow for greater recognition of the benefits of CTs and challenges in access for exploring new access solutions in AP.
- Practical solutions should be created jointly amongst the clinical community, payers and industry, with consideration of investment in health data infrastructure to allow for tracking use among different therapies' indications and pilot programmes of innovative pricing mechanisms.

## 5. Conclusions

- CTs are more likely to be reimbursed if the CT includes off-patent constituents and/or are produced by a single manufacturer.
- Current legal and HTA policies in AP are not conducive for assessing and listing on-patent CTs in oncology, resulting in delayed or no access for these CTs relative to monotherapies.
- Greater awareness of the benefits of CTs, recognition of access issue and co-creation of practical solutions by all stakeholders are needed to improve availability of CTs in the AP region.

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