SCIENTIFIC AND TECHNOLOGICAL RESEARCH AND DEVELOPMENT TAX INCENTIVE GUIDELINES FOR APPLICANTS

Amended version

Making sure it's possible

science & innovation

Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

30 YEARS OF FREEDOM
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ABBREVIATIONS

API	active pharmaceutical ingredient
CRO	contract research organisation
DALRRD	Department of Agriculture, Land Reform and Rural Development
DoH	Department of Health
DSI	Department of Science and Innovation
R&D	research and development
SANCTR	South African National Clinical Trials Register
SARS	South African Revenue Service
STI	science, technology and innovation
WHO	World Health Organization

PREAMBLE

These guidelines are intended to assist companies applying for the scientific and technological research and development tax incentive (the R&D tax incentive) under section 11D of the Income Tax Act, 1962 (Act No. 58 of 1962).

The guidelines explain the objectives of the R&D tax incentive, who can apply, and the requirements that research and development (R&D) activities must satisfy in order to qualify for the incentive. Separate documents explain how to complete an R&D tax incentive project application and how to use the online R&D tax incentive system. Applicants are encouraged to use these guidelines extensively, to contact the tax incentive unit at the Department of Science and Innovation (DSI) if they have any questions, and to provide the DSI with feedback.

The 2015 *Frascati Manual – Guidelines for Collecting and Reporting Data on Research and Experimental Development*[1], published by the Organisation for Economic Cooperation and Development, provides background and internationally agreed definitions of R&D-related concepts that applicants may find helpful. Applicants may also contact the DSI for further R&D advice and assistance where necessary.

[1] https://read.oecd-ilibrary.org/science-and-technology/frascati-manual-2015_9789264239012-en#page1

PART 1: INTRODUCTION

Background

The need for private sector research and development (R&D) was highlighted in the 2002 National Research and Development Strategy for South Africa. In response, the government, through what were then the Department of Science and Technology and the Department of Trade and Industry, together with the National Treasury and the South African Revenue Service (SARS), introduced the R&D tax incentive programme in 2006.

The 2019 White Paper on Science, Technology and Innovation (STI) has set a long-term policy direction to ensure a growing role for STI in a more prosperous and inclusive society, with government working to increase the levels of R&D investment in the economy. The target is for gross expenditure on R&D to reach 1,5% of GDP in the next decade.

The R&D tax incentive was due to come to an end on 30 September 2022. However, in line with the recommendations of a 2015 joint government-industry task team, various policy review activities were undertaken, including an impact evaluation of the R&D tax incentive completed during 2019 by the World Bank, an internal synthesis analysis by the DSI, and the development of a discussion document and survey in 2021. In early 2022, taxpayers were consulted and asked to provide feedback on the public comments received in response to the discussion document. In October 2022, the National Treasury published proposed amendments for inclusion in the 2023 Taxation Laws Amendment Bill.

In February 2023, the Minister of Finance announced that the R&D tax incentive would be extended until 31 December 2033, while refinements would be made to section 11D of the Income Tax Act. These amendments are described in this document and relate to the introduction of a six-month grace period (prior to the date of application) to allow applicants to claim eligible expenditure during this grace period (see pg. 10 to better understand the application of the grace period). Additionally, the amendments refine and simplify the definition of R&D. These amendments were

gazetted in the Taxation Laws Amendment Act, 2023 (Act No. 17 of 2023) and are effective from 1 January 2024.

Objectives of the R&D tax incentive

Scientific research and technological advancements are crucial for innovation, productivity and economic growth. For this reason, through the R&D tax incentive, the South African government encourages private-sector companies to invest in scientific or technological R&D in the country.

By reducing the costs of R&D and encouraging companies to undertake R&D in South Africa, local companies will strengthen their capacity to develop value-added products, technologies and services. In this way, the R&D tax incentive promotes scientific and/or technological advancement and contributes to making South African companies internationally competitive.

The R&D tax incentive is also aimed at encouraging foreign companies to conduct and invest in scientific or technological R&D in the country.

The objectives of the R&D tax incentive can thus be summarised as follows:

- To encourage business to increase investment in scientific and technological R&D, especially R&D that a company would not have invested in were it not for the incentive.
- To advance scientific knowledge and achieve technological advancement aimed at creating new or improved products, processes or services.
- To increase the positive spillover to the rest of society through knowledge transfer and skills development.

Description of the R&D tax incentive

In terms of section 11D of the Income Tax Act, companies undertaking scientific and technological R&D activities in South Africa can qualify for a 150% deduction on their operational R&D expenditure, provided that such activities are approved by the Minister of Higher Education, Science and Innovation ("the Minister").

The R&D tax incentive is a **pre-approval system**, and recent legislative changes allow companies a grace period (which may extend up to six months prior to the date of application) during which expenditure may be claimed even though that expenditure pre-dates the date of application. The onus is on the applicant to prove that the activities performed or to be performed will fall within the scope of R&D as defined in the Income Tax Act.

To be considered for the tax incentive, R&D activities should be systematic investigative or systematic experimental, aimed at resolving scientific or technological uncertainty. The resolution of this uncertainty should not be readily deducible by a person skilled in the relevant scientific or technological field. The activities should also be aimed at discovering new scientific or technological knowledge, creating new or significantly improved products, processes or services, creating or developing a multisource pharmaceutical product, and conducting a clinical trial.

Administration

The R&D tax incentive programme is administered by the DSI in conjunction with SARS and the National Treasury.

The Directorate: Private Sector R&D Promotion ("the unit") is responsible for managing the process of receiving all R&D project applications, processing such R&D project applications to approval or non-approval, communicating with applicants, and managing the receipt of progress reports after the approval of R&D projects. Most of these activities are managed through the R&D Tax Incentive Online System ("online system"), which was launched in October 2022.

The unit reports annually on the performance of the R&D tax incentive to Parliament. The unit also serves as the secretariat for the R&D Tax Incentive Adjudication and Monitoring Committee ("the committee"), established in terms of section 11D of the Income Tax Act.

The committee evaluates applications and makes recommendations to the Minister. It consists of three members from the DSI, three from SARS and one from the National Treasury. In line with the provisions of the Income Tax Act, a panel of external technical experts is appointed by the DSI to assist the committee with assessments on the eligibility of the R&D projects.

All disclosures to, and discussions of, the committee and unit are treated as confidential.

Eligible expenditure incurred on approved R&D activities qualify for a 150% deduction and can be claimed for tax purposes. SARS may audit these expenditures.

Application process

Company representative profile registration	• The representative captures all the required information and registers an online profile. • The representative verifies the system-generated email address. • The representative is assigned with all rights of an external user of the online system.
Company profile registration	• The representative logs into the system, registers the company profile and attaches a letter of authorisation from the company. • The DSI approves the company profile registration.
Project application submission	• The representative creates a project and links it to the company. • The system displays an online form on which the user can capture project details and submit a project application. • The system acknowledges receipt of the project application via an automated message. • The application is assessed by an external expert.
Assessment and adjudication	• The secretariat screens and assigns the project application to a technical expert for assessment. • The assessment report and the project application are made available to committee members for adjudication. • If the committee intends to make a non-approval recommendation, the applicant is given an opportunity to submit additional information in terms of the Promotion of Administrative Justice Act. • The committee makes a recommendation to the Minister.
Decision	• The Minister's decision letter is sent to the company. • This letter serves as proof to SARS that the company's R&D activities have been approved when claiming the tax deduction.
Progress reporting	• A company whose R&D activities have been approved must submit annual progress reports to the DSI, coinciding with their financial year-end tax reporting. • The company should keep records that support tax expenditure claims and progress with R&D.

