



BUSINESS PLAN

ISO/TC 157

Non-Systemic Contraceptives and STI Barrier Prophylactics

EXECUTIVE SUMMARY

ISO/TC 157 covers all areas of non-systemic contraceptives and STI barrier prophylactics. The HIV/AIDS epidemic that began in the early 1980s has changed the lifestyles of people all over the world, and it has also brought about important changes in the work of ISO/TC 157. Once used primarily for family planning purposes, condoms are now widely employed for their efficacy in preventing the spread of HIV/AIDS, as well as protecting against a number of other sexually transmitted infections. This shift in the motivations and expectations of users impacts the focus of ISO/TC 157.

To help ensure that condoms are effective both for contraceptive purposes and in the prevention of STDs, ISO/TC 157 has developed standards requiring that condoms fit the penis properly are free from holes, have adequate physical strength so as not to break during use, are correctly packaged for protection during storage, and are correctly labelled.

Since its first meeting in 1975, ISO/TC 157 has expanded its scope to cover all areas of mechanical contraceptives (which are classified as medical devices in many countries). They vary from the single-use disposable male condom, which can be purchased over the counter or given away free, to multiple-use devices such as the intra-uterine devices (IUD), which is normally available only by prescription and requires correct insertion and monitoring by a medical specialist.

The published standard for male latex condoms, ISO 4074, is the most important output of the technical committee. Providing the basis for much of the world's trade in condoms, the standard is used by procurement agencies and HIV prevention and family planning agencies, and is referenced extensively by the WHO in its purchasing specifications for condoms. Additional guidance on the use of ISO 4074 may be found in ISO 16038.

In addition to ISO 4074, the published standards for IUDs and rubber diaphragms are ISO 7439 and ISO 8009 respectively. These standards are widely used in their respective markets.

Over the past decade, manufacturers of latex condoms have continued to make product improvements based on research and development findings and on changes in ISO 4074, which is used in buyers' purchasing specifications. To compete in the global market, manufacturers have improved their production lines by using better latex formulations, incorporating a wide range of design modifications such as varying shapes, colours and flavour, and meeting the requirements of specifications.

While development work continues apace in all areas covered by the committee, the benefits of the availability of International Standards for are clear – they provide the basis for the specification of effective and safe means of contraception, across a wide range of user-profiles and clinical and social needs, and (especially in the case of male condoms) provide a means of prevention of the transmission of sexually transmitted infections (STI's). The recent and ongoing explosion in infection rates in various parts of the world from the human immunodeficiency virus (HIV) and other STI's has not only contributed to a major upturn in demand for male condoms, but has highlighted the value of the work of the committee in a way that could not have been predicted in the early 1980's.

While normal development and continual upgrading of the quality and the technical performance of mechanical contraceptives in general will take place in the years to come, and will find a place in the standards, the main focus of ISO/TC 157 is likely to remain the male latex condom. There will also be a similar development of standards for condoms made from synthetic materials and female condoms. Guidance documents on the interpretation of condom standards by manufacturers, and guidance on the conduct of clinical trials are also included in the scope of work by the TC. Besides that, there will be a development of standard on latex barrier membranes (dams) that provides requirements for latex barrier membranes (dams) for prophylactic use which is also included in the scope of ISO/TC 157 work.

ISO/TC 157 will continue to be involved in the development and refinement of standards for all non-systemic contraceptives and STI barrier prophylactics and to produce appropriate guidance documents for manufacturers, regulators and procurement agencies.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: [ISO](#) (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of [IEC](#) (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of [ITU](#) (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF THE ISO/TC

