IN THE ESSENTIAL SERVICES COMMITTEE
HELD AT JOHANNESBURG

Case No.: ES469

In re: Investigation in terms of Section 71 of the Labour Relations Act, 66 of 1995:

Whether manufacture, supply and distribution of certain vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants. Covid 19 related products, chronic medicines; and antibiotics should be designated as essential services

---

Designation

Introduction

1. The Essential Services Committee ("the ESC") received a referral in terms of Section 70B(1)(d) from Aspen SA Operations (Pty) Ltd (Aspen) on 13 August 2021 requesting the ESC to investigate whether or not the above-mentioned services should be designated as essential services. On 22 September 2021 the ESC convened a meeting with the referring party and the interested parties as identified by the referring party in its application. These parties are: NBCCI; SACWU; NUMSA; GIWUSA; LAAPI; and CEPPWAWU. Following the meeting the referring party was requested to submit a

motivation for its referral. The other parties were also invited to make submissions in opposition.

2. On 9 November 2021, the referring party served its supplementary submissions and motivation to the ESC and the other parties as identified above. The ESC gave the other parties until the 23rd of November 2021 to file their opposing submissions but did not receive any submissions in opposition. On 28 December 2021 the ESC made a ruling that the referral by Aspen was reasonable and that it would proceed with the investigations.

3. As provided for in section 71, read with section 70(2)(a) of the Labour Relations Act, 1995 (Act No 66 of 1995 as amended), the ESC gazetted a notice that it was conducting an investigation as to whether or not the above services are essential services. (see Government Gazette No 45816, Notice No. 778 of 2022, dated 28 January 2022.

4. SANOFI and Afrigen failed to file notices of their intention to make representations at the hearings and had to apply for condonation. Their applications were condoned.

Details of Hearings

5. The hearings were scheduled as per the notice published in the government gazette. In the hearings the ESC received a number of written submissions, and a number of interested parties also made oral representations to the ESC.

6. The parties that made submissions at the hearings were:

a) South African Health Products Regulatory Authority (SAHPRA)
b) CDH obo National Health Laboratory Services (NHLS)
c) Aspen SA Operations;
d) Medipost Pharmacy;
e) National Department of Health;
f) SANOFI;
g) Pharmaceutical Task Group (PTG);
h) Afrigen;
i) National Bioproducts Institute (NBI);
j) Hospital Association South Africa (HASA); and
k) LAAPI assumed an observer status at the public hearings

Submissions

7. The below submissions are a summary of the submissions (oral and written) made in this application.

SANOFI

8. SANOFI raised questions on the application made by Aspen. The panel has decided to deal with these questions only in so far as they relate to the investigation. SANOFI suggests that Aspen is seeking to have the manufacture, supply and distribution of its own products designated as essential. They further question what if in future there are generics for those products which are not covered in the designation.

9. SANOFI suggests that to overcome the issue of looking at ASPEN's products that the services should be looked at in relation to the type of therapeutic areas a patient may

suffer which requires them at all times to have access to medical preparation, drugs, to treat their condition.

10. SANOFI is of the view that it matters not which pharmaceutical company manufactures which drug to treat a chronic condition, the ESC determination should state instead that the manufacture of all protocols/drugs used in the treatment of named chronic conditions amounts to an Essential Service. A similar approach should be adopted in relation to drugs used during medical procedures such as anaesthetics.

SAHPRA

11. SAHPRA argued that it should be classified as an essential service since its core function is to regulate, review and evaluate all medication for humans and animals that such medication is safe, efficacious and of good quality.

12. SAHPRA also prohibits the existence of communicable disease into the Republic and ensures that all imported health related products are regulated, reviewed, evaluated, monitored, and inspected for compliance with the health requirements as per the Medicines and Related Substances Act.

13. It must be understood that the services of SAHPRA are considered in this investigation and designation only in so far as they relate to the question of whether the manufacture, supply and distribution of certain vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products; chronic medicines; and antibiotics are essential services. The question before the panel is not whether or not the services offered by SAHPRA are an essential service or not.

14. SAHPRA focuses on the registration and control of health products and good regulatory practice and standards; compliance with requirements; inspections and Law Enforcement; sanctions and penalties; etc.

15. In summary, no medical products are supplied and distributed without a stamp of approval from SAHPRA. SAHPRA's mandate goes further to ensure that its review, evaluation, monitoring, and inspection is conducted post the manufacturing of the products in question but also during the supply and distribution.

PTG

16. The Pharmaceutical Task group is an umbrella body representing more than 80% of the pharmaceutical business in South Africa. Member companies are involved in the manufacture or sale and distribution of health products in South Africa.

