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National Treasury / South African Revenue Service

BY E-MAIL:
policycomments@sars.gov.za

Dear SARS

VAT INTERACTIVE WORKSHOP – SAICA SUBMISSION ON ZERO RATING OF CLINICAL TRIAL SERVICES

A VAT Interactive Workshop was held by SARS in May 2023 to discuss various pertinent VAT issues facing industry.

One matter raised during the meeting was the challenge faced by vendors in applying sections 11(2)(l) and 8(5) of the Value-Added Tax No. 89 of 1991 ('the Act') to the supply of clinical trial services by vendors to non-residents.

Pursuant to SARS' request for a more detailed explanation of the issues involved, we herewith present the comments of the South African Institute of Chartered Accountants' (SAICA) VAT Committee concerning this matter.

SAICA continues to believe that a collaborative approach is best suited in seeking solutions to complex challenges and should you wish to clarify any of the matters outlined in the following paragraphs, please do not hesitate to contact us.

Yours sincerely

Leon Oosthuizen
Chairperson: SAICA VAT Committee

Seelan Muthayan
Member: SAICA VAT Committee

Lesedi Seforo
Project Director: Tax Advocacy

The South African Institute of Chartered Accountants

INTRODUCTION

1. This document is a submission to the South African Revenue Service (SARS) regarding the value-added tax ("VAT") implications on clinical trials.

2. Previously in applying the provisions of section 11(2)(l) of the Value-Added Tax No. 89 of 1991 ('the Act'), the South African Revenue Service ("SARS") allowed vendors to zero rate the supply of clinical tests to non-residents. Following an interpretational exercise, SARS concluded that clinical trials do not meet the requirements of section 11(2)(l) of the Act.

3. There has been a vital shift in SARS' application of section 11(2)(l) of the Act. SARS' application of the zero-rating applies to certain phases of the clinical trials and various phases of the supply are broadly subject to VAT at the standard rate.

4. Section 11(2)(l) of the Act allows a vendor to apply the zero-rate instead of the standard rate on a supply of services provided to non-residents that are not present in South Africa at the time when the services are rendered.

FACTUAL DESCRIPTION

5. The vendor is a company undertaking clinical trials which support the research and development of its non-resident clients. As part of the supplies made, the vendor is responsible for managing the laboratory component of clinical trials.

6. The vendor supplies laboratory services to Sponsors.[1]

7. The Sponsors are mainly institutes either in the pharmaceutical and biotech industry or academics, who are involved in the research and development of medicines and require that clinical trials be conducted to evaluate the functioning of a medicine in the blood or urine of healthy and/or sick consented participants.

8. The nature of the contractual deliverables that the Sponsors require the vendor to supply will vary with each contract. However, as a general rule the deliverable relating to the research contracts consists of the production of scientific data in the form of a report.

9. The report will be drafted based on the findings of the research in accordance with the protocol governing the specific clinical trial.

10. The clinical trials consist of various phases which are aimed at testing the effect of new medicine on potential future consumers. 'Phase One' studies are generally performed to determine the safety of an investigational product and Phases 2 and 3 are performed to determine efficacy of the investigational product.

[1] Sponsors are defined as the person for whose benefit the clinical trial is conducted, this is generally known as the person who provides the funding and in whom the research results vest.

11. The vendor is contractually required to provide the Sponsor with the scientific data gathered from the analysis of the specimens.

12. The use of the scientific data by the local principal investigator or any other institution that may be in the Republic at the time the services are rendered are incidental to the services that the vendor supplies.

13. All scientific data in the context of the trial is the exclusive property of the Sponsor and may only be utilized by a third party if authorization is obtained from the Sponsor.

14. The actual clinical trial generally consists of four processes:

    - The first process is where the Sponsor recruits consenting participants for the study. These volunteers declare that they will not benefit personally from the outcome nor share in any future profits derived from clinical trials.

    - The second process ('pre-analytical stage') consists of collecting and returning lab materials, packaging materials and transportation documents to the vendor (including extracted specimens).

    - During the third process ('analytical stage') the pathologist performs the laboratory analysis of the specimens (of blood, urine, etc.), producing the information required by Sponsors.

    - The fourth process ('intermediary storage') is of a temporary nature. This process is essential to the vendor providing the Sponsor with the report.

    - The last process ('post-analytical process') consists of the bio bank storage management of specimens under specific clinical conditions for subsequent testing, data reporting, and project follow-up.

