No. 1012 **26 September 2008**

SOUTH AFRICAN QUALIFICATIONS AUTHORITY (SAQA)

In accordance with Regulation 24(c) of the National Standards Bodies Regulations of 28 March 1998, the Standards Generating Body (SGB) for

Pharmacy

registered by Organising Field 09 – Health Sciences and Social Services, publishes the following Qualification and Unit Standards for public comment.

This notice contains the titles, fields, sub-fields, NQF levels, credits, and purpose of the Qualification and Unit Standards. The full Qualification and Unit Standards can be accessed via the SAQA web-site at **www.saqa.org.za**. Copies may also be obtained from the Directorate of Standards Setting and Development at the SAQA offices, SAQA House, 1067 Arcadia Street, Hatfield, Pretoria.

Comment on the Qualification and Unit Standards should reach SAQA at the address below and ***no later than 27 October 2008.*** All correspondence should be marked **Standards Setting – SGB for Pharmacy** and addressed to

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SOUTH AFRICAN QUALIFICATIONS AUTHORITY

QUALIFICATION:
National Certificate: Pharmaceutical Sales Representation

SAQA QUAL ID	*QUALIFICATION TITLE*		
63969	National Certificate: Pharmaceutical Sales Representation		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
QUALIFICATION TYPE	*FIELD*	*SUBFIELD*	
National Certificate	9 - Health Sciences and Social Services	Curative Health	
ABET BAND	*MINIMUM CREDITS*	*NQF LEVEL*	*QUAL CLASS*
Undefined	120	Level 5	Regular-Unit Stds Based

This qualification replaces:

Qual ID	Qualification Title	NQF Level	Min Credits	Replacement Status
17099	Certificate: Medical Representative	Level 5	120	Will occur as soon as 63969 is registered

PURPOSE AND RATIONALE OF THE QUALIFICATION
Purpose:

This Qualification is for learners who have entered the arena of pharmaceutical sales representation. Since medical doctors and pharmacists comprise the majority of potential customers, the industry requires well-schooled individuals who can provide accurate product information to potential customers but who can also adapt their communication styles to suit each individual customer's needs. The Qualification is intended to produce credible, ethical and informed sales representatives who will be able to take specific product knowledge to the customer.

Although this Qualification and its associated Unit Standards are shown to fall into the subfield 'Curative Health' they are also applicable across all the other recognised sub-fields in the Organising Field: Health Sciences and Social Services.

On completion of this Qualification the learner will be capable of:

> Communicating assimilated information to the customer within the regulated pharmaceutical environment.
> Demonstrating an understanding of disease states and drug actions within the body.
> Accessing and analysing market data to formulate a business plan.
> Evaluating and utilising applicable recognised research findings to achieve a competitive advantage.

Rationale:

The pharmaceutical manufacturing industry recognized a need to formalise the marketing of pharmaceutical products in line with international trends. This need includes the provision of well-researched information on current and new products to the health care industry, so that patients can receive effective, safe and high quality medicines.

National legislation and associated regulations govern the sale of pharmaceutical products. Hence a Qualification for pharmaceutical sales representation, which is approved by the relevant bodies and enables the qualifying learner to provide specific pharmaceutical product information, is required.

Recent developments in the pharmaceutical industry and managed health care require that pharmaceutical sales representatives have a wide knowledge of the efficacy, safety and cost effectiveness of the products available, as well as the ability to convey selected information to customers. Meeting this requirement means that the qualifying learner will have the ability to access and utilise research findings.

With this Qualification as a basis, the qualifying learner can progress into marketing and/or sales' management, specialisation in clinical research or other areas.

Furthermore this qualification will also provide the basis for personal growth and the development of entrepreneurial skills which will contribute to the attainment of the millennium develop goals (MDG) particularly in health care. Within the Chemical Industries Sector Education and Training Authority (CHIETA) sector skills plan, the pharmaceutical sub-sector has identified pharmaceutical sales representation as a scarce skill. Addressing the related skills' gap will enlarge the pool of skilled persons for development into managerial and executive positions within the sub-sector.