17. PTG submitted that health workers cannot save lives without medicines. If medicines are not available, then the patient's health of life is endangered. It does not help to render the services offered by doctors and nurses as essential and leave the medication outside of such designations as the health workers require medication in order for them save the health and the lives of the patients. It therefore follows that the services rendered by workers who manufacture, distribute, and supply the medication that is required to save lives and not endanger the health of the population are also designated as essential services.

18. Unlike other services, in the manufacturing, supply and distribution of the medication under investigation, it is not feasible to source replacement labour as the training, skill and qualifications of the workforce that render these services is highly complex.

19. Stockpiling is difficult in the pharmaceutical industry as many medicines (for example vaccines) are either seasonal or immensely temperature sensitive, leading to a shorter shelf life.

20. Government depends on pharmaceutical manufactures for the supply of critical pharmaceuticals to the public health care facilities, including hospitals, clinics and other health care service points, both urban and rural. A strike leaves the manufacturing, supply and distribution in a position where they cannot assist the public. Alternative supply is also not feasible as some of the products are uniquely manufactured in South Africa.

NBI

21. National Bioproducts Institute is a fractionator of plasma, into therapeutic proteins, which are then purified and become medicinal products. These products are used in replacement therapies for, among others, hemophiliacs and those who suffer from hepatitis B. Immunoglobulins are also used in replacement therapy for those who are inherently immune deficient, and their products improve neurological conditions in those who are deficient, in immunoglobulins. These services, if interrupted, would endanger the life, personal safety and/or health of the whole or part of the population

Medipost Pharmacy

22. The Medipost holdings Group is part of a number of wholesalers and distributors in South Africa who are responsible for the supply and distribution of chronic medication

and special medication which includes, oncology; antiretrovirals, insulin; immunosuppressants; covid 19 related products; vaccines and antibiotics.

23. The pharmaceutical supply chain is complex and involves a myriad of role-players. An interruption to the supply has far reaching effects on patients' well-being and health care professionals' ability to serve patients.

24. Public sector medical depots only procure products on a tender basis from manufacturers. The disruption of supply chains impacts the lives of South Africans whose medical circumstances force them to rely on an uninterrupted supply of life-saving and chronic medication for their existence.

HASA

25. Hospital Association South Africa argued that if there is a shortage in the supply of ARVs, individuals living with HIV could develop complications which may/may not require hospitalization. If hospitalization is required due to lack of availability of medication, it would have a direct impact on the currently strained public health resources within the hospital environment. Furthermore, if an individual living with HIV does not have access to their medication due to limited supply, their condition may worsen, reducing their ability to work and contribute to the social welfare of their families and the economy.

26. Immunosuppressants like corticosteroids are also the mainstay of treatment for COVID and hence could be considered an essential medication. Ensuring a stable supply chain, quality control of products and de-risking South Africa from import constraints should be paramount in our focus on preparation for any future pandemics.

NDoH

27. The National Department of Health submitted that the distribution of medicines, scheduled substances and medical device products commence from the manufacturer or importer. Pharmaceutical products are then sold either to a wholesaler or directly to a dispensing point. This task is either performed by the manufacturer themselves or through their appointed logistics service providers on behalf of the manufacturer /importer.

28. Wholesalers procure from the manufacturer or importer and resell (distribute) the product to private sector dispensing points (Hospitals/Doctors/Pharmacies and other private sector healthcare workers). Private sector dispensing points procure either directly from the manufacturer or through the manufacturers appointed logistics service providers or from a Wholesaler and dispense/sell these products to patients. Public Sector medical depots may only procure products on a tender basis directly from the manufacturer or importer. The procurement process is governed by the Public Finance Management Act 1 of 1999. Supply comes either directly from the manufacturer or through their appointed logistics service providers. The provincial depots may only sell these products into public sector sites within their province.

29. The general public (patients) cannot buy directly from a manufacturer or importer, nor can the function of any of the licensed service providers be outsourced or contracted to any non-licensed entity.

30. There will be adverse effects if the manufacture, supply, and distribution is interrupted, these include
    - Substantial worsening of disease, possible death and increased overall healthcare needs, including cost of more expensive alternative therapies.

- Non-adherence to best effective treatment may result in negative health outcomes for the patient. Healthcare workers may also be negatively impacted as more time and other resources may need to be spent on the patient.
- Risk of death for instance, in those patients in hospital settings, who need access to an immediate supply of potential lifesaving medicines, scheduled substances and medical devices.
- Patients, particularly in rural areas, who are only able to access healthcare services from public sector facilities will be severely impacted if supply is disrupted.

NHLS

31. The National Health Laboratory Services made submissions in respect of only two components, the manufacture, supply and distribution of biologicals and of certain covid 19 related products.

32. NHLS submitted that it is the largest diagnostic pathology service in South Africa. Its primary responsibility is as the sole provider of diagnostic pathology services to the public sector in South Africa. It provides laboratory and related public health services to over 80% of the population through a national network of over 233 laboratories in all nine provinces.