15. For the execution of the services, the vendor supplies, utilises and consumes kits and various other laboratory consumables. Once the specimens are taken, they are collected and shipped to the vendor's laboratory where they are processed and analysed.

16. After the analysis, the specimens are sometimes kept in storage for a period of time before being discarded. The storage is to accommodate retesting in the event that the Sponsor requires additional analysis or if more advance tests become available in the future.

Type of supply	Nature of supply
Standard clinical trials	Consists of several activities and varies depending on the contractual requirements terms. It may include all or some of the following activities: • Analysis of data generated • Report generation (hard copy or electronic format)

	• Storage of specimens (preserving for retesting) • Shipment of specimens The vendor's role generally commences after extraction of specimens by the principal investigator. The vendor may get involved earlier, e.g. laboratory specification manuals, leaflet design, preparation of databases, preparation and provision of kits and transportation of documents.
Sample storage – long-term storage	The vendor is required to store the samples in long term storage. It is important to differentiate between the supply of general storage and the supply of storage as part of the clinical trial process. General storage is merely the supply of storage without testing. Storage as part of the clinical trial process is integral to the clinical trial and enables further testing to provide scientific data in a report. The storage is an element required to provide the single service of the clinical trial.
Sample processing and storage prior to shipment	Samples are stored for minor testing during the clinical trials so that scientific data can be provided.
Provision of kits	The provision of the kits forms part of the supply of the testing when the cost is recovered from a Sponsor. The kits consist of a package, which contains needles and vials required to perform the testing. The vendor is responsible for providing the kits to the clinical trial site. At the clinical site, the kits are used to collect samples. Once the samples are collected, they shipped to the laboratory and logged onto a computer system. The kits remain the property of the vendor. The kits are essential to the testing process and form part of the cost incurred to obtain the samples for testing. The vendor specifies the cost of the kits on the invoice issued to the Sponsor.

LEGAL NATURE - LEGISLATIVE HISTORY OF SECTION 11(2)(l)

17. The very first rendition of section 11(2)(l) in the Act was worded as follows:

"Where, but for this section, a supply of services…would be charged with tax at the rate referred to in section 7(1), such supply of services shall…be charged with tax at the rate of zero per cent where—

the services are supplied for and to a person who is not a resident of the Republic or a specified country and who is outside the Republic and the specified countries at the time the services are rendered, not being services which are supplied directly in connection with —

(i) land or any improvement thereto situated inside the Republic or a specified country; or

(ii) movable property situated inside the Republic or a specified country at the time the services are rendered,

and not being services which are the acceptance by any person of an obligation to refrain from carrying on any enterprise, to the extent that the carrying on of that enterprise would have occurred within the Republic or a specified country; or

18. Section 11(2)(l) was amended in 1994[2] to delete the words 'specified country' and to insert the exceptions to movable property situated in South Africa, this exception was constituted as follows:

"except movable property which —

(aa) is exported to the said person subsequent to the supply of such services; or

(bb) forms part of a supply by the said person to a registered vendor and such services are supplied to the said person for purposes of such supply to the registered vendor,"

19. The above amendment was made in response to criticism that the international competitiveness of South African vendors was negatively impacted.

20. In 1997[3] the opening words of section 11(2)(l) were amended to read as follows (underlined words inserted):

the services are supplied <u>for the benefit of</u> and <u>contractually</u> to a person who is not a resident of the Republic and who is outside the Republic at the time the services are rendered, not being services which are supplied directly in connection with—

21. The explanatory memorandum indicated that the amendment was "*to eliminate any doubt as to the scope of this zero-rating provision, the amendment introduced by this subclause provides that the zero rate will apply only where the services are supplied for the benefit of and contractually to a person who is not a resident of the Republic and who is outside the Republic at the time the services are rendered.*"

[2] Taxation Laws Amendment Act No.20 of 1994

[3] Taxation Laws Amendment Act No.27 of 1997

22. In 1998[4] section 11(2)(l) was once again amended, this time as follows, words in brackets being deleted, and words underlined being inserted through the amendment:

*"…the services are supplied **[for the benefit of and contractually]** to a person who is not a resident of the Republic **[and who is outside the Republic at the time the services are rendered]**, not being services which are supplied directly **[in connection with]**—*

(i) in connection with land or any improvements thereto situated inside the Republic; or

(ii) in connection with movable property situated inside the Republic at the time the services are rendered, except movable property which—

(aa) is exported to the said person subsequent to the supply of such services; or

(bb) forms part of a supply by the said person to a registered vendor and such services are supplied to the said person for purposes of such supply to the registered vendor; or

(iii) to the said person or any other person, other than in circumstances contemplated in subparagraph (ii)(bb), if the said person or such other person is in the Republic at the time the services are supplied,

and not being services which are the acceptance by any person of an obligation to refrain from carrying on any enterprise, to the extent that the carrying on of that enterprise would have occurred within the Republic; or".