RECOGNIZE PREVIOUS LEARNING?
Y

LEARNING ASSUMED IN PLACE
> Communication skills at NQF Level 4.
> Mathematical Literacy at NQF Level 4.
> Computer Literacy at NQF Level 3.

Recognition of Prior Learning:

Learners may provide evidence of prior learning for which they may receive credit towards the qualification by means of portfolios or other forms of appropriate evidence which may include, verified accounts of previous relevant work done and performance records and which evidence is in accordance with the requirements of the relevant ETQA or ETQA that has a Memorandum of Understanding in place with the relevant ETQA.

Access to the Qualification:

> Open: On conditional compliance with the learning assumed to be in place.

QUALIFICATION RULES
In order to be credited with this qualification, learners are required to achieve a minimum of 120 credits, to be compiled as follows:

> All 27 Fundamental component credits are compulsory.
> All 78 Core component credits are compulsory.
> A minimum of 15 Elective component credits are compulsory.

EXIT LEVEL OUTCOMES
1. Communicate assimilated information to the customer within the regulated pharmaceutical environment.

2. Demonstrate an understanding of disease states and drug action in the body.

3. Access and analyse market data to formulae a business plan.

4. Evaluate and utilise applicable recognised research findings to achieve a competitive advantage.

Critical Crossfield Outcomes:

> Identifying and solving problems are demonstrated in the application of ethical principles and in the related interactions.
> Team work is demonstrated in the interactions between both internal and external clients/customers and in the handling of pharmaceutical products.
> Organising of self is demonstrated in the successful handling of products and use of research findings.
> Collating information is indicated in the utilization of research data.
> Effective communicating is demonstrated through the successful achievement of sales call objective.
> Utilising science and technology is clearly indicated in the design of presentations and the access to clinical research data.
> Understanding the world as a set of related systems is indicated in the adherence to legislative requirements, use of clinical research data and interactions with clients/customers, colleagues and competitors.

ASSOCIATED ASSESSMENT CRITERIA
Associated Assessment Criteria for Exit Level Outcome 1:

1.1 A description is given of how ethical principles and behaviour are applied.
1.2 Knowledge is demonstrated of applicable industry legislation and/or codes during client/customer interactions.
1.3 Selling skills appropriate to a given situation are identified and applied during client/customer interactions.
1.4 Own and customer's professional styles are identified and own style is adapted to ensure effective use of time during a sales call.
1.5 Presentations appropriate to the situation are designed, developed and delivered.

Associated Assessment Criteria for Exit Level Outcome 2:

2.1 Human anatomy, physiology and pathology are described to provide information relating to health and medicines.
2.2 The principles of pharmacology and pharmaceutics are explained as they relate to medicines' information.
2.3 The principles of microbiology are applied as they relate to medicines' information.

Associated Assessment Criteria for Exit Level Outcome 3:

3.1 Market data are analysed through the use of appropriate tools.
3.2 Managed health care in South Africa is described in terms of the health care environment and funding approach.
3.3 Territory management plans are developed based on market data analysis and implemented.

Associated Assessment Criteria for Exit Level Outcome 4:

4.1 Clinical research methodology is applied to analyse and interpret clinical trials.
4.2 The findings of clinical research for a product are utilised to develop a competitive sales package.

4.3 The principles of pharmaco-economics are applied to clinical trial outcomes to demonstrate cost-effectiveness of medicines.

Integrated Assessment:

Formative assessment:

Throughout the learning programme, formative assessment strategies are used to ensure that exit level and critical cross-field outcomes are achieved. Strategies include:

> Written assignments.
> Tests (or examination equivalent tests).
> Projects.
> Demonstrations.
> And/or any other applicable method.

Summative Assessment:

Can take the form of:

> Oral.
> Written.
Or
> Practical examinations.

As agreed to by the relevant ETQA or ETQA that has a Memorandum of Understanding in place with the relevant ETQA.