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

- Non-systemic contraceptives and STI barrier prophylactics are medical devices. They vary from the single-use, disposable male condom, purchased over the counter or given away free, to multiple-use devices such as the Intra-Uterine Device (IUD), which is normally available only on prescription and requires correct insertion and monitoring by a medical specialist.
- The purpose of non-systemic contraceptives and STI barrier prophylactics is two-fold – the prevention of pregnancy and the prevention of sexually-transmitted infections (STI's). The former need has not changed for over a thousand years, since the first crude devices were invented, but with the relatively recent advent of new STI's, and in particular the HIV/AIDS pandemic, the demand for barrier contraceptives, and in particular the male condom, has intensified greatly since the 1970's.
- UNAIDS 2008 report indicated that the global HIV epidemic is stabilizing, but still at an unacceptably high level. They estimated that globally 33 million people were living with HIV in 2007, compared with 38.6m people in 2006. The year also saw 2 million deaths from AIDS. This is a high global total, despite antiretroviral (ARV) therapy. Figure 1 shows the distribution of people living with HIV around the world, according to 2007 data.

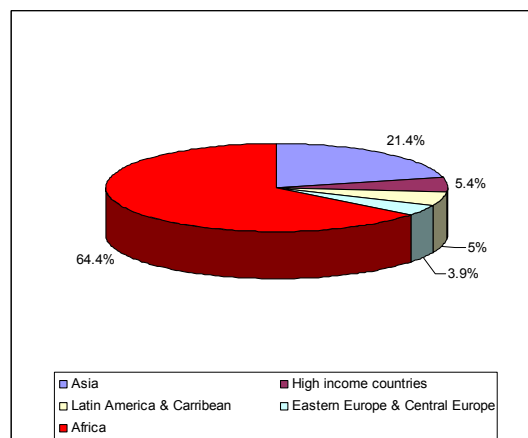


Figure 1 – Distribution of HIV/AIDS around the world

- UNAIDS 2008 report also highlighted that the number of new HIV infections in 2007 is 2.7 million, a decline from 3.0 million in 2001. This could be the results of a six fold increase in financing for HIV programmes in low- and middle-income countries from 2001 to 2007, which is beginning to show positive result. However, the report also disclosed that globally, the percentage of women among people living with HIV has remained stable at 50 % for several years.
- If used correctly and consistently, male latex condoms are the only contraceptive proven to be effective in preventing both unwanted pregnancy and sexually-transmitted diseases, including HIV.

- The huge modern demand for, in particular, the male condom has now changed the market dynamics in this sector, to the extent that many new manufacturers have entered the field alongside the old-established manufacturers.
- The dynamics of the world market for male latex condoms are such that relatively few manufacturers compete for large tenders in the public sector, which accounts for the largest part of the market and the lowest unit cost, while the retail market is also dominated by a relatively small number of large manufacturers, with smaller and niche players producing a great variety of differentiated items for quite a small segment of the retail market.
- Medical devices need to be regulated, both in terms of approval to market and in terms of efficacy, quality and suitability for their intended purpose. The involvement of regulatory agencies in the work of ISO/TC 157 is therefore a prerequisite, as the principal means of regulation is by reference to the International Standards developed by this committee.
- The role that quality IUDs play in the prevention of unwanted pregnancy and the dual role that quality male and female condoms play in preventing both the transmission of sexually transmitted infections (STIs) including HIV and the prevention of unwanted pregnancy, cannot be under-estimated. This is why organizations such as World Health Organizations (WHO), United Nations Population Fund (UNFPA), Programme for Appropriate Technology in Health (PATH), Consumer's International (CI), social marketing agencies, and other international organizations are an integral part of this committee. They work with this committee to support the formulation of standards that ensure that regardless of whether the product is procured and distributed by the private or public sector, the poorest and most vulnerable populations have equitable access to quality products that protect their health.
- The stakeholders in this committee therefore include all the above interest groups, and the development of International Standards by this committee is carried out on several levels simultaneously:
 - the goal of specifying fitness for purpose of the products themselves involves the deliberations of manufacturers, test houses, consumers and medical specialists
 - the need to facilitate regulation involves regulatory agencies
 - the need to foster links between the private and public sector to support the procurement and distribution of quality products that if used appropriately have the potential to prevent unwanted pregnancy and/or the transmission of STIs.
- In the field of male condoms, new, synthetic materials are being used, that have significant different physical properties from the natural rubber latex, which is obtained from the rubber tree, a natural resource. The proposed standard for synthetic condoms therefore requires a different approach.
- Also in the field of male condoms, more and more research is now being carried out into appropriate and meaningful physical methods of test, means of predicting shelf-life, etc., and as the state of the art advances, proven improvements in quality have to be catered for in the standards.

