Policy Position: Radioligand Therapies

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Medicines Australia

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Background and Issue - what is the problem, what is important

There are several advanced radioligand therapies[1] in the commercial pipeline. Only one is currently approved by the TGA.

Historically, copy therapies prepared from a variety of sources have provided patient access to unapproved versions of similar technologies. These compounded therapies have not undertaken the controlled clinical development programs that commercial versions are required to complete, and have not applied for, or been evaluated for, quality, safety or efficacy by the Therapeutic Goods Administration (TGA). They are not manufactured under Good Manufacturing Practice (GMP) which assures quality.

Despite the lack of TGA approval, the Medical Services Advisory Committee (MSAC) have recommended reimbursement of an unapproved, copy radioligand therapy, with subsequent funding provided by the Commonwealth.

This runs counter to the long-standing patient safeguards for other pharmaceuticals funded through the Pharmaceutical Benefits Scheme (PBS), wherein products must be reviewed and approved by the TGA prior to potential PBS reimbursement.

Australia's health technology assessment (HTA) system has not provided any degree of certainty to industry in the reimbursement pathways to secure patient access to radioligand therapies and a framework provided by MSAC for oversight of radioligand therapies (including unapproved versions) falls short of providing the safeguards required for other medicines.

Australia's regulatory and HTA environment must be set up to encourage and support companies to launch commercially developed radioligand therapies in Australia for Australian patients.

Disincentives to bring innovative therapies to Australia will lead to further delays for patients to access breakthrough and cutting-edge technologies. Unapproved, compounded therapies, that lack the appropriate regulatory review for quality, safety, efficacy, and post marketing pharmacovigilance will not meet the high standards and needs of Australian patients.

It is recognised that in the past the absence of a commercial pipeline of radioligand therapies necessitated access to therapeutics through unapproved medicine pathways, but many elements of this historical approach are no longer appropriate.

Medicines Australia is keen to partner with Government and the TGA, PBAC and MSAC in implementing regulatory change and the development of comprehensive processes for registration and reimbursement of radioligand therapies which integrate appropriate regulatory approvals.

[1] Radioligand therapies are a subset of radiopharmaceuticals

MA position – top line messages, what can be done to solve the issue

Medicines Australia is keen to partner with Government and other stakeholders to ensure the success of the emerging and advancing radioligand therapies and nuclear medicines sector to ensure safe and equitable access to TGA approved therapies for patients.

Medicines Australia believes the following principles will promote an evidence-based, safe, effective, cost-effective, and competitive radioligand therapies sector:

1. The default position for funded patient access to all medicines, including radioligand therapies, should be based on high standards of scientific and clinical evidence, with TGA regulatory approval as the default position unless a product is not available otherwise.
2. Once a particular radioligand therapy is commercially available in Australia, to ensure efficacy, safety and quality, the regulatory framework should not permit compounded versions containing the same active ingredient.
3. Medicines supplied in Australia and funded through Government funding mechanisms (e.g. PBS/MBS) must have TGA approval and meet agreed regulatory standards.
4. Under the *National Health Act 1953*, the PBAC cannot recommend a medicine for listing on the PBS unless it has been approved by the TGA and is registered on the ARTG. Similarly, Medicines Australia maintain that TGA approval and ARTG registration must be required for MSAC to recommend funding of a therapy by the MBS.
5. Unapproved medicines should not be funded by government funding mechanisms as this compromises Australian regulatory standards, practices and exposes Australian patients to potential safety concerns and unexpected adverse events.
6. Goods manufactured for supply in Australia must meet the required standards under Good Manufacturing Practice.
7. Intellectual Property/Patent protection are critical and non-negotiable requirements underpinned by legislation through the Patents Act 1990. Compounded, copy products are not eligible for marketing and supply in Australia if they infringe a valid patent.
8. Effective pharmacovigilance is critical for patient safety. All TGA-approved therapies are monitored by the sponsor company (through mandatory adverse event reporting requirements) and the TGA for adverse events. An effective system of pharmacovigilance relies upon the legislated obligation to report. Hospitals and prescribing clinicians are not legally bound to report adverse events for unapproved therapies, so overall patient safety monitoring is inadequate.