INTERNATIONAL COMPARABILITY
In recognition of the reality of globalisation of the pharmaceutical industry, from a wide geographical sweep, the following countries have been identified as representative of the developed and developing worlds.

Australia:

Although only a small part of the world market, the pharmaceutical industry is a key industry in Australia, which sells over A$11 billion worth of medications domestically and directly employs over 14,000 people.

Medicines Australia (MA): A lobby group for major Australian pharmaceutical companies, previously known as the Australian Pharmaceutical Manufacturers' Association; administers a Code of Conduct on pharmaceutical marketing. This applies to all pharmaceutical companies in Australia, whether they are a member of MA or not. The Provisions of the Code; Section 4, apply to Pharmaceutical Representatives.

The following points pertain to their training and education:

> Companies have a responsibility to maintain high standards of ongoing training for company representatives.
> Company representatives should possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and should be cognisant of all provisions of this Code.
> It is the responsibility of company representatives visiting a hospital or other institution to make themselves aware of all hospital policies, including operating theatre procedures and conduct their business accordingly.

> Companies should ensure that company representatives have a thorough knowledge of Australia's Privacy Legislation and its implications for their role.
> All medical representatives who have been employed in the Australian prescription pharmaceutical industry since April, 1983 are required to have completed or be currently undertaking an endorsed Medicines Australia Education Programme for medical representatives.
> All medical representatives entering the Australian prescription pharmaceutical industry for the first time must enrol in the Code of Conduct component of the endorsed Medicines Australia Education Programme within the first six months of employment and must complete the full programme requirements for medical representatives within two years.
> Any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public, including product managers, medical, marketing or sales staff; or has direct interaction with health care professionals for the purpose of promoting a prescription medicine, whether part time or full time, must complete the Code of Conduct component of the endorsed Medicines Australia Education Programme within the first twelve months of commencement of employment.

Medicines Australia Education Programs: (Presented by the University of Queensland, Health InSITU and Medicines Australia):

> MA4200: Introduction to the Human Body:
> CEP Online Program MA4200: This program introduces the student without prior knowledge of human biology to the foundational biological principles of the human body and an introduction to medical terminology.

> Program 1: The Medicines Australia Code of Conduct (2008Sem2):
> CEP Online Program 1: Ethical practices within the pharmaceutical industry, including the obligations and practices of companies in their relationship with the health care industry and the public.

> Program 2: The Pharmaceutical and Healthcare Industry (2008Sem2):
> CEP Online Program 2: The historic development of the industry, government regulatory processes and the industry's role in the Australian health care system.

> Program 3: An Introduction to Pharmacology (2008Sem2):
> CEP Online Program 3: Pharmacokinetics and pharmacodynamics, how drugs are administered, transported through the body and absorbed.

> Program 4: Understanding Product Information (2008Sem2):
> CEP Online Program 4: An overview of the scientific, medical and therapeutic information contained in Product Information, including how the information is structured to comply with Therapeutic Goods Administration requirements.

> Program 5: Understanding Clinical Evidence (2008Sem2):
> CEP Online Program 5: A systematic approach to the analysis of published clinical papers, including how clinical trials are designed and conducted, and the four phases of clinical trials.

India:

The Indian pharmaceutical industry is one of the developing world's largest and most developed, ranking 4th in the world in terms of production volume and 13th in domestic consumption value. India's industry, valued at $5.3 billion in 2005, represents less than one percent of the global pharmaceutical industry of $550 billion. Over the last 30 years, India's pharmaceutical industry has evolved from almost non-existent to a world leader in the production of high quality generic drugs. India has garnered a worldwide reputation for producing high quality, low cost generic drugs.

Pharmaceutical regulation has not matched burgeoning industrial development and India has neither a nationally applicable code of conduct nor regulatory standards applicable to Pharmaceutical Representatives. In the Jan-Mar 2004 issue of the Indian Journal of Medical Ethics, Amitava Guha's article, "A comparison of codes of pharmaceutical marketing practices", ends with this statement on "Regulations in India":

> "The less said about this the better. We have a Magic Remedies (Objectionable Advertisement) Act, 1954. It has only one relevant clause, Clause 4, on misleading advertisements which: "Directly or indirectly gives false impression regarding the true character of the drug; makes a false claim for the drug, or is otherwise false or misleading in any particular material." After almost 50 years, surely it is time to develop a code on pharmaceutical promotional practices that is suitable for India, and the appropriate legislation to enforce it".