The R&D tax incentive process starts with a company submitting an R&D tax incentive project application to the DSI through the online system (available at https://www.dst.gov.za/rdtax/). Such project application can only be submitted after the applicant has registered a company profile on the online system. The online system automatically sends an acknowledgement of receipt email to the applicant, indicating the date of receipt and the reference or case number assigned to the project application. If such an acknowledgement email is not received, the applicant should check their spam/junk folder for the email. **It is best for applicants to ensure that their mailboxes never block any emails from the DSI's domain (dst.gov.za).**

The date of receipt of the application is important to calculate the date from which eligible expenditure may be claimed once the application is approved. From 1 January 2024, a six-month grace period for claiming eligible expenditure prior to the date of application has been in place. This grace period cannot extend further back than the date stated in the Taxation Laws Amendment Act (i.e. 1 January 2024). Thus, if an application is submitted to the DSI on or before 30 June 2024, eligible expenditure can only be claimed back from 1 January 2024; while if an application is submitted on 10 October 2024, eligible expenditure can be claimed back from 10 April 2024, once the R&D project has been approved.

The unit screens the application and, if it picks up possible problems, it may request clarification or additional information from the applicant through an email generated by the online system. The unit then allocates the newly received project to an expert, who is selected based on their field of expertise in relation to the scientific or technological R&D to be undertaken in the project. The expert assesses the project and provides the unit with a report setting out whether, in their opinion, the project activities fit the definition of R&D in terms of section 11D of the Income Tax Act. If the expert is of the view that additional information may assist in the assessment, or if some information is unclear, the unit may request clarification or additional information from the applicant.

The unit schedules committee meetings and prepares agendas that include newly assessed projects. Before the meeting, for each new project, the committee is given the completed application, the expert's assessment report and any other relevant

documentation or communication between the unit and the applicant. During the meeting, the expert presents the project to the committee, which then adjudicates the application and recommends whether to request additional information or clarification from the applicant, or approval or non-approval by the Minister.

If a project is not recommended for approval, a process in line with the Promotion of Administrative Justice Act is followed. The unit prepares a letter/notification to the applicant indicating that it does not intend to recommend the application for approval and giving reasons for this. The applicant is requested to provide the unit with any additional information that may influence the committee's recommendation and upload that information on the online system.

Once the unit receives the additional information from the applicant, the information is sent to the assigned expert to review and consider in the further assessment of the project. The project is then placed on the next agenda of the committee for a final decision on the recommendation to be made to the Minister.

Once a recommendation for approval or non-approval has been made by the committee, the unit prepares the necessary documentation for the Minister, who will review the recommendations of the committee, make a decision, and sign letters to the applicants informing them of the decision. In the case of approved applications, the letter sent to the company serves as proof to SARS that the company's R&D activities have been approved for the 150% deduction in terms of section 11D of the Income Tax Act. If a project is not approved, the company may take the decision of the Minister on judicial review.

The DSI has undertaken to provide applicants with final decisions on their applications within 90 business days of receipt of the applications (provided no additional information is requested from the applicant and excluding periods when the unit is awaiting additional information from the applicant).

Once a project has been approved, the applicant company is required to provide the committee with annual progress reports. The dates on which progress reports are due coincide with the end of the company's financial year end and are set out in the

Minister's decision letter. Although progress reports may seem to be additional work for the companies, the DSI needs the data collected to measure and evaluate the value and impact of the R&D tax incentive. It is important for companies to keep records to support their R&D tax incentive claims and to use as evidence for their progress reports on their R&D.

PART 2: ELIGIBILITY CRITERIA FOR THE R&D TAX INCENTIVE

The R&D tax incentive is available to South African registered companies of all sizes and operating in any sector of the economy. These companies must undertake qualifying R&D (discussed below) in South Africa in order to qualify for the R&D tax incentive.

As explained above, for a company to benefit from the R&D tax incentive, its R&D activities must be approved by the Minister or a person appointed by the Minister. Approval is granted based on a recommendation by the R&D Tax Incentive Adjudication and Monitoring Committee.

Applicant eligibility criteria

For an applicant to be eligible for the 150% deduction, the applicant must be a **company as defined in the Income Tax Act**. The company should therefore be resident in the Republic of South Africa, i.e. incorporated under the laws of, or effectively managed in, South Africa. Such companies are eligible for the R&D tax incentive provided that they conduct eligible R&D within South Africa.

Tax-exempt companies such as non-profit organisations, public benefit organisations and universities are not eligible for the R&D tax incentive.

Other requirements related to the applicant and its expenses are the following:

- The applicant must actually incur the R&D expenses.
- The expenses should be directly and solely in respect of carrying on the R&D activities.
- Only R&D activities undertaken in South Africa are eligible.
- The expenses should be incurred in the production of income. Thus, the applicant should conduct the activities with the intention of income generation, whether through developing new products that will be sold, or carrying on R&D on behalf of someone else and charging a fee for such R&D.
- The expenses should be incurred in carrying on of any trade.

- The R&D tax incentive is based on pre-approval for activities, therefore, R&D activities are only eligible if they occur during the newly introduced grace period or after the date of receipt of the R&D tax incentive application by the DSI.
- The R&D activities must be approved by the Minister.

Eligible R&D activities

To qualify for the R&D tax incentive, the applicant's R&D activities must meet the definition of R&D in section 11D(1) of the Income Tax Act. The definition, discussed below, is reproduced in Annexure A for convenience and came into force on 1 January 2024. All project applications received from this date will accordingly be assessed under this amended definition of R&D.

The detailed legal definition should be seen in the context of the *Frascati Manual* (2015), which offers the following definition:

> *Research and experimental development comprise creative and systematic work undertaken in order to **increase the stock of knowledge** [emphasis added] – including knowledge of humankind, culture and society – and to devise new applications of available knowledge.*

The *Frascati Manual* describes R&D as covering three types of activity, namely, basic research, applied research, and experimental development.

- **Basic research** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view, i.e. extending the boundaries of formal knowledge.

- **Applied research** is original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

- **Experimental development** is systematic work, drawing on knowledge gained from research and practical experience, and producing additional knowledge,

which is directed to producing new products or processes or to improving existing products or processes.

According to the *Frascati Manual*, an R&D activity can be distinguished from a non-R&D activity when five core criteria are met. The activity must be –

- **novel**, i.e. aimed at new findings;
- **creative**, i.e. based on original, not obvious, concepts and hypotheses, and excluding routine changes;
- **uncertain**, i.e. the final outcome is uncertain;
- **systematic**, i.e. planned and budgeted for; **and**
- **transferable and/or reproducible**, i.e. the results can be reproduced.

Experimental development should not be confused with product development or pre-production development. Both types of development may have stages, such as experimental development, that could be classified as R&D, but product development per se is not experimental development, and therefore not R&D.

With the above in mind, the amended definition of R&D provided in section 11D of the Income Tax Act states that activities should be **systematic investigative** or **systematic experimental** activities aimed at resolving **scientific or technological uncertainty**. The resolution of this uncertainty should not be readily deducible by a person skilled in the relevant scientific or technological field.

Systematic investigative or systematic experimental activities aimed at resolving scientific or technological uncertainty therefore lie at the heart of the section 11D definition. These activities are to be performed by the applicant in order to assess whether the scientific or technological uncertainty can be overcome and to attempt to find a solution. At the time of conducting the activities, it should be uncertain whether a solution exists, whether a particular solution is viable, whether the uncertainty can be overcome, or whether the benefits hoped for will materialise. If the outcome of the R&D activities is certain, the activities would not be necessary. If the outcome of the uncertainty can be readily deduced by a person skilled in the relevant scientific or technological field, the activities would not amount to R&D.