- Standardization of female condoms is becoming more relevant, now that more manufacturers are entering the market, and the demand for the product is growing.
- While the technology surrounding diaphragms and IUD's is more mature, developments in technology nevertheless occur, and require ongoing evaluation in terms of potential trade-offs between increases in efficacy and undesirable effects on patient health.
- Possible new areas in which regulation, and therefore standardization, are required, extend to tubal occlusion devices, which is currently at the drafting stage.
- With any medical device, standardization in the field cannot stop at laying down product characteristics in isolation. Pre-clinical and clinical trials have to be carried out by manufacturers in order to obtain approval from regulators to market their products, and standardized procedures for these elements need to be developed.
- The gathering and interpretation of failure data from users of the products covered by this committee are neither easily nor reliably achieved, owing to the personal and private nature of their use. There is therefore a greater need for manufacturers and conductors of clinical trials to share data in the standardization environment than might otherwise be the case with other products.
- New designs for products are appearing all the time, and where these could have an effect on the physical performance of the product in use, there is a clear need for ongoing vigilance to relevant stakeholders e.g. regulatory bodies, standardisation bodies and consumer interest group.
- In a similar vein, the use by the consumer of after-market additives with products (such as the use of spermicides and additional lubricants with condoms), and the development by manufacturers of new lubricants, flavourings, v-rings, erection enhancing device, etc., pose specific and ongoing concerns, in particular relating to compatibility, that have to be addressed by the committee.
- Some countries are imposing additional test requirements or more stringent regulatory requirements, which could cause potential technical barriers to trade.
- The increase of fuel price, cost of latex and other raw materials has increased the cost of manufacturing latex condoms.

2.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the ISO/TC:

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

It is very difficult to obtain comprehensive, reliable and current data on global use of condoms and condom sales. One of the problems faced is the misrepresentation of procurement quantities, for example, some data may not specify procurement by “gross”.

In 2005, the United Nations Population Fund (UNFPA) estimated that 10.4 billion male condoms were used worldwide. Of these, around 4.4 billion were used for family planning and 6.0 billion for HIV prevention (6). A market report (Condoms: A Global Strategic Business Report”, March 2005, Global Industry Analysts Inc.) estimated that in 2005 the global condom retail sales were approximately \$3.2 billion, with the top four companies representing as much as 70 % of the market. The largest manufacturers also dominate the tender markets. At a conservative rate of increase of 10% annually, it can be estimated that in 2009, the total world market for male latex condoms could be around 14 to 15 billion units at a cost of about US 4 to 4.5 billion.

The majority of latex condoms are manufactured in Asia, close to the supply of raw latex, with India, Japan, Thailand and Malaysia having large export industries. Other manufacturers are based predominantly in the USA, Europe and Latin America. Distributors exist in many countries, who purchase bulk quantities of condoms and re-package them, with or without the addition of lubricant. Thus, the number of individual brands available is far in excess of the number of manufacturers.

The tender market is huge, Well over half of all condoms supplied are supplied against large tenders, often for the purposes of social marketing or for donor agencies. The tender market is normally dominated by large manufacturers, but the financial return is less lucrative.

In recent years, the rate of growth in donor funding has slowed in real terms, while the demand for free or subsidized condoms has escalated. UNFPA estimated in 2005 that at least 13.1 billion condoms were needed in 2005 to significantly reduce the spread of HIV, and another 4.4 billion were required for family planning. Of the 17.5 billion condoms needed in 2005, the number of condoms donated was only 1.8 billion representing just 10 % of the need. Although the quantity of male condoms procured by donors in 2007 reached a record high of over 3.1 billion pieces, it was still far from the actual demand. There is thus a growing “funding gap”, which impacts negatively on the supply of such condoms to developing countries, and increases the emphasis on social marketing programmes.