In ICMR Case Studies and Management Resources: Pharma Firms to Stop Gifts to Doctors: Is Self Regulation the Answer? It is stated:

"In January 2007, several pharmaceutical companies in India announced their intention to stop providing incentives (such as, gifts, cash, travel holidays, etc.) to doctors to influence their prescribing behaviour. This voluntary code was developed by The Organization of Pharmaceutical Producers of India (OPPI), which represented major domestic and multinational pharmaceutical companies operating in India. OPPI intended to make the code legally binding, but accepted that it would take a long time to be implemented. Many wondered whether this self-regulation by the industry could break a practice that had been built over the years".

Three-and-a-half years after its "comparison of codes" article, the 2007 Apr-Jun issue of the Indian Journal of Medical Ethics published, "Drug promotional practices in Mumbai: A qualitative study", which summarises the position as follows:

"The study findings indicate the institutionalisation of unethical and illegal drug promotional practices - at the cost of the consumer -- by drug companies, chemists and doctors, with a role played by medical representatives. We suggest that effective action against such practices must involve better regulation of the industry, as well as involvement of all the stakeholders -- doctors, chemists, manufacturers and consumers. However, the various associations have not shown any inclination towards self regulation. In fact, many of them are themselves mired in controversy. There is limited organised consumer action against spurious drugs and unethical promotional practices in the pharmaceutical industry".

The website of the Central Drugs Standard Control Organization of the DGHS, Ministry of Health and Family Welfare of the Government of India, lists all the "Laws Pertaining to Manufacture and Sale of Drugs in India". There are no standards for the training and regulation of Pharmaceutical Representatives listed.

The Indian Institute of Pharmaceutical Marketing, an institutional member of the Indian Pharmaceutical Association, "has been set-up with a view to serve the demand of trained marketing personnel/ executives in this sector of the corporate world".

It offers a course in Pharmaceutical Marketing Management, which covers the following:

> Pharmaceutical Marketing Management.
> Pharma Selling.
> Anatomy, Physiology and Pharmacology.
> Pharma Product Management.
> Pharma Distribution Management.
> Customer Behaviour.
> Advertising.

> Pharmaceutical Marketing Communication.
> Market Research.
> Drug Law's.
> Economics.
> Manufacturing Practices in Pharmaceutical Industry.
> Qualify Control Management.
> Production Planning.
> Fundamental of Management and Practical Training and Case Studies and Introduction to Information Technology.

Kenya:

In Kenya, the pharmaceutical industry consists of three segments, viz., the manufacturers, distributors and retailers, all of which play a major role in supporting the country's health sector. Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the regions' market. Out of the region's estimated 50 recognised pharmaceutical manufacturers; approximately 30 are based in Kenya. About 9,000 pharmaceutical products have been registered for sale. These are categorised according to particular levels of outlet as free-sales/over-the-counter (OTC), pharmacy technologist dispensable, or pharmacist dispensable/prescription only".

The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy, Manufacture and Trade in drugs and poisons. According to the Board:

"Currently, a majority of persons practising as Pharmaceutical Representatives lack Pharmacological training hence are not able to conceptualize medical issues. On the other hand, [legislation], does not provide for training and licensing of the Pharmaceutical Representatives exhaustively".