R&D therefore requires more than the mere solving of a technical problem, for which standard and existing knowledge, practices, techniques or methodologies (known or available in the public domain) would be sufficient and, therefore, systematic investigative or systematic experimental activities would not be needed. The results of the systematic investigative or systematic experimental activities undertaken address a scientific or technological problem and may or may not resolve the uncertainty. Irrespective of whether a resolution is found, the activities conducted will lead to an increase in the stock of knowledge and/or may lead to advancement in the field of technology.

As is now expressly stated in the definition of R&D: if the outcome of the uncertainty can be readily deduced by a person skilled in the relevant scientific or technological field, the activities would not amount to R&D. This means that a suitably competent professional, e.g. an engineer, technician, data scientist or software developer, making use of existing knowledge, technologies or methods, would not necessarily be conducting R&D merely by solving problems that would fall within the normal domain of work of such a professional. More than this is required.

The size and/or complexity of an activity and the product or process to which it is related do not necessarily mean that R&D as defined in section 11D is being carried out. Likewise, the development of a large and complex system is not evidence that uncertainty existed.

A form of uncertainty, called system uncertainty, can arise from or during the integration of technologies, the components of which are generally well known. This is due to **unpredictable interactions** between individual components or sub-systems. It may be difficult or impossible for experts in the field to predict how the integrated system will perform due to unforeseeable adverse interactions. The uncertainty here is not in the individual modules or components, but in the modules or components acting as an integrated system. The attempt to resolve these uncertainties by a systematic investigation or search is necessary for the activities to fulfill this R&D requirement.

Non-obvious means that the resolution of the scientific or technological uncertainty is not readily deducible by a person skilled in the relevant scientific or technological field.

Scientific or technological knowledge is considered non-obvious if it has not been made public anywhere in the world (i.e. it should be new) and it should not be a trivial contribution to the stock of knowledge, but a real step forward, for example –

- a body of reliable new information in the studied nature and behaviour of the material and physical universe, based on observation, experiment, measurement and laws formulated to describe these facts in general; or
- a body of reliable new information on how to apply scientific principles or use scientific knowledge to solve technological problems or to achieve results, which could be products, processes, systems or results that can be modelled.

In terms of section 11D(1), systematic investigative or systematic experimental activities should be aimed at resolving **scientific or technological uncertainty**. Specifically, the R&D activities should be aimed at one or more of the following:

- Discovering **new** scientific or technological **knowledge**.
- Creating or developing new or significantly improved products, processes or services;
- Creating or developing a **multisource pharmaceutical product**[2].
- Conducting a **clinical trial**[3].

An application should indicate in which category or categories its R&D activities fall. To assist in establishing which categories would be appropriate, an explanation for each of the categories is provided below.

[2] As defined in the WHO Technical Report Series, No. 937, 2006 Annex 7 Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability issued by the WHO, conforming to such requirements as must be prescribed by regulations made by the Minister of Health after consultation with the Minister of Higher Education, Science and Innovation.

[3] As defined in Appendix F of the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa issued by the Department of Health (2006), conforming to requirements as must be prescribed by regulations made by the Minister of Health after consultation with Minister of Science and Innovation.

Discovering new scientific or technological knowledge

The core of R&D is its contribution to the stock of knowledge. The knowledge to be discovered under this category is restricted to scientific or technological knowledge that is new and novel (i.e. if the outcome of the uncertainty cannot be readily deduced by a person skilled in the relevant scientific or technological field).

Newness or **novelty** requires that the knowledge should be a global first, i.e. the knowledge should not be in the public domain. It should not have been disclosed by the company or any third party in any way or form and it should not exist anywhere else in the world.

Creating or developing new or significantly improved products, processes or services

The requirement of **significant improvement** means that an assessment will be made against an existing product, process or service, i.e. a comparison against the state of the art is necessary to show how the improvement is significantly different. The improvement could relate to changes in materials, components and other characteristics, or process(es), including significant changes to techniques, equipment and/or the application of software.

Routine or minor improvements that do not involve scientific or technological advances will not be considered for the tax incentive. Examples include routine computer maintenance, system or program-specific enhancements that were publicly available prior to commencement of the work, and work on technical problems that have been overcome previously on the same operating systems or computer architecture; or designs that do not involve significant changes in the product's functional characteristics or its intended uses.

Insofar as the product is a computer program, the following should be considered, bearing in mind that a computer program can be any software, firmware, embedded software or middleware.

Software development is the process of understanding and enumerating requirements for a particular program into a specification; translating those specifications into instructions for the computer; testing them to make sure that specifications and their translations are correct; and documenting and maintaining this program as its users request modifications.

It is important to note that **not all software development activities are R&D activities** in terms of the Act, particularly as the definition of R&D now clarifies that only scientific and technological R&D falls under section 11D when the systematic investigative or systematic experimental software development activities should be aimed at resolving a scientific or technological uncertainty (rather than a business uncertainty). This type of investigative/experimental development should accordingly not be confused with product development or pre-production development. Both types of development may have stages, such as experimental development, that could be classified as R&D, but product development per se is not experimental development, and therefore not R&D.

The use of existing software for a new application or purpose does not, by itself, equate to systematic investigative or systematic experimental activities, the result of which is uncertain. Unless the systematic investigative or systematic experimental nature of the activities can be shown aimed at resolving a scientific or technological uncertainty, the activities will not be considered R&D. The creation of a computer program using known methods of existing software tools without the need for systematic investigative or systematic experimental activities, i.e. where no uncertainty exists, will not be considered either.

It follows that the creation of a software programme similar to what already exists, but on a more cost-effective platform or with other, different and/or better business terms or considerations, will not be considered scientific or technological R&D unless the applicant can show that systematic investigative or systematic experimental activities are aimed at resolving a scientific or technological uncertainty.

Software may represent the embodiment of R&D outcomes, irrespective of the particular industry. However, in the software/computer services industry, software

may not always represent the embodiment of R&D outcomes. The development of software can be an integral part of an R&D activity, while only part of software development is R&D. Software can be an end product of R&D or embedded in an end product that is a subject of R&D.

The *Frascati Manual* states that, "for software development to be classified as R&D, its **completion must be dependent on the development of a scientific and/or technological advance**, and **the aim of the project must be the systematic resolution of a scientific and/or technological uncertainty**".

The list below, taken from the *Frascati Manual*, indicate types of software-development activities that may typically be deemed scientific or technological R&D. Although the list below may not be fully aligned with the definition of scientific or technological R&D in terms of section 11D, it will assist applicants to consider their own software development critically and shed light on the type of information that may assist the committee to recommend approval:

- Theoretical computer science
  - R&D producing new theorems and algorithms.
  - The design and implementation of new search engines based on original technologies.
  - Creating new and original encryption or security techniques.
- Operating systems
  - Technological advances or improvements in resource and interface management.
  - New operating systems.
  - The conversion of an operating system to a significantly different hardware environment.
  - The effort to resolve conflicts within hardware or software based on the process of re-engineering a system or a network.
- Programming languages – technological advances that include the development of the following:
  - New languages.
  - A significant extension of an existing language.
  - New or significantly different language translators.

- Data management – technological advances that include the development of the following:
  - Algorithms to achieve better basic operations (e.g. retrievals from a database).
  - New or enhanced query languages for databases that significantly increase the power of search or manipulation.
  - New object representations or data structures.
- Software engineering – advances in the methodology required to construct computer programmes that are more flexible, reliable, efficient and easy to maintain.
- Artificial intelligence – scientific and technological advances made in the following domains:
  - Machine vision.
  - Robotics.
  - Inference.
  - Knowledge representation.
  - Expert systems.
  - Theorem proving.
  - Understanding of natural language.
  - Automatic language translation.
  - Logic programming.
  - Future generation systems.