23. The explanatory memorandum accompanying this amendment described its purpose as follows:

The amendment is aimed at eliminating any doubt as to the scope of this subsection. The supply of the services must be made to a recipient who is not a resident, and neither the recipient nor any other person to whom the services are rendered may be in the Republic at the time the services are rendered, for the zero rate of VAT to apply.

It is not the intention that any incidental benefit derived by a person who is in the Republic should disqualify the supply of the service from being zero-rated. Where, for instance, a local newspaper contracts with a foreign advertiser to publish an advertisement, the local newspaper will supply the service to the foreign advertiser at the zero rate. The fact that local readers of the newspaper may also benefit from reading the advertisement is merely incidental and will not require the service to be supplied at the standard rate.

The word "directly" in the subsection ensures that an incidental benefit will not affect the zero-rating of the supply.

[4] Taxation Laws Amendment Act 30 of 1998.

24. The final amendment to section 11(2)(l) came into effect in 1999[5] and was as follows (the word in brackets deleted, and the underlined word being inserted):

"(iii) to the said person or any other person, other than in circumstances contemplated in subparagraph (ii)(bb), if the said person or such other person is in the Republic at the time the Services are ***[supplied]*** *rendered,".*

25. The Explanatory Memorandum in respect of the 1999 amendment stated:

'This amendment is aimed at putting it beyond doubt that the presence in the Republic of the recipient of a service, or of any other person to whom the service is rendered, at the time the service is physically rendered ... will prohibit the zero-rating provided for in this subsection from being applied.'

26. The Tax Court in VAT 969 noted:

"There can be no doubt that the Legislature, by inserting the words "at the time the services are rendered", rather than the usual reference to a "supply of services", in paragraph (iii) of subsection 11(2)(l) intended that the zero rated provisions would not apply if the recipient was in the Republic at the time the services were actually supplied, even though such recipient was not in the Republic when the services were deemed to have been supplied as provided for in terms of s 9(1) of the Act. (The general rule relating to time of supply is that the supply is deemed to have taken place where an invoice is issued or any payment in respect of the supply is received, whichever is earlier except as otherwise provided for in the Act.)"

27. The SCA in **CSARS v United Manganese of Kalahari (Pty) Ltd** ZASCA 16 (2020] stated in paragraph [17] that the legislative history may provide useful background in resolving interpretational uncertainty.[6]

28. The **SCA in XO Africa Safaris v CSARS** at paragraph [30] "*We were taken to the various* amendments *of this section which led to the current version of the section around which the dispute between the parties revolves. That history showed that the statutory purpose underlying s 11(2)(l) was to ensure that where services were rendered to a foreigner by a person liable to pay VAT, but the services themselves were rendered in South Africa and the benefit of them was enjoyed in the Republic, they would not enjoy the benefit of zero rating. VAT would be payable at the standard rate.*"

INTERNATIONAL LAW AND OTHER JURISDICTIONS

Australia	**New Zealand**
Section 38-190 sets out supplies which are GST free (equivalent of our zero-rate) - Supplies of	(k) subject to subsection (2), the services are supplied to a person who is a non-resident and

5 Taxation Laws Amendment Act No.53 of 1999.

6 As occurred with the Labour Relations Act 66 of 1995. See Explanatory Memorandum by the Ministerial Task Team 1995 ILJ 278 and Sidumo and Another v Rustenberg Platinum Mines Ltd and Others [2007] ZACC 22; 2008 (2) SA 24 (CC) para 94, fns 100- 102.