The Pharmacy and Poisons Board, accordingly define the following criteria for registration as a Pharmaceutical Representative:

> Pharmaceutical Representative is a representative of manufacturing company, importer, distributor, wholesaler, who conducts promotional activities through provision of information about drugs to health care professionals. They are also licensed to carry drugs as samples in the course of their duties.
> Order Takers means that the pharmaceutical representative shall be involved in taking orders on behalf of their companies. They shall not be involved in provision of scientific information about drugs and will not carry and/or issue out samples.
> Training and Academic Qualifications. The following qualifications shall be the minimum criteria for consideration as a Pharmaceutical Representative by the Pharmacy and Poisons Board:
> A diploma in Pharmacy, Cap 244.
> A degree in Medicine and Surgery, Cap 255.
> A degree in Veterinary Medicine, Cap 366.
> A degree in Dentistry, Cap 253.
> A degree in Nursing, Cap 257.
> A diploma in Clinical Medicine, Cap 260.
> A diploma in Nursing, Cap 257.
Or
> Any other qualification the Pharmacy and Poisons Board deems satisfactory.

United Kingdom:

Pharmaceutical companies carry out nearly a quarter of all industrial research and development in the United Kingdom (UK), and spend more than 20 per cent of their gross output on research and development. Around 20 per cent of the world's top medicines were discovered and developed in Britain. The Pharmaceutical industry employs 72 00 people, generating another 250,000 jobs in related industries.

The Association of the British Pharmaceutical Industry (ABPI) is the trade association representing manufacturers of prescription medicines. The Code has been regularly revised since its inception in 1958 and is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Royal College of Nursing and the Medicines and Healthcare products Regulatory Agency of the Department of Health. The Code is accepted by virtually all pharmaceutical companies operating in the UK".

The ABPI Code incorporates the principles set out in:

> The International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices.
> The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.
> The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.
> Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC.
> The World Health Organisation's Ethical criteria for medicinal drug promotion.

Clause 16 of the ABPI: Code of Practice states the following on Training:

> All relevant personnel including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material or of information to be provided to members of the UK health professions and to appropriate administrative staff or of information to be provided to the public and recognised patient organisations must be fully conversant with the requirements of the Code and the relevant laws and regulations.

> All personnel (including persons retained by way of contract with third parties) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented.

> Representatives must pass the appropriate ABPI representatives examination, as specified in Clause 16.4. They must take the appropriate examination within their first year of such employment. Prior to passing the appropriate examination, they may be engaged in such employment for no more than two years, whether continuous or otherwise.

> The Medical Representatives Examination is appropriate for, and must be taken by, representatives whose duties comprise or include one or both of:

> Calling upon doctors and/or dentists and/or other prescribers.
> The promotion of medicines on the basis, inter alia, of their particular therapeutic properties.

The Generic Sales Representatives Examination is appropriate for, and must be taken by, representatives who promote medicines primarily on the basis of price, quality and availability.

The ABPI examinations for medical representatives and generic sales representatives are based on a syllabus published by the ABPI which covers, as appropriate, subjects such as body systems, disease processes and pharmacology, the classification of medicines and

pharmaceutical technology. Information on the National Health Service and pharmaceutical industry forms an additional core part of the syllabus. The syllabus is complementary to, and may be incorporated within, the company's induction training which is provided to representatives as a pre-requisite to carrying out their function.

The Medical Representatives Examination formats - the ABPI offers two options:

> The traditional examination, comprising a Morning Paper.
> The Accredited Programme (only offered to companies).

Generic Medicines Representatives sit the same Morning Paper as Medical Representatives.

The Morning Paper is in three parts:

> Paper 1: The industry and the Code of Practice (30 questions, 23 on the Code of Practice).
> Paper 2: The human body, pathology, pharmacology (30 questions).
> Paper 3: Body systems (140 questions):
> Cardiovascular.
> Respiratory.
> Central nervous system.
> Digestive.
> Musculo-skeletal.
> Endocrine.
> Urinary.
> Reproduction.
> Skin.
> Special senses.

Candidates need to pass all three papers with a mark of at least 60 per cent. Candidates scoring 80 per cent in all three papers at the same sitting will be eligible for a 'distinction' certificate, subject to passing all 3 specialist papers at the same sitting with 80 per cent or more.

The morning papers have an equal distribution of questions drawn from the ten topic areas under 'body systems'.

