

CONSULTATION ON MEDICAL PRODUCTS ROADMAP

**Response to the Department of Industry,
Science, Energy and Resources Survey**

November 2020

ABOUT RESEARCH AUSTRALIA

We are the national peak body representing the whole of the health and medical research pipeline.

Our vision: Research Australia envisions a world where Australia unlocks the full potential of its world-leading health and medical research sector to deliver the best possible healthcare and global leadership in health innovation.

Our mission: To use our unique convening power to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

Our goals:

Engage

Australia in a conversation about the health benefits and economic value of its investment in health and medical research.

Connect

researchers, funders and consumers to increase investment in health and medical research from all sources.

Influence

government policies that support effective health and medical research and its routine translation into evidence-based practices and better health outcomes.

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RESPONSE TO THE DEPARTMENT OF INDUSTRY, SCIENCE, ENERGY AND RESOURCES SURVEY

Introduction

Research Australia is pleased to have the opportunity to make this submission to the Australian Government Department of Industry, Science, Energy and Resources on the Modern Manufacturing Initiative and the proposed Medical Products Roadmap.

The Consultation is being undertaken using an electronic survey, which has restricted the response to each question. Research Australia's response to each of the questions posed by the survey is provided below. Our responses emphasise:

- the opportunity to support the manufacture of products and materials for clinical trials;
- the opportunity this provides to scale to full scale manufacturing, keeping the full scale manufacturing of medical products developed in Australia on shore; and
- the opportunity to support manufacturing in high value medical products.

Responses to Survey Questions

Which areas of pre-production, production and post-production do you think should be included in this National Manufacturing Priority?

This National Manufacturing Priority should include not only the manufacture for commercial sale of products but for the production of materials for clinical trials from Phase 2 onwards.

Why are these areas important to this priority?

The manufacture of medical products for clinical trials provides a particular opportunity for Australia. It requires facilities that are flexible enough to produce small batches of products to GMP standard for use in clinical trials but at a scale that is beyond research facilities. Having this manufacturing capacity in Australia helps support Australia as a destination for clinical trials, builds Australian expertise in manufacturing for the latest types of medicines and drugs, and supports Australian research which is reliant on access to clinical trial materials to be able to continue their research into promising new therapies. It is also a good starting point from which to scale up to the manufacture of a range of new medical products on a fully commercial scale in areas that prove to be viable.

What are the opportunities for scaling Australian manufacturing in this priority area?

The opportunities for scaling Australian manufacturing in this priority area exist on two axes. The first is the opportunity to increase the breadth of different types of materials we can produce for clinical trials. The second is the opportunity, once having produced material for successful clinical trials, to then scale up manufacturing for those products to the commercial scale.

What are the challenges to seizing these opportunities, and what are your proposed solutions?

The challenge to seizing these opportunities are capital and skills. The opportunity is to take our current expertise in research labs and scale this up to support both small and large scale manufacturing. This is particularly the case in novel areas in which Australia has world leading expertise and therefore a competitive advantage, such as RNA based therapies.

What do you think are the measures of success for Australian manufacturing in this priority area?

There are several measures of success in the short medium and long term:

- Replacement of the import of materials for clinical trials conducted in Australia by international and domestic sponsors
- Attraction of more international clinical trials to Australia because of the capacity to access clinical trials materials in Australia
- Manufacture of clinical trials material in Australia for the overseas sites of international clinical trials
- Manufacture at commercial scale of new therapies that have successfully completed clinical trials and achieved commercialisation, for both the domestic and overseas markets

Do you have anything else you'd like to share with us in relation to the national priority areas or the manufacturing strategy?

Focusing on manufacturing materials for clinical trials is a way of ensuring we are working on new high value products where quality is paramount and where the relative disadvantages of Australia's high living standards and production costs are less of a barrier.

Are there any action plans, strategies or related documents which should be considered in the development of the road maps?

Research Australia has been working with a group of our members with a group of members who make up the Australian RNA Production consortium (ARPC) on a proposal specific to manufacturing of RNA based therapies. We would be pleased to provide you with this document.

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