The following would typically not qualify as scientific or technological R&D in terms of the amended Income Tax Act:

- Routine software-related activities for the development of computer programs, irrespective of their size or complexity.
- Activities that do not involve any aspects of systematic investigation or systematic experiments, of which the result is uncertain.

The following are some more specific examples of activities that would not qualify:

- Routine computer and software maintenance work on system-specific or program-specific advances that were publicly available prior to the commencement of the work.
- Technical problems that have been overcome in previous projects on the same operating systems and computer architecture.
- Business application software and information system development using known methods and existing software tools.
- Support for existing systems.
- Converting and/or translating computer languages.
- Adding minor user functionality to existing application programs.
- Debugging systems.
- Adaptations of existing software.
- Post-R&D activities such as the preparation of user documentation and maintenance of existing systems.
- Data migration from one system to another.
- Solving technical problems where similar problems have been overcome in previous projects on the same operating systems and computer architecture.

Creating or developing a multisource pharmaceutical product

A multisource pharmaceutical product is a generic pharmaceutical product, i.e. medication, created to be a bioequivalent of an already marketed medication; or a medication that is the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Multisource pharmaceutical products are pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. It is advisable to consult the World Health Organization (WHO) Technical Report Series, No. 937, 2006 Annex 7 Multisource (generic) pharmaceutical products: Guidelines on registration requirements to establish interchangeability.

The following are explanations for some relevant terms:

- **Pharmaceutically equivalent products** – These are pharmaceutical products that contain the same molar amount of the same active pharmaceutical ingredients (APIs) in the same dosage form, if they meet comparable standards and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variable can lead to differences in product performance.
- **Pharmaceutically alternative products** – These are products that contain the same molar amounts of the same active pharmaceutical moieties but differ in dosage form (e.g. tablets versus capsules) and/or chemical form (e.g. different salts or esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may not be bioequivalent or therapeutically equivalent to the comparator product.
- **Therapeutically equivalent products** – Two pharmaceutical products are considered to be therapeutically equivalent if they are pharmaceutically equivalent or pharmaceutically alternative and, after administration in the same molar dose, their effects, in respect of both efficacy and safety, are essentially the same when administered to patients by the same route under the same conditions specified in the labelling. This can be demonstrated by appropriate bioequivalence studies, such as pharmacokinetic, pharmacodynamic, clinical, or in-vitro studies.
- **Interchangeable pharmaceutical products** – Products that are therapeutically equivalent to comparator products and can be interchanged with the comparator in clinical practice.

R&D activities conducted in creating or developing a multisource pharmaceutical product should constitute one or more of the following:

- An activity in respect of analysis or characterisation of the properties of a pharmaceutical product with the purpose of determining the excipients and other ingredients to be used in the formulation of the multisource pharmaceutical product:
  - Compatibility tests between the APIs, excipients and other ingredients.

- Dosage form design:
  - Laboratory-scale reformulation through experimentation on the APIs, excipients and other ingredients.
  - Pilot plant-scale reformulation.
  - The activities, tests, design and formulation of multisource pharmaceutical products.

- The determination of analytical and stability testing methods, if those methods are determined in conjunction with –
  - the activities, tests and design of multisource pharmaceutical products;
  - the formulation of APIs, excipients and other ingredients; or
  - the activities, tests and design of multisource pharmaceutical products and the reformulation of APIs, excipients and other ingredients.

Relevant to multisource pharmaceutical products is that there should be a pharmaceutical product against which equivalence can be measured. This means that you can only develop a generic product of an already existing pharmaceutical product. In the WHO Technical Report Series, No. 937, 2006 Annex 7 Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability, such product is called a "comparator product".

Conducting a clinical trial

A clinical trial is any investigation in human participants (including patients and other volunteers) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism and excretion of one or more investigational products with the objective of ascertaining their safety and/or efficacy.

For the purpose of the R&D tax incentive, any R&D being carried out in respect of a clinical trial should be carried out in accordance with Appendix F of the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South

Africa issued by the Department of Health (DoH).[4] For any R&D activities to qualify, a clinical trial should already be registered with the DoH when an R&D tax incentive application for such clinical trial is submitted. The trial number assigned by the DoH as indicated in the documentation available on South African National Clinical Trials Register (SANCTR) [5] typically has the format DOH-27-XXXXXX-XXXX. No R&D tax incentive project application for a clinical trial should be submitted before a DoH number has been issued as they will not be considered for adjudication.

Additionally, the sponsor of a clinical trial should benefit under the R&D tax incentive. In the case of an R&D tax incentive applicant (i.e. a taxpayer) being the sponsor, clinical trial documentation available on the SANCTR website will be used to establish the role of the taxpayer as sponsor of the particular clinical trial. If a sponsor is not a registered South African taxpayer or is an institution, board or body that is exempt from normal tax under section 10(1)(cA); or is a government entity and therefore cannot benefit from the incentive, the appointed contract research organisation (CRO) or the sponsor's local subsidiary may benefit. In such circumstances, it is unlikely that clinical trial documentation available on the SANCTR website will indicate the identity of the CRO/local subsidiary or the relationship between the sponsor and the CRO/local subsidiary. It would therefore be necessary for the R&D tax incentive applicant to provide, in addition to the submission of the R&D tax incentive application, documentary proof of the applicant's association with the sponsor of the clinical trial.

Section 4.5 of the Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa allows for a sponsor to transfer any or all of the sponsor's trial-related duties and functions to a CRO. It further provides that such assignment should be specified in writing. The committee will accept a copy of such assignment as documentary proof of the association. An approved protocol indicating the assignment of tasks/duties to the applicant may also suffice. If such documentation is not available, the unit can be contacted to discuss what other documentation would be acceptable.

[4] https://www.samrc.ac.za/research/ethics/guideline-documents
[5] https://sanctr.samrc.ac.za/

Only in circumstances where neither the sponsor nor the CRO/local subsidiary of the sponsor will apply for the R&D tax incentive may the principal investigator for the project be eligible for the R&D tax incentive. The onus would be on the principal investigator to provide sufficient documentary proof that similar applications will not be made by the sponsor, CRO or local subsidiary of the sponsor.

Clinical trials are typically conducted in accordance with the following phases:

- **Phase I** – These are the first trials of a new active ingredient or new formulation in humans, often carried out on healthy volunteers. The purpose is to establish a preliminary evaluation of safety and, where possible, a pharmacodynamic profile of the active ingredient in humans.

- **Phase II** – These trials are performed on a limited number of subjects, often at a later stage of a comparative (e.g. placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims to determine appropriate dose ranges or regimens and (if possible) clarify dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

- **Phase III** – These trials are performed in a larger (and possibly varied) patient group with the purpose of determining the short and long-term safety/efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g. clinically relevant drug interactions and factors leading to differences in effect such as age).

- **Phase IV** – These are studies performed after marketing of the pharmaceutical product. Trials in Phase IV are carried out based on the product characteristics on which the marketing authorisation was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or

treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally considered to be trials for new pharmaceutical products.

The activities of Phase IV clinical trials, as defined in Appendix F of the Guidelines, are not eligible under section 11D, except in the case of a clinical trial conducted for the purpose of developing of new indications, developing new methods of administration or developing new combinations of pharmaceutical products.