Afternoon specialist subject examination papers:

Candidates must select 3 examination subjects from the following list of topics. Examinations are based on materials contained within Volume 2 of the ABPI learning material:

> Paper 1: Arthritis and bone disease.
> Paper 2: Pharmacology.
> Paper 3: Oncology.
> Paper 4: Hypertension and Coronary Artery Disease.
> Paper 5: Dyslipidaemia.
> Paper 6: Respiratory diseases.
> Paper 7: Immunology.
> Paper 8: Alzheimer's and Parkinson's disease.
> Paper 9: Depressive illness and schizophrenia.
> Paper 10: Gastro-duodenal diseases.
> Paper 11: Osteoporosis.
> Paper 12: Diabetes.
> Paper 13: Female reproductive health.
> Paper 14: Male reproductive health.
> Paper 15: Dermatology.

Criteria for passing the exam:

The exam is divided into six papers; all have to be passed with a score of 60% or more. Candidates who fail one paper only, in either or both of the morning/afternoon exams may re-sit the single paper that they failed (in either session). Candidates who fail more than one paper in either or both of the morning/afternoon exams must resit the entire exam session (morning or afternoon).

In order to register a valid overall 'pass' the morning and afternoon papers must be taken and passed within 3 years of each other.

> ABPI Accredited Programme:

This programme is also essentially a modular approach to the ABPI examination, whereby the examination is normally taken in several stages. Candidates study learning materials based on company product training manuals which have been accredited by the ABPI. Copyright and other intellectual property rights in the company training manuals vests in the individual pharmaceutical company concerned and the training materials themselves are treated as confidential outside the company and the ABPI.

> Persons who have passed the Medical Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Generic Sales Representatives Examination are exempt from the need to take that examination. Persons who have passed the Generic Sales Representatives Examination whose duties change so as to become those specified in Clause 16.4 as being appropriate to the Medical Representatives Examination must pass that examination within two years of their change of duties.

> Details of the numbers of medical and generic sales representatives who have passed the respective examinations above, together with the examination status of others, must be provided to the Prescription Medicines Code of Practice Authority on request.

Conclusion:

Gift-giving; ethical vs. unethical promotion; transparency and self-regulation appear to be the main issues in the pharmaceutical industry right across the globe. Owing to inadequate national legislation and the lack of universally accepted self-regulatory codes, the pharmaceutical industry in India has yet to tackle the problem of "Unethical and illegal drug promotional practices". Kenya's embryonic industry is taken up with such issues as (in the words of the Pharmacy and Poisons Board), "the challenge of striking a balance between promotional activities for branded names and the Who recommended rational use of Essential Medicines" and the more elementary, "As we grapple with various dilemmas in the industry, the big question remains 'is there need for pharmaceutical representatives?".

Of the four countries studied, Australia and the United Kingdom have longer histories of dealing with pharmaceutical development, and therefore have the most developed legislation and mechanisms for dealing with the pharmaceutical industry. The pharmaceutical industries in these countries have developed controlling bodies and codes which deal comprehensively with the education, standards, and relationships within the industry, of pharmaceutical representatives.

Both Medicines Australia and the ABPI have defined expected behaviours and distilled required knowledge - pharmacological, industrial and legal - into manuals and codes, which pharmaceutical representatives are expected to master, and which they are rigorously examined upon within limited time frames. The codes have been compiled with the participation of the relevant learned bodies and government health departments - UK: British Medical Association,

the Royal Pharmaceutical Society of Great Britain, the Royal College of Nursing and the Medicines and Healthcare products Regulatory Agency of the Department of Health. In Australia, Medicines Australia's Continuing Education Program (CEP) has been redeveloped by the UQ Health Institution "the lifelong learning arm of the University of Queensland Faculty of Health Sciences". Maintaining self-regulation is the incentive for bodies like Medicines Australia or the ABPI to keep standards up to the mark.

