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2009/10 Multi-product Tender

The RMI is most concerned about the changes proposed this year to PHARMAC's annual multi-product tender.

Timelines

The RMI does not support the proposal to bring forward the tender timelines.

While you are now consulting on revised timelines for the remainder of this year's process and next year, it is notable that your consultation letter on the draft invitation to tender (ITT) and deadline for alternative commercial proposals (ACPs) was over a month earlier than usual. PHARMAC provided no opportunity to comment on this change to the process. Suppliers in our association were largely caught off guard by the revised timing of the consultation process and were consequently under prepared to respond to PHARMAC. The subsequent extension to the ACP deadline is some acknowledgement of this fact. However, PHARMAC should more properly have signaled its intentions to bring the process forward before doing so.

We do not support the proposed revised closing date for tender bids at the end of January. Even with an earlier call for tender bids at the end of November, the majority of the time in which suppliers will need to prepare tender bids will be unusable. The first 3-4 weeks (between Christmas and mid to late January) of current period of time between the issue of the ITT and the closing date for bids is already effectively useless because of the Christmas and holiday period. However, the month of February does provide at least some time in which suppliers can more reliably liaise with overseas counterparts. Exchanging those four weeks for a maximum of three useful weeks in December, without due notice, is unreasonable.

While the further movement of the tender timelines in the 2010/11 Tender would shift the tender process away from the Christmas period, we can only support this change if it guarantees that suppliers will be notified of tender results as early as January. It is difficult to see how this would be possible as long as PHARMAC continues to delay the start of many some Sole Supply and/or Hospital Supply periods because PHARMAC it intends to award the tender to an unregistered product. A closing date for bids of late December with continued uncertainty around start dates could simply extend the amount of time suppliers are left in limbo regarding the outcome of the tender. Such delays already leave suppliers at significant risk in terms of inventory control and exposure to exchange rate fluctuations and changes in material costs.

In summary, we consider that if the timelines are to be altered:

- the key tender dates should be moved in one step, in the next tender round (not this) to the proposed 2010/11 timelines; and
- the SSS and HSS start dates should be moved in alignment or at least time limited (i.e. so that tenders cannot be awarded more than 6-12 months after bids close).

Audit

The RMI is appalled by the proposed amendment to clause 3 of Schedule 4 of the Invitation to Tender, which includes provision for an auditor to access the premises of any wholesaler or other distributor.

This amendment is unnecessary. Out of stock situations are completely undesirable for suppliers. The damage to our customer relationships, sales and reputation, not to mention the penalties imposed by PHARMAC and the opportunity cost of dealing with stock shortages mean that it makes very poor commercial sense to run short of or out of stock. However, these shortages do unavoidably occur from time to time. We might add that the risks are often heightened by PHARMAC's sole supply policies. However, on these occasions, suppliers willingly provide PHARMAC with considerable information about stock holdings including as much information as they can obtain about stock remaining in the supply chain. This information is provided in good faith. Even if PHARMAC were to obtain that information by independent means, it would not change the outcome (in terms of ability to supply or penalties imposed) of the usual situation in which the supplier had notified PHARMAC of the problem as was doing all it could to rectify it.

The new proposed provisions would also place an obligation on suppliers that they cannot currently fulfill. The contractual arrangements between suppliers and wholesalers/distributors do not permit access to records and any other information held by them to a third party. There appears to be an unstated expectation that suppliers will seek to amend these terms to accommodate PHARMAC's requirements. Wholesalers and distributor are likely to seek concessions in exchange for such amendments. The expectation is therefore unreasonable and, in our opinion, symptomatic of PHARMAC's complete disregard for the commercial interests of suppliers.

The RMI considers that, if PHARMAC believes it requires information from wholesalers and distributors in order to better manage supply continuity and/or enforce its contracts, then it should negotiate its own access to such data with wholesalers. Indeed, we suggest that PHARMAC may have had the opportunity to do so when it implemented the Wholesaler uplift fee earlier this year.

Withdrawal or suspension of Sole Supply Status and/or Hospital Supply Status

The RMI also opposes the proposed new provisions that would enable PHARMAC to withdraw or suspend SSS and/or HSS for other forms or strengths of the same chemical if PHARMAC has had reason to withdraw or suspend SSS and/or HSS on another line item.

There is no valid clinical basis to the proposal since there are already examples of where PHARMAC has awarded HSS and SSS to different suppliers for the same product. PHARMAC has also awarded SSS or HSS to different suppliers for different strengths of the same product.

This clause would allow PHARMAC to potentially exploit a supply glitch on a minor line item in order to take advantage of better commercial terms that might have become available since the tender was awarded for a major line item.

The RMI considers that each SSS/HSS arrangement must be regarded as a separate contract and that any attempt to link arrangements of different presentations is unfair.

Price

The proposed new provisions in clause 3 of both Schedule 5 and Schedule 6, which effectively amount to an enforced declaration by suppliers that the price offered by a supplier through the tender process would incorporate any costs incurred following the subsequent delisting of the product, is completely unreasonable. In proposing these provisions, PHARMAC has once again demonstrated its disregard for the commercial interests of suppliers and its expectation that PHARMAC should carry almost none of the risk associated with the transition periods within this tender process.

The new provision 1.2(e) in Schedule 3 should also be deleted.

The "evergreen" supply obligations within the tender document already require suppliers to place orders for stock without any certainty of how much longer they will remain in the market. This uncertainty may persist for months or even years beyond the end of the guaranteed period of exclusivity – especially where PHARMAC awaits registration of the incoming pharmaceutical. The nature of global supply arrangements mean that suppliers in New Zealand have to place minimum stock orders of 6 months or more and these orders may have to be placed 6-9 months in advance. However, PHARMAC seldom if ever provides notice of much more than 1 month of a transition period. The risks to suppliers are therefore high but cannot realistically be estimated based on the amount of notice PHARMAC currently provides of a change of suppliers and the communication (or lack thereof) leading up to such notification.

If PHARMAC wishes to include the new provisions then there must be a definite End Date. This seems an unlikely concession given PHARMAC's obvious desire to retain the right to allow unregistered suppliers to bid in its Tender.

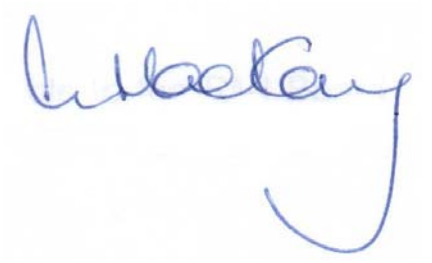
We assume that the need for this particular proposed change has arisen because suppliers have occasionally sought compensation for poorly managed transitions via Stock Guarantee arrangements and the like.

The RMI suggests that, as an alternative to the proposed changed, PHARMAC could address this issue by improving its own communication. It should advise incumbent suppliers as soon as it identifies a potential new supplier and maintain regular communication with incumbent and incoming suppliers until the transition is complete. PHARMAC could also spread the risk associated with transition periods more fairly by placing defined and limited supply obligations (based on the expected in-market date for the new supplier) on the incumbent supplier and requiring the incoming supplier to indemnify against any delays beyond that date.

Summary

The industry has come to expect each successive tender document to contain additional layers of complexity and greater regulation. This year is no exception. However, the RMI considers that the changes proposed this year places too much of the risk of this process on pharmaceuticals companies. PHARMAC has offered no reasons or explanations for most of the changes or any concessions in exchange for the additional burden they represent. While we do not support any of the changes as presented, we have endeavored to provide some more practical and reasonable alternatives for PHARMAC to consider.

Yours sincerely



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