New drug treatments in healthcare

As more than 45% of chemotherapy treatments\(^1\) are currently delivered in private hospitals, the fact that more than a third of new biopharmaceuticals under development are for treatment of cancer, is both good and bad news for private hospitals.

A recent report published by the Pharmaceutical Research and Manufacturers of America (PhRMA) provides some interesting insights into the future of new drug treatments. The report states that pharmaceutical research companies are currently developing over 900 biopharmaceutical (or biologic) products targeting more than 100 diseases.\(^2\) The medicines and vaccines in development include:

- 338 cancer therapeutics which target several different types of solid tumors, leukaemia and lymphoma. Monoclonal antibodies account for 170 of these products;
- 176 candidates in development for an array of infectious diseases, including 134 vaccines;
- 71 medicines for autoimmune diseases, such as lupus, multiple sclerosis and rheumatoid arthritis;
- 58 treatments for cardiovascular diseases, such as congestive heart failure and stroke; and
- the remainder, which are for other diseases including diabetes, digestive disorders, and genetic disorders, neurologic and respiratory disorders.

Background

Biologics are drugs which are developed through biological processes using living cells or organisms. Monoclonal antibodies (or mAbs or ‘mabs’) are antibodies produced in a laboratory from a single clone of B-lymphocyte cells. Many mAbs have been developed (and as the PhRMA report, says, many more are on the way) to treat various cancers. The specificity of action of mAbs allows clinicians to target therapy and achieve optimum outcomes.

The number, and mechanism of action, of mAbs for the treatments of cancer and other disease is good news for patients and those involved in providing care.

\(^1\) (AIHW, 2011-12a, pp. 174, Table 8.11)

The downside of the explosion in new biologic therapies is that many may not be subsidised by the Pharmaceutical Benefits Scheme (PBS) leaving private hospitals to meet the cost, if they allow the prescribing of these new biologics.

There is the emerging potential for a 'triple hit' for private hospitals coming from chemotherapy costs because of:

- the slowness of listing of new biologics on the PBS;
- the lack of biosimilars in the market; and
- the increasing unwillingness of private health insurers to reimburse drug costs outside of fixed payment arrangements.

**PBS approval**

Evidence suggests that there are significant lags in the time taken to obtain subsidy for medicines under the PBS and that this lag time seems to be increasing. This has not been helped by the less than subtle way that Government has intervened in the Pharmaceutical Benefits Advisory Committee (PBAC) approval process. In 2011 the Federal Government changed from its customary practice of automatically listing new products approved by the PBAC to one which required Cabinet approval before PBS listing. Following pressure from industry and consumer groups, the Government amended this process to requiring Cabinet approval only for new drugs likely to cost more than $10 million a year. Most new biologics would fit into this category.

**Biosimilars**

An added concern is that the successful production of biosimilars is proving to be in some cases problematic. Biosimilars (also known as follow-on biologics) are subsequent versions of innovator biopharmaceutical products made by a different pharmaceutical manufacturer following patent and exclusivity expiry on the innovator product. In effect, a biosimilar is the biologic equivalent of the generic version of a branded pharmaceutical. However, whilst conventional pharmaceuticals can be readily demonstrated to be structurally equivalent or bioequivalent, the same cannot be said for biosimilars. For this reason, regulators have been slow to develop policy on biosimilars and very few bodies have a position on marketing approval for these agents.

**Managing high cost new drugs**

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To deal with this threat before it becomes a major cost concern, private hospitals should consider developing a framework which allows them to assess the value of new (unsubsidised) drugs compared with current treatment. This framework should be based on the principles used by the PBAC but applying a less complex methodology, in consideration of the fewer resources available to hospitals compared with the PBAC.

Such frameworks are already in place in many leading private hospitals and are used to assess the cost effectiveness of new equipment, robotics, prosthesis, and processes. With some tailoring the assessment process could be applied to new drugs.

If this framework was in place for new drugs including biologics, the financial challenge that the wave of new biologics presents, would be lessened and the benefits of these products more warmly embraced.

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