But even in Australia and the United Kingdom, ethical questions remain problematic. Choice, the largest consumer organisation in Australia, points out, "that it is a conflict of interest for the Code to be administered by the industry peak body." and "it is also concerned that the sanctions available in the Code do little to prevent breaches]". Similar worries obtain in the United Kingdom. Clearly vigorous public participation, freedom of the press, and efficient national controlling bodies are essential for the success of this system.

Given the issues raised in this report, the exit level outcomes and the associated unit standards as envisaged in the National Certificate: Pharmaceutical Sales: Level 5 currently being generated for South Africa is in line with best practice internationally, and if developed along the lines indicated will be compatible with those countries which engage with outcomes-and-standards-based qualifications.

ARTICULATION OPTIONS

This Qualification articulates horizontally with:

> ID 59201: National Certificate: Generic Management, NQF Level 5.

The Qualification articulates vertically with:

> ID 61593: National Diploma: Marketing Management, NQF Level 5.
> ID 20901: First Degree: Marketing Management, NQF Level 6.

MODERATION OPTIONS

> Providers offering learning towards this Qualification or the component unit standards must be accredited by the relevant ETQA or ETQA that has a Memorandum of Understanding in place with the relevant ETQA.

> Moderation of assessment will be overseen by the relevant ETQA or ETQA that has a Memorandum of Understanding in place with the relevant ETQA, according to moderation principles and the agreed ETQA procedures.

> Internal and external moderation must be conducted by moderators appointed by the provider and accredited through the relevant ETQA or ETQA that has a Memorandum of Understanding in place with the relevant ETQA.

> Both internal and external moderators must be in possession of an appropriate qualification, as well as relevant clinical expertise and current experience.

NOTES

This qualification replaces qualification 17099, "Certificate: Medical Representative", Level 5, 120 credits.

UNIT STANDARDS

	ID	UNIT STANDARD TITLE	LEVEL	CREDITS
Fundamental	259362	Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country	Level 5	6
Fundamental	242585	Analyse the dynamics of different interactive styles in client relationships	Level 5	3

	ID	UNIT STANDARD TITLE	LEVEL	CREDITS
Fundamental	259359	Conduct a sales call in a professional environment	Level 5	8
Fundamental	259357	Design, develop and deliver presentations	Level 5	10
Core	259360	Apply the principles of pharmacoeconomics to clinical study outcomes	Level 5	4
Core	259358	Conduct a sales territory analysis	Level 5	8
Core	259363	Describe human anatomy, physiology, pathophysiology and treatment options for common conditions	Level 5	45
Core	259365	Describe managed health care in the pharmaceutical environment	Level 5	3
Core	259364	Utilise pharmacology and pharmaceutics to provide information about medicines and their appropriate use	Level 5	10
Core	259361	Utilize applicable clinical research findings of pharmaceutical products to achieve a competitive advantage	Level 5	8
Elective	115311	Apply advanced driving skills / techniques in defensive and offensive situations	Level 5	9
Elective	13648	Apply appropriate social protocols in the workplace and community	Level 5	4
Elective	15234	Apply efficient time management to the work of a department/division/section	Level 5	4
Elective	244523	Conduct an ergonomic assessment and take appropriate action	Level 5	5
Elective	15096	Demonstrate an understanding of stress in order to apply strategies to achieve optimal stress levels in personal and work situations	Level 5	5
Elective	244570	Demonstrate knowledge and application of efficient study skills	Level 5	5
Elective	114863	Implement basic safety procedures in emergencies	Level 5	3
Elective	256075	Plan events	Level 5	3

LEARNING PROGRAMMES RECORDED AGAINST THIS QUALIFICATION
None

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Design, develop and deliver presentations

SAQA US ID	*UNIT STANDARD TITLE*		
259357	Design, develop and deliver presentations		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	10

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Design a presentation to meet specific client needs.

SPECIFIC OUTCOME 2
Develop a presentation for a group/individual.

SPECIFIC OUTCOME 3
Deliver a presentation to a group/individual.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Fundamental	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Conduct a sales territory analysis

SAQA US ID	*UNIT STANDARD TITLE*		
259358	Conduct a sales territory analysis		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	8

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Gather data relevant to the sales environment to operate effectively.

