

# Five or six doses? Controversy over Pfizer vaccine vials

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A special syringe is needed to get six doses of the BioNTech-Pfizer vaccine, but there is a shortage of them

The US pharmaceutical giant Pfizer, which is manufacturing the COVID-19 vaccine developed by Germany's BioNTech, now considers each vial contains six doses compared to five previously.

The difficulty in obtaining that sixth dose in practice means many countries are at loggerheads with Pfizer and facing a drop in supply.

# How many doses?

Until recently, each vial of the BioNTech-Pfizer vaccine was considered to officially contain five doses.

After being thawed, the contents of each vial are diluted with 1.8 ml of saline solution, creating a total of 2.25 ml of injectable solution. With each dose 0.3 ml, in theory there are just over seven doses.

But theory and practice are different. Medical personnel are unable to measure so precisely the doses to get seven doses they can inject into

people.

But the found they could—with the right equipment—reliably get six doses out of the vials.

Both EU and US regulators now consider that the vials contain six doses and have authorised the use of the sixth dose.

However the European Medicines Agency noted that this sixth dose depends on the availability of specific syringes.

### **Doses not vials**

Pfizer has revised higher its production target for this year from 1.3 billion doses to 2 billion. While part of that reflects plans to further increase output, it also reflects the effect of the label change on vials.

Pfizer said its contracts specify the delivery of a certain number of vaccine doses and not vials.

This means customers are now receiving fewer vials than they did before regulators approved the change.

## 'Niche' syringes

But in order to obtain that sixth dose medical a special syringe is required with a low "dead space". The dead space is the amount of the product left in the <a href="syringe">syringe</a> when the plunger is completely pushed down.

To get the sixth dose of the BioNTech-Pfizer vaccine syringes with very low dead spaces are needed, but medical device manufacturer Becton Dickinson (BD) says there is a supply crunch for them.

"Low dead space syringes are niche products and there has... traditionally been minimal market



demand based on health care provider needs," a company spokesman said.

Manufacturing capacity of these syringes is limited and it will take time to boost production.

Many vaccination centres in France have not received low dead space syringes and are finding it difficult to obtain a sixth dose with regular syringes.

If Pfizer delivers fewer vials "we'll vaccinate fewer people than planned" initially, warned Du Cote de la Science, a group of French doctors and researchers who have sought to influence the public debate in France about the pandemic.

# Governments on their guard

Pfizer's decision sparked an outcry in Belgium.

Retirement homes hoping to step up their vaccination campaign thanks to using the sixth dose in vials are now receiving fewer vials than initially promised, one director told AFP.

Sweden's health authority has demanded an explanation from Pfizer, but has so far not frozen its payments.

France's health ministry has launched an effort to acquire the necessary syringes and developed training materials to help medical personnel learn the method to obtain the sixth dose.

The European Commission says it has already launched a joint supply initiative that should allow member states to buy the necessary syringes.

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