things, other than goods or real property, for consumption outside Australia: **Supply to *non-resident outside Australia.** a supply that is made to a *non-resident who is not in Australia when the thing supplied is done, and: (a) the supply is neither a supply of work physically performed on goods situated in Australia when the work is done nor a supply directly connected with *real property situated in Australia; or (b) the *non-resident acquires the thing in *carrying on the non-resident's *enterprise but is not *registered or *required to be registered. Supplies used or enjoyed outside Australia. a supply: (a) that is made to a *recipient who is not in Australia when the thing supplied is done; and (b) the effective use or enjoyment of which takes place outside Australia; other than a supply of work physically performed on goods situated in Australia when the thing supplied is done, or a supply directly connected with *real property situated in Australia	who is outside New Zealand at the time the services are performed, not being services which are: (i) supplied directly in connection with land situated in New Zealand, or with an improvement to such land, or are supplied in connection with such land or improvement and are intended to enable or assist a change in the physical condition, or ownership or other legal status, of the land or improvement; or (ii) supplied directly in connection with moveable personal property, other than choses in action or goods to which paragraph (h) or (i) applies, situated in New Zealand at the time the services are performed; or (iii)the acceptance of an obligation to refrain from carrying on a taxable activity, to the extent to which the activity would have occurred within New Zealand; or

29. The Australian Tax Office (ATO) has ruled that services supplied by a GST-registered supplier to a foreign/overseas based start-up company which has developed a new product, which is part of a trial in hospitals on the Australian mainland in an early-stage clinical trial[7] is GST free (our equivalent of the zero-rate) based on the application of the Australian GST provisions in the table above.

30. The ruling was concerned with early-stage clinical trials, but clinical trials at any stage would to our mind also be GST free, if supplied to a foreign or overseas based company.

31. The legislative context in which the ATO has expressed a view on the GST free (zero-rated) nature of clinical trials differs significantly from our own legislation here in South Africa. Their view however does provide a useful indication that the ATO is of the opinion

[7] The product is a new type of medical device (the product). The foreign start up owns the technology.

that clinical trials supplied to recipients who are not in Australia should be zero-rated and that even though it concerns a new product it is not connected to property situated in Australia.

32. As far as we are aware the New Zealand Inland Revenue has not expressed a public view on the GST treatment of clinical trials.

33. South Korea has introduced a rule that zero-rates the supply of clinical trial services to foreign pharmaceutical companies located outside of South Korea and receive consideration in foreign currencies, to apply zero-rated VAT on these services.[8]

34. In Israel, section 30(19) of the Israeli VAT Law was amended in December 2014 to clarify that services comprising the supervision, coordination and control with carrying out medical experiments on humans to foreign residents shall be subject to zero VAT. The amendment emphasises the importance of clinical research and its contribution to the health of Israeli citizens and improves competition with other countries which already exempt such clinical research from VAT.[9]

APPLICATION OF EXISTING SOUTH AFRICAN LAW

Type of supply	Application of zero-rating provisions
Standard clinical trials: **Includes:** • **Provision of kits for the initial extraction of blood** • **Analysis of data generated** • **Report generation (hard copy or electronic)** • **Storage of specimens (preserving for retesting)** • **Shipment of specimens**	This supply should qualify for the zero-rate. The only potential difficulty is the application of section 8(15) of the Act and the interpretation expressed in *Diageo South Africa (Pty) Ltd v CSARS SCA* [2020], where it was held that: • The purpose of section 8(15) of the Act was to provide, by way of a deeming provision, for a situation where the provisions of sections 7(1)(a) and 11(2)(l) of the Act were implicated in a single supply of goods and/or services, so that the appropriate rate of VAT was charged. • The single supply provided by the taxpayer consisted of both goods and services that were distinct and clearly identifiable from each other. • Had separate considerations been payable in respect of the goods and services, part of the supply (the goods consumed in the Republic) would have been standard-rated and the part consisting of the services supplied to non-residents would have been zero-rated. However, by the application of section 8(15), each part of the supply was deemed to be a separate supply.

[8] Source: https://www.vatupdate.com/2015/02/16/korea-zero-rated-vat-for-clinical-trial-services-michaela-merz/

[9] Source: https://michaelamerz.org/2015/02/23/israel-zero-rated-vat-for-clinical-trial-services/