A new trend in condom manufacture is the small but growing use of synthetic materials. At present such products are only available in limited markets. While synthetic materials promise better consumer acceptance and consistency of manufacture than latex, together with a ready solution to the problem of condom users who are sensitive to latex protein, they also have shortcomings such as higher slippage and breakage rates. In addition, the synthetic condom normally comes at a higher price, and the newer materials have a totally different set of performance characteristics to latex. The criteria used for specifying the performance of latex condoms are not applicable, and it is therefore necessary to develop new standards for synthetic products.

Accurate market figures for diaphragms and IUD's are not available, although it is known that the demand for diaphragms has been in steady decline for the last 10 years or so. In part this is due to the limited level of protection they offer against sexually transmitted infections.

Condoms are either obtained over the counter in pharmacies or supermarkets, or from donor sources or family planning agencies, while other types of mechanical contraceptives are typically obtained with the assistance of the medical profession. IUD's, in particular, are normally obtained by prescription, and need to be fitted by a medical practitioner. In some countries, for religious, cultural or political reasons, contraceptives of all types are limited in availability, while in others organized government-run or private family planning programmes exist.

The International Standards developed by ISO/TC 157 have been adopted as National Standards in many countries, and are referred to extensively in purchasing specifications, most notably the 2003 model condom specification of the WHO ("*The male latex condom – Specification and guidelines for condom procurement*"), which uses ISO 4074 as its technical basis. A competitor standard to ISO 4074, published by ASTM, is used as the basis for purchasing specifications by US-based donor agencies.

Until recently the condom standard used in the European Union was an EN standard that differed from the ISO standard. This situation has now been resolved, with the EN standard being withdrawn and has been replaced by ISO 4074 (as EN ISO 4074), under the Vienna Agreement, where the ISO technical committee has the lead.

The reverse situation existed with IUD's, where the standard in use is ISO 7439 developed under the Vienna Agreement with lead of CEN. ISO has the lead for the revision of the standard.

Various commercially available and frequently updated comprehensive market research reports exist, which outline in greater detail the changing dynamics of the market for the various types of mechanical contraceptives.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 [Countries/ISO members bodies that are P and O members of the ISO committee](#)

4.2 *Analysis of the participation*

The current membership of the committee (25 P-members and 27 O-members) represents a healthy balance between geographic regions, between manufacturing and consumer countries, and between developed and developing countries. Of the P-membership (as at August 2009), one was from Australasia, four from Africa, seven from Asia, four from the Americas, and nine from Europe. A similarly wide distribution was evident among the O-membership.

Several major organizations are listed among the liaison members, with the WHO, PATH, UNFPA and Consumers International being most active in the committee.

Regulatory authorities are very active in the committee, and are represented mainly as part of national delegations.

It is felt that the ISO/TC 157 requires more experts to participate in the committee and it is hoped that some of the more interested O-members will eventually elevate their status to full P-membership. There is room for more of the major family planning, donor and social marketing agencies to join the committee.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

Based on the considerations above, ISO/TC 157 has as its general objectives the development and continual refinement of standards for *non-systemic contraceptives and STI barrier prophylactics*, together with appropriate guidance documents for manufacturers, regulators and procurement agencies. Added to these general objectives is the commitment of members to monitor developments in the world condom market and the ongoing evaluation of methodologies for, and data from, clinical studies, as these elements impact on the future direction of standardization. Given the differing levels of expertise among condom manufacturers, differing needs and usage practices among users, and demographic, climatic and cultural variables between member countries, the committee feels the need to provide an open forum for the exchange of information between delegates, as a precursor to the standardization effort, and aimed at providing future direction for the work of the committee.

