

**The Chief Executive Officer (CEO)**  
**South African Health Products Regulatory Authority (SAHPRA)**  
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**Att:** *Dr Boitumelo Semete-Makokotlela (PhD, MMFI)*

*Via Email: [Boitumelo.Semete@sahpra.org.za](mailto:Boitumelo.Semete@sahpra.org.za)*

**CC:** *To Whom It May Concern*

**Ref to** *P L NUTT*

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10 October 2022

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## **Re: EXPIRY DATE OF COMIRNATY® VACCINE (MRNA COVID-19 VACCINE) FROM PFIZER-BIONTECH – 3-MONTH EXTENSION ON SHELF LIFE WHEN STORED BETWEEN -90°C AND -60°C**

***Dear Dr Semete-Makokotlela***

We count on your urgent attention and appropriate action regarding this vital matter of national interest:

According to a notice issued by the Director-general of health on 21 May 2021, the notice gave the following:

- Extend the approved storage period of the unopened thawed vaccine vial at 2-8°C (i.e. in a vaccine fridge after taking out of deep-freeze conditions) from five days to one month (31 days),
- Storage at -80 to -60°C, for the full period up until the expiry date of the product,
- Storage at -25 to -15°C, for 14 days, not exceeding the original expiry date of the product,
- Storage at 2 to 8°C, for 31 days, not exceeding the original expiry date of the product. Note, once thawed the vaccine may never be frozen again.

No references for shelf testing data were provided in the circular.

According to a 4<sup>th</sup> subsequent notice issued by the Director of affordable medicine on 10 May 2022, the notice gave the following:

- The manufacturer submitted new stability data to SAHPRA for review and approval,
- Based on the data available, SAHPRA has approved a further 3-month extension of the shelf-life for all vaccines when stored between -90°C and -60°C, resulting in a total shelf life of 12 months from the date of manufacture,
- This shelf-life extension applies to all Pfizer batches listed in the table attached. The extension does not apply if the vaccine doses have already been moved to -20°C and 2-8°C storage.

No references for shelf testing data were provided in the circular.

A list of 34 batch numbers [1F1028A - PCA0063] were provided with new extension dates for expiration in South Africa. On the current Pfizer-BioNTech site, <https://lotexpiry.cvdvaccine.com/> all 34 listed batches elicit the same result of expired. The site notes the batch expiry date and lot number. Of significance was the default location of the United States of America for all batch testing. The same batch number has no permissible extension of expiry date in one country, namely the United States of America, however SAPHRA has announced a further extension of several batches beyond their expiry dates to the South African population. The respective data received by SAPHRA has not yet been released to the public for the purposes of information transparency and for inspection for facilitation of informed consent. These findings are consistent with the most recent publication of 26/09/2022 from Pfizer-BioNTech, "Vaccine may be stored between -90°C and -60°C (-130°F and -76°F) until the expiration date."

### **SA "Vaccine" Injury Medico-Legal Study-Group - SAVIMS**

Social Responsibility Network - Professional Network - Scientific Network - Expertise Network

#### **Founding Members**

*Dr Herman Edeling (Neurosurgeon) – Dr Ivan Jardine (ENT Specialist) – Dr Pinky Ngcakani-Ncula (Physician) – Dr Barbara Cawood (General Practitioner) – Dr Sharon Williams (ENT Specialist)  
Dr Roy Breeds (Rheumatologist) – Dr Anton Janse Van Rensburg (General Practitioner) – Dr Geoffrey Drew (General Practitioner) – Mr Richard Baird (Businessman)  
Dr Leunis Van Rooyen (Specialist Wellness Practitioner) – Dr Stephen Schmidt (Gastroenterologist) – Ms Tamara Victor (Attorney) – Dr Zandré Botha (Integrative Medicine Practitioner)  
Dr Susan Vosloo (Cardiothoracic Surgeon) – Dr Shankara Chetty (General Practitioner) – Prof Johann Holm (Risk Management Specialist) – Mr Gerhard Kriel (Businessman) – Dr Alwyn Carstens (Radiologist)  
Dr Peter John Berlyn (Paediatrician) – Dr Stefanus Snyman (Occupational Medicine Practitioner) – Dr Robert Rapiiti (General Practitioner) – Dr Michelle Weyers (General Practitioner) – Dr Craigie Golding (Physician)  
Dr Jackie Stone (Primary Care Physician) – Dr Estie Maritz (General Practitioner) – Mr Peter Nutt (Systems Engineer) – Dr Masha Maharaj (Nuclear Physician) – Dr Charné Copeland Gerber (General Practitioner)  
Dr André Groenewald (General Practitioner) – Dr Faan Oosthuizen (General Practitioner) – Mr Willem Smuts (Civil Engineer) – Mr Nick Hudson (Actuary – Chairman of PANDA)*