PART 3: EXCLUSIONS AND LIMITATIONS

Specific activities are excluded from the R&D tax incentive, because they are –

- considered post-R&D activities;
- conducted outside South Africa (even if they are funded from within the country); or
- excluded in the proviso in section 11D(1).

The section 11(D)(1) proviso excludes the following activities from R&D:

- Routine testing, analysis, collection of information or quality control in the normal course of business.
- Market research, market testing or sales promotion.
- Social science research, including the arts and humanities.
- Oil and gas or mineral exploration or prospecting, except R&D carried out to develop technology used for that exploration or prospecting.
- The creation or development of financial instruments or financial products.
- The creation or enhancement of trademarks or goodwill.

Deductions are excluded for expenditure incurred in respect of –

- immovable property, machinery, plants, implements, utensils or articles, excluding any prototype or pilot plant created solely for the purpose of the R&D and which is not intended to be used or is not used for production purposes after that R&D is completed; and
- financing, administration, compliance and similar costs.

The following activities in respect of multisource pharmaceutical product and clinical trial R&D projects (typically falling under Phase IV clinical trials) are not eligible:

- Post-marketing research.
- Cost-effectiveness research.
- Any activities undertaken for the purpose of compliance with regulatory requirements.
- A product familiarisation programme.
- Research carried out for statistical purposes (meta-analyses).
- Epidemiological research.

- Research activities undertaken in preparation for the registration of a clinical trial.

PART 4: OTHER CRITERIA RELEVANT TO THE R&D TAX INCENTIVE

Extent of R&D eligibility

Applications for pre-approval for the R&D tax incentive should set out R&D activities in terms of R&D projects. It is therefore important that the project is described in the context of the R&D to be performed and the uncertainty to be investigated, rather than in the context of a "company project".

Every project for which an application is made must fall within the definition of scientific or technological R&D set out in the Income Tax Act. The R&D project must comprise a set of interrelated activities that –

- are collectively necessary in attempting to resolve a scientific or technological uncertainty and therefore achieve a scientific or technological advancement defined for the project (should multiple uncertainties be addressed, it has to be considered whether the application is for a single R&D project or whether there are indeed several R&D projects);
- are pursued in a systematic investigative manner in a field of science or technology by means of experiment or analysis performed by qualified individuals;
- have the characteristics to meet the definition of scientific or technological R&D, while the project focus and goals in a commercial sense are not relevant (the project's success or failure in terms of meeting commercial goals is not a factor in determining its eligibility for the R&D tax incentive);
- are identified at a level where all effort captured by the project falls within the definition of scientific or technological R&D (which requires that appropriate internal procedures and accounting methods are in place and sufficient to link the activities and associated expenditure to the project).

Company projects vs R&D projects

A distinction must be drawn between a company project and an R&D project. The term "company project" refers to undertakings by a company to have an impact on its business, e.g. building new facilities or expanding facilities, developing new products

and product lines, changing business practices, upgrading processes and facilities, and engineering projects.

A company project has a commercial purpose, whereas the purpose of an R&D project is resolving a scientific or technological uncertainty, therefore for the advancement of scientific knowledge or to achieve technological advancement. The definition of scientific or technological R&D requires that systematic investigative or systematic experimental activities are aimed at resolving a scientific or technological uncertainty for the purposes of discovering new scientific or technological knowledge, creating or developing new or significantly improved products processes or services, etc.

Eligibility time frames for R&D activities

Only R&D expenditure incurred **during the grace period, on and after the date of receipt** of the R&D tax incentive application by the DSI will be eligible for deduction. The R&D tax incentive application may be submitted to the DSI after the project has already started. However, expenditure incurred on R&D activities undertaken before the grace period will not be eligible.

In instances where a company has estimated that a project will be conducted for a year but, owing to circumstances beyond its control, the project overruns its schedule and continues in the following year, the company should inform the DSI of this, indicating the stages already concluded and those still to be conducted. This information must be provided by the company in the progress report required in terms of section 11D(13) of the Income Tax Act.

Applications involving multi-year R&D projects

Some R&D projects may be planned to run over several years to achieve their intended objectives. In such situations, the application must indicate the planned duration of the R&D project on the application form. The form enables the company to indicate the end goal of the R&D project, and time frames that will enable effective

monitoring. However, there is no need for the company to re-apply annually for the approval of multi-year R&D projects.

Again, any stages of the R&D project that have to be carried over should be indicated in the progress report submitted in terms of section 11D(13) of the Income Tax Act.

Applications involving multiple companies in an industry association, joint venture or group

For companies belonging to an association and wishing to conduct R&D on issues pertinent to the industry using the services of the association, the procedure is as follows:

- The association must provide details of each company participating in the R&D project.
- The association must link the R&D project to all member companies concerned, and provide details of the project and other eligibility criteria as with any other company applying.
- The association must provide details of the financial and/or any kind of contribution by each company to the R&D project.

In an unincorporated joint venture, companies should apply individually and must indicate –

- which company or companies it is working with in the joint venture;
- the total cost of the whole project;
- the company's financial contribution to the project.

For companies in a group, either the parent company or each company in a group can apply, taking into account consideration the requirements of section 11D(4) and (6) of the Income Tax Act.

Applications involving contracted R&D

A company can contract its R&D to other companies, either in the same group of companies or to unrelated/unconnected companies, science councils and/or higher education institutions when it wishes to complement its resources to undertake the R&D.

A company will not be eligible for the R&D tax incentive unless it has some level of control over the research methodology to be followed during the R&D project, i.e. unless the company can determine or alter the research methodology of the R&D activities.

Where company A funds another company (company B) to undertake R&D on its behalf, company A may deduct 150% of the actual expenditure in respect of the R&D carried out by company B if –

- the R&D is approved by the Minister;
- the expenditure is incurred in respect of R&D funded by company A and undertaken by company B;
- the expenditure is incurred on or after the date on which the DSI receives the application for approval;
- company B is –
  - a tax-exempt company such as non-profit organisation, public benefit organisation or a university (i.e. an institution, board or body that is exempt from normal tax under section 10(1)(cA));
  - the Council for Scientific and Industrial Research; or
  - a company that is part of the same group of companies and does not claim a deduction for the R&D expenditure itself.

Institutions, boards or bodies that are exempt from normal tax under section 10(1)(cA) include public benefit organisations (e.g. a non-profit company incorporated in South Africa), companies owned by public institutions, and higher education institutions and universities.

Directly related R&D activities

Approval for R&D activities may include supporting activities, where it is demonstrated that such activities –

- are commensurate with and directly related to the actual undertaking of the core activities of the eligible R&D project;
- involve engineering, design, operations research, mathematical analysis or computer programming, taking into account examples of activities, such as –
  - literature searches or other investigative work in the early stages of a project to establish the knowledge and experience in the public domain;
  - the design and construction of equipment directly used in experiments;
  - the design, construction and operation of prototypes in experiments;
  - data collection relating to the experiment, where data is used in experiments;
  - mathematical analysis and modelling used to analyse the results of experiments; and/or
  - the development of specialist computer software to assist in designing experiments.

R&D in a production or manufacturing environment

There are activities that are part of the innovation process but cannot be categorised as R&D, e.g. patent filing and licensing, market research and manufacturing start-up. However, activities such as tooling up, process development, design, and prototype construction may contain an appreciable amount of R&D, making it challenging to differentiate R&D from normal industrial or production activity.

Prototyping and **pilot plants** may qualify as R&D provided that they are **created solely** for the purpose of R&D and that the prototype or pilot plant is not intended to be utilised or is not utilised for production purposes after the R&D is completed.