33. NHLS manufactures biologicals in that the Applicant manufactures antivenom. Without these services, it will affect the life, safety and health and wellbeing of the South African public and the rest of Africa. In relation to biologicals, it is submitted that these are essential because of our antivenom production line, and existing essential services provided by technicians and technologist – SAVP.

34. NHLS manufacturers and supplies a range of Covid-19 related products, from the Covid-19 nucleic acid to the material that informs the process of vaccinations. The vaccination manufacturers would get this information from NHLS and test their products against what they intend to supply in order to test the efficacy. NHLS further does research on Covid-19 vaccinations.

35. In conclusion Mr. Patel argued that at the least, the services submitted by NHLS, if their application fails are part of the general health screening, testing and control of infectious and communicable diseases as designated by the ESC on 11 February 2022 under GN45903.

36. NHLS is the sole manufacturer of boomslang Anti-venom. Anti-venoms are biologicals. An interruption in the manufacturing, supply and distribution of these biologicals (including anti-venom) will endanger the life and health of the population. The omicron covid 19 virus was discovered by the NHLS. NHLS researches and provides information on vaccines that can be used to save the lives and preserve the health of the population or part thereof.

37. NHLS submitted a list of the anesthetics; antiretrovirals; immunosuppressants; covid 19 related products; chronic medication and antibiotics, the manufacture, supply and distribution of which it seeks to have designated as an essential service

Legal Framework

38. In this matter the issue that the committee has to determine is whether the manufacture, supply and distribution of certain vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products;

chronic medicines; and antibiotics should be designated as essential services. In determining the matter, it is important that one should set out the legal framework.

39. Section 23(2) of the Constitution of the Republic of South Africa, 1996 ("the Constitution") states that… "Every worker has the right … (c) to strike."

40. Section 36 (1) of the Constitution states inter alia that… "The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom".

41. Section 65 (1) (d) (i) of the LRA states that … "No person may take part in a strike … if that person is engaged … in an essential service".

42. An 'essential service' is defined in section 213 of the Act as:
    (a) a service the interruption of which endangers the life, personal safety or health of the whole or any part of the population;
    (b) the Parliamentary service;
    (c) the South African Police Service".

43. The *Constitutional Court in South African Police Service v Police and Prisons Civil Rights Union and Another [2011] 9 BLLR 831 (CC)* said the following: -

> "In order to ascertain the meaning of essential service, regard must be had to the purpose of the legislation and the context in which the phrase appears. An important purpose of the LRA is to give effect to the right to strike entrenched in section 23(2)(c) of the Constitution. The interpretative process must give

effect to this purpose within the other purposes of the LRA as set out in Section 1(a). The provisions in question must thus not be construed in isolation, but in the context of the other provisions in the LRA. For this reason, a restrictive interpretation of essential service must, if possible, be adopted so as to avoid impermissibly limiting the right to strike (footnotes excluded)"

44. It is trite that strike action is an important element of collective bargaining and it is recognised as a primary mechanism through which workers exercise collective power (See *Ex-Part Chairperson of the Constitutional Assembly in re: Certification of the Constitution of the Republic of South Africa, 1996 (4) SA744 (CC)* at par [66]).

45. Having regard to the above, it is clear that our law requires essential services to be restrictively interpreted, and that this means, inter alia, the following:

- It is the service which is essential, not the industry or the institution within which the service falls;
- Only those employees who are truly performing an essential service, may be prohibited from striking; and
- Essential and non-essential service workers may be found working side by side in the same institution.

46. Before the ESC can designate any service as essential, it must be satisfied that the interruption of the said service is likely to to endanger life, personal safety or health of the whole or part of the population.
47. It is further trite that in view of the fact that the right that would be affected by such a designation limits or takes away a fundamental right, such a designation must be

reasonable and justifiable. If the ESC finds that parts of the service are not essential the Committee is obliged not to designate such services, as such a designation would be unreasonable and unjustifiable.

Analysis of Evidence

48. The services in question are the manufacture, supply and distribution of certain vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants. Covid 19 related products, chronic medicines; and antibiotics irrespective of who manufactures, supplies, and distributes the said products. The view as expressed by SANOFI that the services in question are limited to ASPEN is ill informed, the services that are being investigated are not only limited to any manufacturer, supplier and distributer. When the ESC investigates and designates a service, the designation is applicable to anyone who renders such a service.

