## 6 steps to approve a vaccine

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|  | In Australia, the **Therapeutic Goods Administration (TGA)** approves all vaccines before they can be used. |
|  | The TGA is a group of independent medical experts.  This means they make their own decisions using the scientific information they have. |
|  | The TGA makes sure the medicines we use in Australia:   * are safe * work well. |
| 6 | The TGA always follow the same 6 steps to approve a vaccine in Australia. |
| Step 1 – Before making an application to have a vaccine approved | |
| 1 | There are many companies around the world that make vaccines.  Companies must apply to the TGA for their vaccine to be approved. |
|  | Before a company can send the TGA an application, the company must tell the TGA:   * about the vaccine they want to be approved |
|  | * why people need the vaccine * what **clinical trials** they have run. |
|  | A clinical trial is research to test if a vaccine:   * is safe * works well. |
|  | The company must also tell the TGA how they will make sure in the future their vaccine:   * is safe * works well.   If the TGA decides the company made the vaccine in the right way, they will tell them to apply. |
| Step 2 – The application to have a vaccine approved | |
| 2 | The company must send an application to the TGA for their vaccine to be approved. |
|  | When they apply, the company must tell the TGA:   * how the clinical trials show the vaccine is safe and works well * how the ingredients in the vaccine are safe. |
|  | The company must also tell the TGA:   * how they will make the vaccine * if there are any risks for people who have the vaccine. |
| Step 3 – Looking at the application | |
|  | The TGA will carefully look at the:   * vaccine to make sure it is safe * information the company provided. |
|  | The TGA will:   * work with other experts to make sure the vaccine is safe |
|  | * look at every ingredient in the vaccine to make sure it is safe. |
|  | The TGA will also:   * look at the clinical trials to make sure the vaccine is safe for everyone in Australia |
|  | * make sure the vaccine meets Australian standards |
|  | * look at how other countries around the world have used the vaccine. |
|  | The TGA might also ask the company more questions if they need to. |
| Step 4 – Making the decision | |
| 4 | The TGA decides if they will approve the vaccine. |
|  | If the TGA approves the vaccine, they will approve it for 2 years.  After 2 years, the company can ask the TGA to approve the vaccine for up to 6 more years. |
| Step 5 – Registering the vaccine | |
| 5 | After the TGA approves the vaccine, they will add it to the Australian Register of Therapeutic Goods (the Register). |
|  | The Register is a record of all the vaccines the TGA has approved in Australia.  The record includes:   * the name of the company * the name of the vaccine * what ingredients are in the vaccine * information for people who get the vaccine. |
|  | After the vaccine is added to the Register, the company can start to send out the vaccine. |
| Step 6 – Keeping track of the vaccine | |
| 6 | The TGA will keep checking the vaccine as more people get it. |
|  | This is to make sure it:   * is still safe * still works well. |
|  | If there are any problems, the TGA can:   * look into the problem with the vaccine * give people new information about how safe the vaccine is * take away the approval, if needed. |
| More information | |
|  | You can visit the Department of Health website at[www.health.gov.au](http://www.health.gov.au)[/covid19-vaccines-languages](http://www.health.gov.au/covid19-vaccines-languages)for more information about the vaccine in your language. |
|  | You can call the National Coronavirus Helpline on **1800 020 080. Select option 8 for free interpreting services.** |