The following are circumstances under which such activities may qualify as R&D:

- **Prototyping** may qualify as R&D if the primary objective is to make further technological improvements. When the necessary modifications to the prototype have been made and testing has been completed, the R&D end point is reached.

"Prototype" means an original model constructed to include all the technical characteristics and functions of the anticipated new product. The design, construction and testing of a prototype would be characterised as R&D when this is done as part of an R&D process. This applies whether only one or several prototypes are made and whether they are made consecutively or simultaneously. Once the modifications to reflect the test findings are completed and the testing is satisfactory, the R&D is complete. The construction of several copies of a prototype after successful testing of the original, even if undertaken by R&D staff, is not considered R&D.

- **Pilot plant** – The construction and non-commercial operation of a pilot plant may qualify as R&D as long as the purpose is to get the experience and to compile engineering and other technical data to be used in –
  - evaluating a hypothesis;
  - writing new product formulae;
  - establishing product specifications;
  - designing special equipment and structures required by a new process;
  - preparing operating instructions or manuals about the process.

"Pilot plant" means an experimental industrial system constructed to evaluate R&D hypotheses, develop new product formulae, establish new product specifications, design special equipment and structures, and prepare operating instructions or manuals on the process as part of an R&D process. If, as soon as this experimental phase is over, a pilot plant switches to operating as a normal commercial production unit, the construction and non-commercial operation of a pilot plant is no longer considered R&D.

- **Industrial engineering and tooling up** – In most cases this is considered to be part of the production process, but qualifies as R&D if such activities are conducted to –
  - develop production machinery and tools;
  - introduce changes to production and quality control procedures; or
  - develop new methods and standards.

- **"Feedback" R&D –** After a new product or process has been handed over to production, technical problems will still need to be solved. Some of these may require that production be stopped and the product taken back to the pilot plant for further R&D to take place. This may qualify as R&D.

- **Industrial design** – Elements of the design that include plans and drawings aimed at defining procedures, technical specifications and operational features important to the conception, development and manufacturing of new products and processes may qualify as R&D.

Requirements to show that R&D is conducted

Companies will have to demonstrate that their research activities are systematic investigative or systematic experimental aimed at resolving a scientific or technological uncertainty, undertaken primarily to acquire new scientific knowledge about the nature and behaviour of materials and the physical universe, and formulate laws to describe the findings.

Systematic investigative or systematic experimental work undertaken to acquire new technological knowledge or understanding of how to use or apply scientific principles or use scientific knowledge to solve technological problems is also considered R&D.

Alternatively, the aim should be for the R&D activities to be conducted for the creation or development of new or significantly improved products, processes or services.

PART 5: R&D EXPENDITURE

Qualifying R&D expenditure

Determination and/or audit of expenditure is a function of SARS. The following may be taken into account in relation to qualifying R&D expenditure:

- As a general rule, only the expenditure incurred directly and solely in respect of the eligible R&D activities will be accepted for the purposes of claiming the deduction.
- The onus is on the company to prove that the expenditure is related to approved R&D activities.
- The following expenditure may be considered to be directly and solely in respect of R&D:
  - Labour costs of personnel involved in R&D, which is attributable to the time spent directly and solely on eligible activities.
  - Materials and consumables directly related to the eligible activities.
  - Overheads solely related to approved R&D activities, including water, gas, electricity.
- The following expenditure on activities directly supporting eligible R&D may be considered:
  - Activities to create or adapt software, materials or equipment needed to resolve a scientific or technological uncertainty, provided that the software, material or equipment is created or adapted solely for use in R&D.
  - Scientific or technological planning activities.
  - Scientific or technological design, testing and analysis undertaken to resolve the scientific or technological uncertainty.
  - Design and construction of apparatus used directly for experiments, such as a pilot plant. Pilot plants qualify for deduction under section 11D(2)(b)(i).
  - Data collection for use in experiments.
  - Mathematical modelling used to analyse the results of experiments.
  - Design, construction and operation of prototypes used in experiments. Scientific and technical information services, insofar as they are

conducted for the purpose of R&D support, such as the preparation of the original report of R&D findings.

- Training required for directing and supporting an R&D project.
- Costs incurred on Phase IV clinical trials conducted for the purpose of developing new indications, developing new methods of administration, or developing new combinations.
- R&D feasibility studies to inform the strategic direction of a specific R&D activity.

The expenditure on the following activities will not be considered as directly or solely related to R&D, even if necessary for R&D:

- Commercial, legal and financial activities necessary for R&D and for marketing of the new intellectual property created.
- Manufacturing and distribution of goods and services.
- Administration and general support activities such as –
  - human resources costs;
  - special transportation and storage of scientific materials;
  - cleaning of the R&D facility;
  - repair and maintenance of the R&D facility, including maintenance of R&D equipment;
  - security.
- Economic and engineering feasibility studies that have limited or no bearing on the specific R&D activity.
- Indirect expenditure like insurance, rent, security, travel, financing, administration, compliance and similar costs.

The following capital expenditure will not qualify for a deduction under section 11D, but may be eligible for deductions under other sections of the Income Tax Act (e.g. sections 12C and 13):

- Immovable property.
- Machinery, plants, implements, utensils and articles.

SARS administers provisions related to qualifying R&D expenditure for the R&D tax incentive. Questions on qualifying expenditure should therefore be directed to SARS.

Treatment of government grants and other incentives to promote R&D and innovation in South Africa

Where a company is due to receive or has received any amount from a government department, public entity or municipality towards approved R&D activities, expenditure equal to such a grant will not qualify for a 150% deduction under section 11D of the Income Tax Act. However, the expenditure actually incurred by the company will qualify.

This means that, even if a project has received funding from other government grant programmes, the project may still be approved under section 11D of the Income Tax Act, but the expenditure on which the 150% deduction may be claimed will be affected by the government funding received. In this regard, it must be considered that government funding may be relevant to part, but not all, of a project.

PART 6: PROGRESS REPORTS, RECORD KEEPING AND CHANGES AFTER APPROVAL

Preparing a progress report

If a company's R&D activities have been approved, the company is required to report to the DSI on the progress made with its R&D activities annually (coinciding with the company's financial year-end reporting). To make reporting easier for the company, it should keep adequate records to substantiate claims for each R&D tax incentive project. These records should also indicate the status of the project and R&D activities undertaken. Ultimately, the company must prove to SARS that the amount of expenditure on which the R&D tax incentive deduction is claimed was incurred on the approved R&D activities.

A progress report function has been included in the R&D tax incentive online system to submit progress information on future applications. Among other things, the following information is to be submitted:

- Actual R&D expenditure incurred.
- Whether the company attained its R&D goals.
- How the project assisted the company in terms of increasing its R&D activities.
- Outcomes related to R&D such as new patent applications filed, new products developed, the creation of new economic activities, employment, and collaboration with other companies.

A good R&D record-keeping system is important to support the company in generating the above information. Companies are advised to keep records of the following to make progress reporting and audits easier:

- The R&D plan, which stipulates the activity milestones and resources used on the project. It should be a living document that is updated as major changes occur and should be used to inform the DSI of any changes introduced.
- Records of any preliminary research, including literature and patent searches, feasibility studies, and a risk management analysis.

- Personnel timesheets and other time-recording data, clearly showing what proportion of time production staff are used in R&D, for example, to confirm that the expenditure claimed is directly related to R&D.
- Records of experiments, indicating the aim of the experiment, how and when it was conducted, and the outcome. Where use is made of a production line for R&D, it is important to define the period for which the line was used for R&D.