SPECIFIC OUTCOME 2
Interpret data and marketing information to identify key issues in the specific territory.

SPECIFIC OUTCOME 3
Make recommendations to meet identified objectives.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Conduct a sales call in a professional environment

SAQA US ID	*UNIT STANDARD TITLE*		
259359	Conduct a sales call in a professional environment		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	8

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Preparing for a sales call.

SPECIFIC OUTCOME 2
Making the sales call.

SPECIFIC OUTCOME 3
Following up on the sales call.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Fundamental	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Apply the principles of pharmacoeconomics to clinical study outcomes

SAQA US ID	*UNIT STANDARD TITLE*		
259360	Apply the principles of pharmacoeconomics to clinical study outcomes		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	4

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Explain the theory of pharmacoeconomic analysis.

SPECIFIC OUTCOME 2
Apply the appropriate method of pharmacoeconomic analysis for specific clinical study results.

SPECIFIC OUTCOME 3
Differentiate between the cost-effectiveness of medicines and the cost-effectiveness of specific treatment modalities.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Utilize applicable clinical research findings of pharmaceutical products to achieve a competitive advantage

SAQA US ID	*UNIT STANDARD TITLE*		
259361	Utilize applicable clinical research findings of pharmaceutical products to achieve a competitive advantage		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	8

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Explain the principles of clinical research methodology.

SPECIFIC OUTCOME 2
Interpret clinical study results and reports.

SPECIFIC OUTCOME 3
Communicate the findings effectively.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country

SAQA US ID	*UNIT STANDARD TITLE*		
259362	Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	6

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Demonstrate ethical behaviour.

SPECIFIC OUTCOME 2
Develop self as professional person.

SPECIFIC OUTCOME 3
Act in an advocacy role to protect human rights.

SPECIFIC OUTCOME 4
Maintain customer confidentiality.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Fundamental	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Describe human anatomy, physiology, pathophysiology and treatment options for common conditions

SAQA US ID	*UNIT STANDARD TITLE*		
259363	Describe human anatomy, physiology, pathophysiology and treatment options for common conditions		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	45

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Describe the structure and explain the function of the listed systems of the human body.

SPECIFIC OUTCOME 2
Describe the pathophysiology of common conditions.

SPECIFIC OUTCOME 3
Apply knowledge of microbiology as it relates to common conditions.

SPECIFIC OUTCOME 4
Discuss therapeutic options used for the management of common conditions.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Utilise pharmacology and pharmaceutics to provide information about medicines and their appropriate use

SAQA US ID	*UNIT STANDARD TITLE*		
259364	Utilise pharmacology and pharmaceutics to provide information about medicines and their appropriate use		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	10

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Explain the principles of pharmacokinetics and pharmacodynamics.

SPECIFIC OUTCOME 2
Explain the influence of pharmaceutics on the effects of medicine in the body.

SPECIFIC OUTCOME 3
Describe the factors that affect the safety of medicines.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

UNIT STANDARD:

Describe managed health care in the pharmaceutical environment

SAQA US ID	*UNIT STANDARD TITLE*		
259365	Describe managed health care in the pharmaceutical environment		
ORIGINATOR		*PROVIDER*	
SGB Pharmacy			
FIELD		*SUBFIELD*	
9 - Health Sciences and Social Services		Curative Health	
ABET BAND	*UNIT STANDARD TYPE*	*NQF LEVEL*	*CREDITS*
Undefined	Regular	Level 5	3

This unit standard does not replace any other unit standard and is not replaced by another unit standard.

SPECIFIC OUTCOME 1
Describe the South African health care environment.

SPECIFIC OUTCOME 2
Describe and demonstrate knowledge of health care funding to operate effectively as a pharmaceutical sales representative.

QUALIFICATIONS UTILISING THIS UNIT STANDARD

	ID	QUALIFICATION TITLE	LEVEL
Core	63969	National Certificate: Pharmaceutical Sales Representation	Level 5