6.12 IMATINIB
100 mg and 400 mg tablets (as mesylate); Glivec®, Novartis Pharmaceuticals Australia Pty Ltd

1 Purpose of application

1.1 The submission sought to change the pack size of imatinib for treatment of patients with gastrointestinal stromal tumor (GIST) in both metastatic and adjuvant settings. This request was for the 100 mg tablet (PBS item codes 5443L, 9111M) and 400 mg tablet (PBS item codes 5444M and 9112N). The requested change would reduce the current pack size and the maximum quantity units from 60 to 56 tablets per pack for 100 mg strength (PBS item codes 5443L, 9111M) and 30 to 28 tablets per pack for 400 mg strength (PBS item codes 5444M, 9112N).

2 Requested listing

2.1 The submission did not request a change to the wording of the listing, except for the changed pack size.

3 Background

3.1 Imatinib is currently PBS listed in two pack sizes (100 mg /tablet; 60 tablets/pack and 400 mg/tablet; 30 tablets/pack) for the following indications:

- chronic myeloid leukaemia (CML)
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy
- relapsed or refractory Ph+ ALL as monotherapy
- myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements, where conventional therapies have failed
- aggressive systemic mastocytosis (ASM), where conventional therapies have failed
- hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL)
- unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
- CD117 positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST)
- adjuvant treatment of patients at high risk of recurrence following complete resection of primary GIST (at a dose not exceeding 400 mg per day for a period of 36 months)

3.2 The submission only requested pack size changes for the treatment of GIST (for metastatic and adjuvant settings).

3.3 The new pack sizes of imatinib (100 mg, 56 tablets and 400 mg, 28 tablets) for use in the patients with GIST were registered by the TGA on 24 September 2014.

3.4 During the period of January 2014 to December 2014, 23% of the services of imatinib processed by Medicare were for the treatment of GIST (see table below).

PBS indication (PBS item code)	Strength, pack size		Number of services of imatinib processed from Jan 2014 to December 2014 (PBS/RPBS)
	100 mg/60	400 mg/30	
GIST (adjuvant) 5443L/5444M	88	1384	1472
GIST (metastatic) 9111M/9112N	848	3,793	4641
Total for GIST indications			**6113**
Total for non-GIST indications (codes: 09113P, 09115R, 09123E, 09172R, 09174W, 09176Y, 09178C, 09114Q, 09116T, 09124F, 09173T, 09175X, 09177B, 09179D)			**20983**
Total all indications			**27096**
Percent: GIST of all indications			**23%**
Percent: non-GIST of all indications			**77%**

Source: http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp, searching for Item codes: 05443L, 09111M, 09113P, 09115R, 09123E, 09172R, 09174W, 09176Y, 09178C, 05444M, 09112N, 09114Q, 09116T, 09124F, 09173T, 09175X, 09177B, 09179D
See above for abbreviations of each indication.

4 Pricing considerations

4.1 The submission proposed the same ex-manufacturer price per tablet as the current pack sizes. However the reduced pack size resulted in an increased number of packs used per treatment year. The submission estimated the impact to be an extra 0.87 packs per year for the 400 mg strength and 1.74 packs per year for the 100mg strength.

4.2 The submission stated that listing of the new pack sizes would result in net cost to the Government (extra mark-ups) and to patients (additional co-payments). The table below shows the net annual cost to Government was estimated to be less than $10 million in year one and up to less than $10 million in year 5 is due to the extra mark-ups (pharmacy, wholesaler and dispensing fee minus patient average co-payment).

Net costs for listing of proposed packs using estimates of patient numbers applied in the submission (total costs for proposed packs minus total costs for current packs)

Year	1	2	3	4	5
	2015	2016	2017	2018	2019
Net costs with proposed packs (with DPMQ)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net costs to government with proposed packs (i.e., DPMQ minus copay)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net cost to patient with proposed packs (i.e., using average patient copayment)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]

Source: Page 14 of the submission (Financial Estimates spreadsheet (attachment 1)," Financial Estimates" worksheet rows 124-126)

4.3 The sponsor acknowledged the net cost to government arising from the listing of the proposed 28/56 packs sizes of imatinib for GIST and proposed a special pricing arrangement to ensure that any extra cost can be rebated by the sponsor to ensure cost neutrality for the Government.

5 Other relevant factors

5.1 There was no hearing for this item as it was a minor submission.

5.2 The PBAC noted that no consumer comments were received for this item.

5.3 The submission claimed that:

- the reduction of the pack sizes is more likely to improve patient's adherence
- patients stopping therapy before they have finished their current pack (i.e., patients stopping or changing therapy) will dispose of fewer tablets resulting in less wastage reduce wastage,

No data were provided to support these claims in the submission.

5.4 The submission assumes that pack sizes being specific to GIST would reduce erroneous item numbers entered at a pharmacy level thereby improving the ability to track the use by indication.

No data were provided to support this claim in the submission.

6 PBAC Outcomes

6.1 The PBAC advised the Minster that there is no community need for the listing of alterative pack sizes of imatinib, namely 56 tablets per pack for 100 mg strength (PBS item codes 5443L, 9111M) and 28 tablets per pack for 400 mg strength (PBS item codes 5444M, 9112N) for treatment of patients with gastrointestinal stromal tumor (GIST) in both metastatic and adjuvant settings.

6.2 While noting the submission and the sponsor's pre-PBAC response, the PBAC considered that the magnitude of benefit claimed for adherence and wastage was not established in the submission over the currently available pack sizes.

6.3 The PBAC noted that the submission was only to change the listing for a minor proportion of the total utilisation of imatinib.

6.4 The PBAC noted that there was no mechanism to counterbalance the additional cost to patients, considering the sponsor's pre-PBAC response proposal to address this through maximum quantities of 35 and 70 to be inconsistent with the current practice of recommended maximum quantities that supply one month of treatment at usual doses for medicines used longer term.

Outcome:
Rejected

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor has no comment.