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**⊗ Vaccine is expired.**

Based on the shelf life currently authorized or approved in United States of America (USA), the Expiry Date for Lot # (PCA0063) is:

**July 31, 2022**

*Figure 1 This is the last batch number listed **PCA0063** for the South African population with expiry extended from 31/07/2022 to 31/10/2022*

<p><b>Storing UNPUNCTURED Vials</b></p> <p><b>Ultra-Cold Freezer</b></p> <p>Vaccine may be stored between -90°C and -60°C (-130°F and -76°F) until the expiration date</p> <ul style="list-style-type: none"> <li>■ Store vials upright in the tray or box protected from light</li> <li>■ Vaccine expires 12 months after the manufacture date printed on the vial. Determine the expiration date by:</li> </ul>	<p>Use Pfizer expiration date tool at <a href="https://lotexpiry.cvdvaccine.com">lotexpiry.cvdvaccine.com</a></p> <p><b>OR</b></p> <p>Using the month printed on the vial as month 1, count out 12 months. The vaccine expires on the last day of the 12th month</p>
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*Figure 2 Extracted from Pfizer-BioNTech COVID-19 Vaccine: Handling and storage summary*

<p><b>Check the vial label to ensure the expiration date or beyond-use date/time has not passed.</b></p> <ul style="list-style-type: none"> <li>■ Use Pfizer expiration date tool at <a href="https://lotexpiry.cvdvaccine.com">https://lotexpiry.cvdvaccine.com</a></li> <li>■ Check beyond-use date/times             <ul style="list-style-type: none"> <li>▪ Unpunctured vials may be stored between 2°C and 8°C (36°F-46°F) for up to 10 weeks</li> <li>▪ Unpunctured vials may be stored between 8°C and 25°C (46°F and 77°F) for a total of 12 hours</li> <li>▪ Once mixed, punctured vials can be stored between 2°C to 25°C (35°F to 77°F) for up to 12 hours</li> </ul> </li> <li>■ <b>NOTE:</b> The beyond-use date/time replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest</li> </ul>	<p>date. Do NOT use vaccine if the expiration date or beyond-use date/time has passed.</p> <p><b>Follow aseptic technique</b></p> <ul style="list-style-type: none"> <li>■ Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled. Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.</li> <li>■ Use a new, sterile needle and syringe for each injection</li> </ul> <p><b>Mix vaccine with 0.9% sodium chloride; preservative-free diluent if indicated.</b></p> <ul style="list-style-type: none"> <li>■ Use a new vial of diluent for each vial.</li> </ul>
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*Figure 3 Extracted from Pfizer-BioNTech COVID-19 Vaccines: Vaccine Preparation and Administration Summary*

- SA “Vaccine” Injury Medico-Legal Study-Group (SAVIMS) hereby makes the following statements:
- According to our calculation there has been a further 3-month extension of expiry date from the proposed 12-month expiration from date of manufacture.
  - There are discrepancies in the storage, expiration date and shelf life for expired trial medicine permissible to the South African population. This goes against the Department of Health *MEDICINES AND RELATED SUBSTANCES ACT, 1965* definition of “expiry date” which is stated as follows, “expiry date means the date up to which a medicine will retain the strength and other properties stated on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used.”
  - Any promoter of Covid-19 “vaccines” wishing to obtain informed consent for “vaccination” would ethically and morally have to inform the patients of these discrepancies. Are these discrepancies stated clearly on the informed consent forms?
  - SAPHRA and the Department of Health should publicise notices that the South African population are exposed to trial products which are in use post their expiration dates.

- It is noted that these products are not approved. They remain within the confines of clinical trial governance and are only authorised under “emergency use to *prevent* COVID-19.”
- In the absence of independently audited evidence-based data which would have to be accepted in every country, SAVIMS stands against the promotion of expired clinical trial products in South Africa and calls for immediate recall and discard of these vials.

**References:**

1. <https://www.health.gov.za/covid19/assets/downloads/posters/DG%20letter%20Notice%20Pfizer%20updated%20storage%20.pdf>
2. [https://bhekisisa.org/wp-content/uploads/2022/05/Circular-Exp-Pfizer-vaccine-extension-70KJ\\_May-2022\\_v2-1.pdf](https://bhekisisa.org/wp-content/uploads/2022/05/Circular-Exp-Pfizer-vaccine-extension-70KJ_May-2022_v2-1.pdf)
3. <https://lotexpiry.cvdvaccine.com/>
4. <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf>
5. <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf>

Trusting this matter of patent national interest, as shown above, to be resolved with due promptness by your office, faithfully,



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