



## *1. Position*

The RACGP:

- supports the development and implementation of a no-fault vaccine injury compensation scheme for all vaccines listed on the National Immunisation Program schedule
- proposes that COVID-19 vaccines should be included in a no-fault vaccine injury compensation scheme
- highlights the benefits of introducing such a scheme, including:
  - protecting the broader community,
  - ensuring fair compensation for vaccine injury,
  - enhancing confidence in vaccinations, and
  - increasing uptake of vaccination programs
- considers that the eligibility criteria, standard of proof and compensation should be aligned with community expectations

## *2. Definition*

Vaccine injury compensation scheme (VICS): A scheme that compensates individuals who have a vaccine injury following administration of properly manufactured vaccines.

No-fault policy: An insurance policy or compensation plan that is valid regardless of whether the claimant was at fault.

### 3. *Background*

Immunisation is a safe and effective way to prevent serious disease, including tetanus, diphtheria, and whooping cough. General practitioners (GPs) have a key role in vaccine delivery and acceptance in the general community.<sup>1</sup>

Safety testing is an essential component of vaccine development and use, and most vaccine reactions are minor and do not result in long-term injury.<sup>2,3</sup> Australia does not currently have a vaccination injury compensation scheme (VICS). As such, while individuals who experience a vaccine injury can access treatment via the Australian health system, they will not receive compensation for their injury through a national compensation scheme.<sup>4</sup> Individuals can commence litigation to seek compensation for vaccine injuries.

Many countries around the world have VICS. These include United Kingdom, New Zealand, Canada (Quebec province), USA, Japan and South Korea as well as several European countries such as Denmark, Austria, France, Germany, Finland, Sweden, Italy and Russia.<sup>5,6</sup>

In 2015, the Senate Standing Committee on Community Affairs recommended Australian government investigate the merits of a national vaccine compensation scheme as part of their inquiry into Social Services Legislation Amendment (No Jab, No Pay) Bill 2015 (Bill).<sup>7</sup> Following this inquiry, access to certain benefits and early childhood services was made dependent on children meeting immunisation requirements.<sup>8</sup>

The COVID-19 pandemic and subsequent rollout of the national COVID-19 vaccination program has reignited calls for a no-fault VICS in Australia.

### 4. *Discussion*

#### 4.1. Rationale for a no-fault VICS

At a population level, the very small risk of individual vaccine injury is outweighed by the significant and ongoing benefits of widespread population immunisation.<sup>2</sup> However, this can occasionally mean that a significant burden, ie vaccine injury, is placed on an individual for the protective benefit that vaccines provide to the rest of the Australian population.

The RACGP supports the introduction of a VICS on the basis that:

- immunisation significantly benefits the population as well as individual
- vaccinations carry a very small risk of serious adverse reaction
- government should compensate individuals who experience a severe adverse reaction in the interest of protecting the broader community, enhancing confidence in vaccinations, and increasing uptake of vaccination programs.<sup>4,6</sup>

#### 4.2. Vaccinations in Australia

In Australia, the National Immunisation Program provides free vaccines to eligible people to help reduce diseases that can be prevented by vaccination. A schedule of vaccines sets out a series of immunisations given at specific times from birth through to adulthood. Generally, Australia has quite high immunisation coverage rates. In March 2021, the national coverage rate for children aged five was 95.22%.<sup>9</sup>

Vaccine safety in Australia is monitored through passive surveillance by the Therapeutic Goods Administration, as well as AusVaxSafety, which is a national, collaborative active vaccine safety surveillance initiative.<sup>10</sup>

In 2021, the Federal government introduced a national vaccination scheme for COVID-19. Under the national COVID-19 vaccination scheme, as of June 2021, Australians have access to two vaccines: AstraZeneca and Pfizer (Comirnaty).

The Australian Technical Advisory Group on Immunisation (ATAGI) has noted the evidence of a rare but serious side effect involving thrombosis (clotting) with thrombocytopenia (low blood platelet count) following receipt of COVID-19 Vaccine AstraZeneca.<sup>11</sup>

In June 2021, ATAGI recommended the Pfizer (Comirnaty) vaccine is preferred over AstraZeneca in adults aged under 60 years.\* This recommendation is based on the increasing risk of severe outcomes from COVID-19 in older adults (and hence a higher benefit from vaccination) and a potentially increased risk of thrombosis with thrombocytopenia following AstraZeneca vaccine in those under 60 years.<sup>11</sup>

The identified risk of serious adverse reaction from the AstraZeneca COVID-19 vaccine has fuelled GP and community concerns about the delivery of COVID-19 vaccines. Given these concerns, a no-fault VICS could have great utility in promoting confidence in the Australian national COVID-19 vaccination scheme.<sup>4</sup>

### 4.3. VICS implementation considerations

#### Eligibility criteria

Eligibility criteria for VICS varies significantly across different countries. Notably, most VICS include vaccine injuries that result from vaccines that are registered in the country and are recommended by authorities for routine use in children, adults (eg influenza vaccines), pregnant women and for special indications.<sup>5,6</sup> Most countries have a time limit on eligibility, either from the date of vaccination or the initial appearance of symptoms of the vaccine injuries.

#### Standard of proof

All VICS require a standard of proof showing there is a causal association between the injury and the vaccination.<sup>6</sup> This often utilises the 'balance of probabilities' approach. This approach considers if it is 'more likely than not' that the injury was caused by the vaccine, considering factors such as the medical evidence, timing of the injury, the nature of the vaccine and other supporting information.

#### Compensation

Compensation can be provided for medical costs, disability pensions, coverage for non-economic loss and death benefits.<sup>12</sup> In most jurisdictions, individuals have the right to seek damages either through a VICS or civil litigation but not both simultaneously.<sup>6</sup>

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\* ATAGI advice regarding vaccine delivery and eligibility continues to be frequently updated according to local and national circumstances. The most up-to-date ATAGI advice can be accessed via the Australian government [Department of Health website](#). The most recent ATAGI advice may supersede the information within this position statement.

## 5. References

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