Specific objectives are as follows:

- The TC had replaced the ten parts of the rubber diaphragm standard, ISO 8009, with a single volume revision, to include silicone diaphragms, which was published in 2004.
- The standard on copper-bearing IUD's, ISO 7439, which has been revised and approved as an amendment to ISO 7439 (Amd. 1), The amendments takes into consideration the safety, efficacy and performance of graded copper intra-uterine devices.
- ISO 4074, latex rubber condom standard, in the process of revision and has been circulated as a draft international standard. The revision of the standard is part of a process of continual improvement to the quality and applicability of the standard, which will enhance its role as a key instrument in improving condom quality.
- A guidance standard on the use of ISO 4074 in the quality management of natural rubber latex condoms, published as ISO 16038:2005, in the process of revision and has been circulated as a draft international standard. The revision of ISO 16038 will be taken up to keep in pace with the development of standard on rubber latex condoms ISO 4074 and also will incorporate developments in standards of related areas such as that on clinical trials.

- A standard on male condoms made from synthetic materials (ISO 23409) is in the process of development and has been circulated as a draft international standard. As the physical properties of synthetic materials differ from traditional natural rubber latex, the requirements of the standard will include a different approach to ensure that synthetic condoms are effective for contraceptives purposes and in preventing the transmission of STDs. This is a complex undertaking for which the document is now under active deliberation by WG 17.
- A guidance document on the clinical studies will be developed as a series of standards under a general title "*Condoms – Guidance on clinical studies*". The document has been registered in the TC work programme for deliberation by WG 20.
- A standard on female condoms will be developed. The document has been circulated as a draft international standard for balloting. The standard will define requirements to ensure that female condoms are effective in preventing pregnancy and sexually transmitted infections when used correctly and consistently.
- A standard which specifies the method of detection of nitrosamines migrating from natural rubber latex condoms into various media will be developed. Due to the number of products and the rapid development of new condoms types and the dramatic different specifications, this standard was proposed and has been approved as new project under this committee. WG 21 has been established to work on this project. The document has been circulated for as a draft international standard for balloting.
- A standard on requirements for latex barrier membranes (dams) for prophylactic use, which applies to natural rubber latex barrier membranes (dams) to prevent the spread of sexually transmitted infections, will be developed. WG 22 has been established to work on this project. The document has been circulated as a draft international standard for balloting.
- WG 12 has been re-established, currently investigating a promising new method for lubricant recovery via an inter-laboratory study. It is hoped to provide an acceptable method to replace the current method in ISO 4074:2002.
- WG 24 is a working group that has been tasked to develop a new standard on tubal ligation/fallopian ring.

5.2 Identified strategies to achieve the ISO/TC's defined objectives

- It is recognized by the TC that, with research work going on across many fronts, the updating of an important standard such as ISO 4074 has to be carried out according to a responsible timeframe. Manufacturers need to become accustomed to working to new versions of the standard, while regulators and organizations such as the WHO need to keep pace with developments in the standard. Inputs into the updating of ISO 4074 are made by numerous Working Groups (WG's 10, 11, 12, 13, 15 and 19), whose work areas overlap and are often interdependent. It is of paramount importance to avoid sowing confusion in the marketplace, while at the same time it is necessary to make technical progress to reflect new knowledge and requirements, together with advances in the "state of the art". For these reasons, the TC prefers to release major updates to ISO 4074 at intervals of several years. This does not preclude the interim issue of minor updates by amendment, or any necessary corrigenda.