49. The panel acknowledges the suggestion made by SANOFI of looking at the services in relation to the type of therapeutic areas a patient may suffer which requires them at all times to have access to medical preparation, drugs, to treat their condition, but the panel is of the view that this would be too wide and in the view of the panel it would create future problems,

50. What the panel has considered is that it would not be appropriate to limit its investigation only to the list of ASPEN's anesthetics; anti-retrovirals; immunosuppressants covid 19 related products, chronic medication and antibiotics as other manufacturers, suppliers and distributers might not manufacture, supply and distribute the exact products but generics thereof, so to deal with this issue, the panel has decided to consider whether the services of manufacture, supply and distribution of

vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products, chronic medicines; and antibiotics should be designated as essential services.

51. The panel has done the above on the strength that anesthetics are used for the treatment of persons where pain is present; anti-retrovirals are used for the treatment and suppression of the HIV virus; Immunosuppressants are used to lower the human body's ability to reject a transplanted organ; covid related products are used for the treatment in support of the immune response to patients who have contracted the Covid infectious virus; chronic medication is required to be taken regularly; and antibiotics is medication used to destroy or slow down the growth of bacteria. These medication or treatments have the same objective or outcome irrespective of who the manufacturer is.

52. The panel accepts the unopposed evidence contained in Mr. Bosman's affidavit that vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products, chronic medicines; and antibiotics are lifesaving medication and or treatments, and that the interruption of their manufacturing, supply and distribution will endanger the life and health of the population or part thereof.

53. Diagnostic pathology as submitted by NHLS identifies the cause of diseases. The panel is of the view that diagnostic pathology is not part of manufacturing, supply and distribution of the medication or treatments in question. As argued by Mr. Patel, for the present investigation, what NHLS is arguing is that it manufactures, supplies and distributes an antivenom which is a biological, and it manufactures and supplies covid 19 related products. The panel accepted this submission and has dealt with the issue of the antivenom as part of its investigation on designating the manufacture, supply and distribution of biologicals and covid 19 related products.

54. The submissions made by SAHPRA indicated that quality control of the medication in question is spread along manufacturing, supply and distribution stages as SAHPRA, regulates, reviews, monitors and inspects during the entire value chain to ensure that the medication is safe, efficacious and of good quality.

55. The following designations by the ESC bear reference to this application:

a) Emergency health services and the provision emergency health facilities to the community or part thereof; nursing; and medical and paramedical services. (12 September 1997 under GN R1216, GG 18276) and (19 March 2021 under GN44293)

b) The service of distribution of chronic medication (11 May 2018 under GN41621)

c) The services rendered by Medical Officers in public health (11 May 2018 under GN41621)

d) General health screening, testing and control of infectious and communicable diseases (11 February 2022 under GN45903)

56. Given that the ESC has already designated the distribution of Chronic medication. For the present purposes the panel has only dealt with the manufacturing and supply of chronic medication

57. The main argument of the parties submitting that the services in question should be designated as essential is based on the following broad grounds:

a. Public health and Private health designated essential services are unable to function without medication. The manufacture, supply and distribution of the above-mentioned medication is a critical part of the services that are already designated in both public and private health and consequently the

services rendered by medical officers, nurses and the rest of those already designated is incomplete without designating the provision of life saving medication.

b. Because of the short shelf life of the medication attached to the services applied for, stockpiling to deal with periods where there is an interruption of the service of manufacturing, supply and distribution of this medication is impossible.

c. The skill and qualification of the employees who render the service of manufacturing, supply and distribution of the medication attached to the services applied for make is impossible to secure replacement labour during periods of interruption of the service. This means that there is no real alternative to the service when it is interrupted.

d. The processes of procuring alternatives, whether of medication or of personnel in the public service in the event of an interruption (strike) does not allow for quick turn around time. Therefore, an interruption of the service of Manufacturing, supply and distribution of the medication in question will be catastrophic to the patients who depend on them.

58. What is clear from the submissions made is that the health and lives of patients requiring vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products; chronic medicines; and antibiotics medication or treatment will be endangered if the services of manufacturing, supply and distributing them is interrupted. Whilst the panel accepted that the said medication or treatments are life saving the panel seriously considered if any alternatives exist to the manufacturing, supply and distribution of these medicines and or treatments. The panel

accepted the unopposed submissions that the said medication and or treatments have a limited shelf life, more so that it difficult to know how long the interruption will take.

Designation

59. On the submissions made, the panel is convinced that if the manufacture, supply and distribution of certain vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products; chronic medicines; and antibiotics is interrupted there would be an endangerment to the life and health of the population.

60. Consequently the panel hereby designates:

    a. the services of manufacture, supply and distribution of vaccines and or biologicals; anesthetics; antiretrovirals to treat HIV virus; Immunosuppressants; covid 19 related products; and antibiotics; and
    b. the manufacture and supply of chronic medicines as essential services.

61. The parties are hereby ordered to negotiate and conclude a Minimum Service Agreement no later than 30 June 2022.

Adv. L Bono
ESC Panel Chairperson
14 April 2022