The DSI may conduct site visits on approved projects as part of monitoring and evaluation. This may involve examination of physical evidence, such as R&D plans, pilot plants, prototypes and/or facilities; and discussions with the management of the company and/or the technical personnel undertaking the R&D.

Claiming the R&D tax incentive deduction

Once the Minister or their delegate has made a decision on a company's R&D tax incentive application, the company will be informed of the decision through a letter, indicating which R&D activities are approved and which are not. This letter serves as proof to SARS that the company's R&D activities are approved when claiming the 150% deduction.

The company must prove to SARS that the expenditure was incurred on the approved R&D activities. For SARS audits, additional documentation may be required.

Decision of the Minister

The decision of the Minister, or a person delegated by the Minister, is final; however, companies have the right to take the Minister's decision on review in terms of the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000).

Changes in company structures after submitting an application to the DSI

Name change

Companies that have applied for approval in respect of R&D projects and have simply changed the name of the company must notify the unit of such change. In such an instance, there is no need for the R&D tax incentive application to be resubmitted; the decision of the Minister in respect of a project will remain unchanged.

For example, company A decides to change its name to company B. It undertakes all the activities previously undertaken, including project X, which was previously approved by the Minister. Nothing has changed except the name of the company.

- Company A (now operating as company B) must inform the Minister of such change through a notification of change form.
- A certificate issued by the Companies and Intellectual Property Commission confirming such change of name is required for record purposes.

Transfer of a project to another entity

Where a company transfers its R&D project to another entity, the other entity must submit a new application for approval by the Minister, with a full report on what activities have been undertaken, which activities are still to be undertaken, and who will incur the costs in respect of such projects.

The decision of the Minister will apply from the date that such application is received from the new entity, subject to the grace period and effective date of transfer. For example:

- Company A transfers its assets to its sister company B as part of a reorganisation to streamline its operations.
- As part of the reorganisation, all R&D projects will be undertaken by company B.
- Company A had already submitted and received approval for project X before the reorganisation took place.
- Company B will have to apply for approval in respect of project X, notify the unit of the previous approval and the change, and provide the unit with details of all activities undertaken by company A and activities to be undertaken by company B in respect of project X.

Changes to the scope of a project

Companies that have received approval in respect of R&D projects and have simply changed the scope or objective of the project must inform the Minister of such change through a notification of change form.

PART 7: WITHDRAWAL OF THE APPROVAL ALREADY GRANTED

The Minister may withdraw the approval granted to a company if or when –

- there is any material change of fact that would have had the effect that approval would not have been granted had that fact been known to the Minister at the time of granting approval;
- the taxpayer doing the R&D fails to submit the required progress reports to the DSI; or
- the taxpayer doing the R&D is guilty of fraud, misrepresentation or non-disclosure of a material fact, which would have had the effect that approval would not have been granted.

The decision to withdraw the approval of R&D activities by the Minister will be based on the recommendations of the R&D Tax Incentive Adjudication and Monitoring Committee.

PART 8: GUIDANCE FOR SPECIFIC INDUSTRIES

Research and development activities undertaken vary from one industry to the next. This section provides additional guidance that may assist applicants to determine whether potentially qualifying R&D activities in areas related to specific industries may be eligible.

The industry examples covered include agricultural chemicals, animal and plant breeding (including research on genetically modified organisms), agrifood industries, exploration, as well as prospecting and mining. The list is not exhaustive. From time to time, the DSI will publish brief guidelines on specific industry sectors or technical areas relevant to the R&D tax incentive on the DSI website.

As with all projects that qualify for the R&D tax incentive deduction, the R&D activities performed in these industries must be performed in South Africa and the applicant must be able to determine or alter the methodology of research.

Agricultural chemicals

R&D tax incentive applications for projects in which the R&D activities are undertaken solely for the registration of products as required by the Department of Agriculture, Land Reform and Rural Development (DALRRD) are unlikely to be deemed R&D in terms of section 11D of the Income Tax Act.

The DALRRD provides guidelines on data and documents required for the registration of agricultural remedies in South Africa. Registration is necessary to regulate the manufacturing, distribution, sales, use and advertisement of agricultural remedies through the Fertilizers, Farm Feeds, Seeds and Remedies Act, 1947 (Act No. 36 of 1947). The Act and associated Regulations require that applicants must submit data generated from scientific studies, carried out according to prescribed standards, for the evaluation of the safety, efficacy and quality of products.

An extensive definition of "agricultural remedy" is provided in the Act, but for the purpose of these guidelines, agricultural remedy will mean any chemical substance

or biological remedy, or any mixture or combination of any substance or remedy intended or offered for use as a pesticide, herbicide, insecticide, fungicide or fertilizer.

For the purpose of the R&D tax incentive, agrochemical research may include R&D activities being carried on in respect of the **formulation or reformulation** of the agricultural remedies as defined in the Fertilizers, Farm Feeds, Seeds and Remedies Act. This effectively means that for R&D activities to qualify, activities should relate to the following:

- A product with a new active ingredient, i.e. activities relating to synthesising a new compound/active ingredient, and/or determining a delivery system and formulating a product for use.
- A new end-use product based on an existing active ingredient, i.e. activities to determine new modes of action, including efficacy and safety studies with respect to a new mode of action.
- An existing product with a new application, i.e. activities finding a new application/delivery system for an existing product (in a completely unrelated species or in an area that has not been studied before).
- An existing product for which new data is available, i.e. activities to determine optimum methods of application and stability testing (following the reformulation of a product).

The above is in contrast with activities that are undertaken solely for the registration of products as required by DALRRD. In such cases products that have already been developed elsewhere are tested under local conditions (as prescribed by the Act) for registration in South Africa. Without additional clarification, motivation and documentation, R&D activities are considered to have occurred and to have been completed in such foreign jurisdictions.

However, if the activities and testing (required for registration by DALRRD) indicate that a new formulation or reformulation is required, the uncertainty identified by the testing and required for formulation/reformulation may well be deemed scientific or technological R&D in terms of section 11D of the Income Tax Act.

In order to assess whether the proposed activities will be carried out solely for the

DALRRD registration or as the eligible activities listed above, the applicant should provide the following additional information for every product that the R&D tax incentive application would cover:

- The active ingredient(s) of the product.
- If there are any parallel products, the following:
  - The name of the parallel product.
  - The countries in which the product is being tested/registered.
  - How far the testing of each product is in every country.
  - Whether registration has been completed for each product. In cases where no standard (parallel) product exists, it is still possible to include an alternative or equivalent registered product, the use of which is intended to give the same control result as that planned with the new product/formulation.
  - The R&D activities already completed for each product.
  - Details of the R&D activities to be undertaken for each product.
  - The specific uncertainties that still exist.

In the light of the above, the following information on the R&D activities proposed for South Africa is required:

- Specify the scientific or technological uncertainties and questions that still need to be answered in South Africa.
- List the R&D activities already completed in South Africa for the South African product.

Activities that will be deemed ineligible under the R&D tax incentive include the following:

- Post-marketing research.
- Any activities undertaken solely for the purpose of compliance with regulatory requirements.
- A product familiarisation programme.
- Activities undertaken in preparation for the registration of agricultural remedies.

Animal and plant breeding

For the purpose of the R&D tax incentive, breeding is defined as a systematic effort to alter the genetic characteristics of an animal or a plant through selective mating or propagation. For animal and plant breeding activities to be eligible, they may not be undertaken for registration purposes only.

In respect of breeding, eligibility is limited to activities aimed at genetically engineering a transgenic plant or animal but excludes any and all routine activities aimed at confirming the subsequent transgenic status of the stable progeny and subsequent propagation of any part of the transgenic plant or animal.