	The above may potentially be applied to the following: • Kits for initial extraction. • Storage of specimens. • Shipment of specimens to other parts of South Africa (specimens exported will not be subject to section 8(15) of the Act). In our view the kits are not supplied to the foreign sponsor, this represents nothing more than a recovery of a portion of the costs incurred while supplying the services of analysing the data and generating the report.
Sample storage – long-term storage • **Long term storage is storage for a long duration without future testing.** • **Storage as part of the clinical trial process for future testing, the objective is to generate scientific data or a report.**	The difficulty in applying section 11(2)(l) in this case is that the storage is directly connected to movable property situated in South Africa, which disqualifies it from the zero-rate. There is potentially a close connection (direct connection) between a service (storage) and land or movable property (the storage facility and specimen). It is however interesting to note that in *Diageo* there was no question of the advertising and promotional services being directly connected to any goods, and it was only section 8(15) of the Act that deemed the supply separate.
Provision of kits and other goods • **The supply of the kits often forms part of the supply of the testing.** • **The supply of the kits to local clients will qualify as a separate supply.** • **The kits consist of a package, which contains needles and vials.** • **At the clinical site, the kits are used to collect samples.** • **the samples are subsequently shipped to the lab and logged into the system. The kits remain the property of the vendor.** ***Composite supply*** • **The kits are essential to the testing process and form part of the cost incurred to obtain the samples.**	As indicated above, section 8(15) of the Act and its interpretation in *Diageo* may apply and deem the testing services a separate and distinct supply from the testing kits. • It is our view, however, that the kits are not supplied to the foreign sponsor, this represents nothing more than a recovery of a portion of the costs incurred while supplying the services of analysing the data and generating the report. • It is important to note that the kit is not supplied to anyone and remains the property of the vendor. • The zero-rate in section 11(2)(l) of the VAT Act should apply. Separate supply of kits • This supply should be subject to VAT at the standard rate unless the kit is supplied in terms of a sale where it is exported to an export country.

• **The vendor specifies the cost of the kits on the invoice to the Sponsor.** ***Separate supply*** • **The vendor sells the kits to local clients for testing purposes.** • **No testing services are supplied by the vendor.**	

POLICY CONSIDERATIONS

35. The manner in which the zero-rating provisions are interpreted and applied disadvantages South African vendors, making it very difficult to compete with suppliers of clinical trials in other jurisdictions. Suppliers in those markets are more attractive for Sponsors, since the standard rating of VAT does not become a cost to the non-resident recipient, which is potentially the case in South Africa.

PROPOSAL

36. The size of the global clinical trials market was valued at USD 47 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 5.8% from 2022 to 2030. However, the growth of the market was hindered in 2020 due to the COVID-19 pandemic.[10]

37. Disproportionately few clinical trials are undertaken on the African continent, with South Africa and Egypt being the most attractive destinations for clinical trials on the continent.[11] It is certain that increasing South Africa's facilitation of international clinical trial participation is beneficial for the country.

38. In our view, ensuring that the services supplied to foreign sponsors of clinical trials qualifies for the zero-rate will secure the international competitiveness of South African vendors who supply clinical trial services. It will also organise research ethics committees of clinical trial testing and improve skills through training and knowledge-sharing.

39. We submit that SARS should issue guidance on the current application of the zero-rating provisions to clinical trials where the recipient of the supply is a non-resident.

40. We furthermore propose that a zero-rating provision, section 11(2)(z), constituted as follows, be inserted:

"(2) Where, but for this section, a supply of services, other than services contemplated in section 11 (2) (k) that are electronic services, would be charged with tax at the rate

[10] Source: https://www.grandviewresearch.com/industry-analysis/global-clinical-trials-market

[11] Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7928546/

referred to in section 7(1), such supply of services shall, subject to compliance with subsection (3) of this section, be charged with tax at the rate of zero per cent where—"

"(z) the services comprise the supply of clinical trial activities supplied directly to a foreign sponsor, not being services which are supplied directly:

(i) to a foreign sponsor present in the Republic at the time the services are rendered or;

(ii) to a branch or main business of the foreign sponsor situated in the Republic, or

(iii) to any other person present in the Republic at the time the services are rendered"

41. An amendment to section 1 of the Act to define 'foreign sponsor' should also be inserted.

"A foreign sponsor: means a person, enterprise or business which is not a resident of the Republic and is not a vendor, who is the recipient of services contemplated in section 11(2)(z)"

42. The above will require an amendment to section 8 which deems the supply of goods and services contemplated in section 11(2)(z) to be the supply of services, and can be constituted as follows:

"Section 8(30) For the purposes of this Act, a supply of any goods made to a foreign sponsor in respect of clinical trial activities as defined and as contemplated in section 11(2)(z), shall be deemed to be a supply of services."

43. This will overcome the potential issues presented by section 8(15).

44. Stakeholders can be consulted to define what clinical trial activities are, and a definition can be inserted in section 1 of the Act to tightly limit the zero-rating provisions and regulate its application.