- In view of the interrelationship between the work areas of the above named WG's, it is necessary that their work be advanced on a broad front. All WG's are encouraged to make progress mainly by advancing their work in between plenary meetings, by holding physical meetings where necessary, but by using electronic means where possible. It is recognized, however, that the interdependence of these WG's will necessitate a regular overview in Plenary session in order to maintain focus.
- The work of this TC, 90 % of which is condom-related, has historically been carried out by WG's, which report, together with the diaphragm and IUD WG's, to the main TC. In the current structure, there are no sub-committees (SC's). The tendency has been for detailed technical discussion of condom related work to spill over into the Plenary sessions, for the simple reason that there has been no other forum in which all the condom WG conveners and other affected role players could discuss issues of common interest, and which affect the overall progress of projects, especially that of ISO 4074. While there is an argument for a "condom" subcommittee which deals with these issues and reports in summary form to the TC, this has been seriously considered but is believed to be unworkable in the sense that the remaining members and delegates (who are regulators, consumer organizations, etc) still require to be kept in the broad picture. Also, the inevitable duplication discussion between a "condom" SC and the main TC would be unproductive timewise.
- The structure of this TC will therefore remain for the time being, a single TC with no SC's and numerous WG's, but with a Chairman's Advisory Group (CAG). The CAG, which was established in 2003, will provide a forum for all WG conveners, the Chair and the Secretariat to discuss policy issues of interest to TC 157. Provision will also be made for open discussion sessions on condoms to be held at regular meetings of the TC (but separate from the formal TC Plenary sessions), in which issues relating to the progress of condom standardization will be debated. One or more Rapporteur(s) will provide summary feedback to the Plenary, which will continue to take policy decisions.
- Ongoing cooperation and liaison with CEN committees will be maintained.
- The TC is cognizant of the extended range of ISO deliverables, and in view of the regulatory aspect, the possible use of faster-track, lower consensus options for some projects, especially for guidance documents, will need to be discussed further in the CAG before any firm decisions are taken.
- WG's 17, 18 and 20 have been established to carry out the necessary work in the areas of synthetic condoms, female condoms and clinical trials, respectively.
- WG's 21, 22, 23 and 24 have been established to carry out the necessary work in the subjects of determination of nitrosamines, latex barrier membranes (dams), revision of ISO 4074 and tubal ligation/fallopian ring.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

- As with other ISO/TCs in the field of medical devices, it is not always a simple matter to balance the interests of manufacturers and consumers, while at the same time taking account of the needs of other stakeholders, in particular regulators, procurement agencies, etc. This can lead to delays in standardization.
- The use by regulators in different jurisdictions of competing standards, makes global acceptance of the principle of “*one standard, one test, recognized everywhere*” difficult to achieve. Achieving convergence between competing standards will remain a goal of the TC, but is a long-term objective.
- The global manufacturing industry base, especially for condoms, is a mixture of multinational healthcare manufacturers and significantly smaller players. As in other technical standardization fields, there is an ever-present situation that the larger multinational manufacturers, who are represented on more than one national delegation, possess both the bulk of the available expertise in certain areas and might have a commercial interest in driving the standardization effort in a particular direction. This can lead to a delay or to a stalemate in achieving consensus.
- The dynamics of Mergers and Acquisitions activity in global big business might be such that the interests of a major manufacturer, and hence of a national member body of the committee, might change overnight, again either threatening the achievement of consensus, or perhaps causing a reopening of discussion of points already agreed upon.
- The greatest need for mechanical contraceptives is in those parts of the world where affordability is least; there is a significant and growing “funding gap” between the amount of money that is needed for the cheap or free distribution of, especially, condoms, and the amount that donors are prepared to provide. This inevitably brings the focus onto the unit cost of these items, which is affected by the degree of testing required. The development of standards therefore requires that a balance be achieved between the state of the art, and the costs that go with it, and affordability. While this should not be a concern for standardizers in the pure sense, it nevertheless plays a major role in the uptake and use of standards and has to remain a practical consideration in the deliberations of the TC.
- Reliable data remain difficult to obtain from clinical trials. While this could be alleviated over time by the successful introduction of standardized protocols, the work of the TC will always be subject to delays and uncertainties caused by the lack of reliable scientific data upon which to base requirements and tests.
- The ongoing introduction of new product designs, new materials, and the end use of different additives such as spermicides, lubricants, flavourings, etc., dictate that the work of the TC has to include a significant market vigilance aspect, and take into account new developments. This can have a retarding effect on the development of standards, and can under certain circumstances bring about the need for a re-think of the scope of a published standard or the need for a completely new approach to standardization. An example of this is the fairly recent introduction of condoms made from synthetic materials, which possess completely different physical properties to latex, and therefore need to be considered separately.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 [Structure of the ISO committee](#)

7.2 [Current projects of the ISO technical committee and its subcommittees](#)

7.3 [Publications of the ISO technical committee and its subcommittees](#)

Reference information

[Glossary of terms and abbreviations used in ISO/TC Business Plans](#)

[General information on the principles of ISO's technical work](#)