The following breeding activities are considered to be eligible R&D activities, provided all other eligibility criteria are met:

- Breeding to obtain new or improved products using a scientific method.
- Activities in respect of the analysis of the distinctness, uniformity and stability of a new variety of plant or animal.
- Activities in respect of the determination of yield, resistance to pests and diseases, salt and drought resistance, adaptation to climatic stress, and processing qualities.
- The development of new or improved techniques and the application of these techniques.
- The development of new or improved processes, equipment or instrumentation for the implementation of breeding.
- Activities involving micro-grafting will be eligible up to the point of propagation, while those involving tissue cultures will exclude all routine work undertaken after tissue culture.

Agrifood industries

R&D involving systematic investigative or systematic experimental activities related to chemical and physical properties, as well as components of food and how they respond to processing, preservation and storage of food, may be eligible. These

activities should involve the application of food chemistry, biochemistry, microbiology and engineering to provide innovative, safe and quality products.

Niche and emerging areas such as the use of genomics, biotechnology and nanotechnology to improve the nutritional value and safety of food, as well as nutrient uptakes, may be supported.

Activities aimed at enhancing technology development in agroprocessing, leading to state-of-the-art infrastructure, including new generation process equipment and sophisticated analytical instrumentation, may be eligible.

Physical modifications and the artistic preparation of food, which causes no change to the functionality of food items, are ineligible.

Routine laboratory activities aimed at the analysis of different components and attributes of food will be excluded.

For the R&D to be eligible, the activities may not be for testing or registration purposes only.

Exploration, prospecting and mining

Activities related to the development of new or improved exploration techniques or methodologies may be eligible for the R&D tax incentive, provided they comply with other eligibility requirements.

Certain activities in the mining industry are excluded from the definition of R&D unless the R&D is limited to the development of technology.

Examples of activities that are not systematic investigative and systematic experimental are prospecting, exploring and/or drilling for minerals or for natural gas for the purpose of discovering deposits, as well as determining more precisely the location of deposits or determining the size and quality of deposits.

PART 9: DSI ASSISTANCE TO COMPANIES

The Directorate: Private Sector Research and Development Promotions ("the unit") is responsible for the administration of the R&D tax incentive programme. The unit processes applications and serves as the secretariat for the R&D Tax Incentive Adjudication and Monitoring Committee, which is established in terms of section 11D of the Income Tax Act.

Status updates for applications filed through the R&D tax incentive online system can be found on the system. For older cases, the unit can assist. The DSI will only disclose information on the application to the applicant concerned or the applicant's appointed representative (as indicated on the R&D tax incentive application form).

The DSI's assistance to companies on matters of the R&D tax incentive is provided free of charge. The DSI does not request or appoint any external person or business entity to render these services on its behalf.

Companies are welcome to contact the DSI directly for assistance in registering company profiles on the online system or answering questions on a project application.

PART 10: FURTHER INFORMATION AND CONTACT DETAILS

Further information on the R&D tax incentive can be accessed at: https://www.dst.gov.za/rdtax/, where various guidelines and videos are available. Taxpayers can also contact the DSI from Monday to Friday (except public holidays) between 08:00 and 16:30 at rndapplications@dst.gov.za.

All project applications must be submitted through the R&D tax incentive online system at https://taxincentive.dst.gov.za. Participants whose R&D applications were submitted and approved prior to the launch of the online system, and are not yet loaded onto the system, should contact the DSI when it is time to submit their annual progress reports.

Any other correspondence should be sent to the Directorate: Private Sector R&D Promotion, Department of Science and Innovation, as follows:

Email	**By hand/courier**
rndapplications@dst.gov.za	Building 53 Scientia (CSIR) Campus Meiring Naudé Road Brummeria Pretoria

Visit the SARS website here for more information about the R&D tax incentive.

As is the case with many areas of taxation, the legislation governing the R&D tax incentive may be amended from time to time to address policy changes and other relevant developments. Although we endeavour to keep documentation up to date with the latest changes, taxpayers are advised to visit the National Treasury website (www.treasury.gov.za) regularly to see whether there are any amendments or proposed amendments to section 11D of the Income Tax Act or a Taxation Laws Amendment Bill. Alternatively, the DSI can be contacted for further discussions.

REFERENCES AND RECOMMENDED FURTHER READING

Department of Health, 2006. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa.

Department of Science and Innovation, 2019. White Paper on Science, Technology and Innovation.

Department of Science and Technology, 2002. South Africa's National Research and Development Strategy.

Fertilizers, Farm Feeds, Seeds and Remedies Act, 1947 (Act No. 36 of 1947).

Income Tax Act, 1962 (Act No. 58 of 1962).

Medicines and Related Substance Control Act, 1965 (Act No. 101 of 1965).

National Treasury, 2021. Reviewing the Design, Implementation and Impact of South Africa's Research and Development Tax Incentive.

Notice No. R. 344 published on 23 April 2015 in Government Gazette No. 38730. Regulations in terms of paragraph (e) of definition of "research and development" in section 11D (1) of the Income Tax Act, 1962, on criteria for clinical trials in respect of deduction for research and development.

Notice No. R. 346 published on 23 April 2015 in Government Gazette No. 38732. Regulations in terms of paragraph (d) of definition of "research and development" in section 11D(1) of [the] Income Tax Act, 1962, on additional criteria for multisource pharmaceutical products.

Organisation for Economic Cooperation and Development, 2002. Frascati Manual: Proposed standard practice for surveys on research and experimental development.

Organisation for Economic Co-operation and Development, 2015. Frascati Manual. Guidelines for Collecting and Reporting Data on Research and Experimental Development.

South African Revenue Service, 2009. SARS Interpretation Note No. 50. Deduction for Scientific or Technological Research and Development.

World Health Organization, 2005. Guidelines on submission of documentation for multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part.

World Health Organization, 2006. The WHO Technical Series No. 937. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability.

ANNEXURE A

Section 11(D) of the Income Tax Act, as amended, currently reads as follows:

11D. Deductions in respect of scientific or technological research and development. *– (1) For the purposes of this section,* ***"scientific or technological research and development"*** *means systematic investigative or systematic experimental activities aimed at resolving scientific or technological uncertainty for the purpose of –*

(a) discovering new scientific or technological knowledge;

(b) creating or developing new or significantly improved products, processes or services;

(c) creating or developing a multisource pharmaceutical product, as defined in the World Health Organisation Technical Report Series, No. 937, 2006 Annex 7 Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability issued by the World Health Organisation, conforming to Regulation 344 of 23 April 2015 and any requirements as must be prescribed by regulations made by the Minister after consultation with the Minister of Higher Education, Science and Innovation; or

(d) conducting a clinical trial as defined in Appendix F of the Guidelines for good practice in the conduct of clinical trials with human participants in South Africa issued by the Department of Health (2006), conforming to Regulation 346 of 23 April 2015 and any requirements as must be prescribed by regulations made by the Minister after consultation with the Minister of Higher Education, Science and Innovation.

Provided that for the purposes of this definition, scientific or technological research and development does not include activities for the purpose of –

(a) Routine testing, analysis, collection of information or quality control in the normal course of business;

(b) Market research, market testing or sales promotion;

(c) Social science research, including the arts and humanities;

(d) Oil and gas or mineral exploration or prospecting except research and development carried on to develop technology used for that exploration or prospecting;

(e) The creation or development of financial instruments or financial productions;

(f) The creation or enhancement of trademarks or goodwill; or

(g) Any expenditure contemplated in section 11 (gB) or (gC).

To see the whole section 11D, visit https://www.sars.gov.za/legal-counsel/primary-legislation/.

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