

## 7.2

### Tobacco Product Regulation, Testing and Laboratory Strengthening

The adoption of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) by the 56th World Health Assembly in May 2003 was a landmark accomplishment for public health. The regulation of tobacco products is an important component of a comprehensive tobacco control strategy and also features prominently in the FCTC. Several countries, including some developing nations, have already enacted domestic legislations that incorporate provisions for tobacco product regulation. The Indian Tobacco Control Legislation of 2003 calls for testing and disclosure of the tar and nicotine content of tobacco products.

Such a regulatory surge, however, will have to confront and overcome several challenges. A major barrier is the limited laboratory capacity for testing of tobacco products and their emissions. Increasing levels of activity in tobacco product regulation and the growing search for so-called 'harm reduction' products is sharply raising the demand for such laboratory services. These are inadequate even in developed countries and grossly deficient in developing countries.

While the tobacco industry has developed its own laboratory resources for tobacco product testing or hires the services of independent laboratories, government regulators in developing countries are now attempting to identify mechanisms by which they can acquire or upscale laboratory capacity to meet their regulatory needs. Laboratories are required for the purpose of regulation (pre-marketing

evaluation and post-marketing surveillance) as well as for conducting research into new developments that are likely to influence the composition, characteristics and health effects of tobacco products.

Ideally, government regulators need to access laboratories that are not owned, operated or influenced by the tobacco industry. Such 'independent' laboratories may be (i) those operated by the government, or (ii) accredited independent private-sector laboratories, or (iii) research laboratories in academic institutions which could be accredited by the government. Each such laboratory must meet the inviolable criterion of freedom from the tobacco industry's influence.

#### Purpose of product regulation

As long as tobacco products continue to be legally permitted for sale, they need to be regulated with respect to their constituents and emissions. The purpose of regulation is to progressively reduce the levels of harmful chemicals and alter their physical characteristics that influence the delivery of these chemicals. Regulation should not, however, be construed to mean that any permitted level of a chemical is 'safe' or that the product is endorsed by the regulator. This is because there is no safety limit for such chemicals in terms of habitual human consumption. While upper limits are periodically set by the regulator for each chemical under regulation, it is merely a step in reducing the levels of harmful chemicals but not a guarantor of reduced harm of the product itself. The principles related to tobacco product regulation, as spelt out by the WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob), are listed in Box 7.2.

The potential end-points of regulation are: reducing initiation or maintenance of addiction, reducing uptake, reducing harm to active smokers and other tobacco users, eliminating toxic non-tobacco additives, facilitating quitting and protecting non-smokers from second-hand

### Box 7.2 Tobacco product regulation: WHO spells out why and how

#### Observations and principles

- Tobacco products have the capacity to cause addiction due to their nicotine content and other substances in the emissions.
- Manufacturing processes can further add to the toxicants and make nicotine more readily available for absorption into the body (for example, through the manipulation of pH, selection of aerosol particle size, addition of chemicals and changes in other physical parameters of the materials such as paper porosity and size of the cut tobacco material).
- Combustion and pyrolysis of tobacco material in tobacco products, such as cigarettes (both manufactured and hand-made), pipes, cigars and *beedis*, result in the formation of additional toxicants and can increase the addictive effects of nicotine.
- Regulation of cigarette ingredients and emissions is intended to support tobacco control efforts, prevent initiation and stimulate cessation.
- One of the purposes of this regulation of tobacco products is a progressive reduction in the level of toxic chemicals in tobacco product ingredients and emissions through periodic setting of standards. The upper limits set by the regulations do not in any way indicate an acceptable level of safety for any tobacco product and its emissions.
- The development of regulations on tobacco ingredients and emissions should aim to reduce health risks, although there is no expressed or implied measure of disease reduction.
- Smokeless tobacco products also produce emissions that are addictive and toxic.

#### Recommendations

- Regulations in terms of setting upper limits for ingredients and emission of toxicants need to be developed for all tobacco products whether they are intended for smoking or non-smoking methods of consumption. Variation in the ways in which tobacco products are used needs to be considered in establishing performance standards.
- For tobacco products intended to be smoked, the manufactured product needs to be differentiated from the product actually intended for consumption which is its emission ('smoke'); therefore, the critical focus of regulation must be on the emission.
- Ongoing surveillance and research must be instituted to assess the consequences of regulation on initiation, cessation and health effects to modify the regulatory process on a regular basis.
- With respect to nicotine, it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine per unit (e.g. cigarette), and further study of this issue is required.
- No health claims can be permitted based on the level of ingredients or emissions, or whether the products meet regulatory standards for ingredients and emissions.

Source: WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACtob), 2002

smoke. However, these expectations must be tempered by the fact that 'harm reduction' is as yet an illusory goal and may, sometimes, prove to be a decoy that diverts tobacco users away from tobacco cessation. It must also be recognized that, so far, most of the focus of product regulation has been on reducing the levels of cancer causing chemicals and more research is needed on the modifications that are required to have the potential for reducing the risk of other diseases such as cardiovascular disorders.

### The position of SACtob on testing methods and 'low'-level products

The WHO established SACtob in 2000 for providing technical guidance on matters related to tobacco product regulation. One of the early recommendations of SACtob was on the limitations of currently available testing methods. SACtob was of the opinion that machine-tested emission yields do not correspond to the actual levels of human consumption of toxic chemicals through inhaled smoke. While the International Standards Organization/United States Federal Trade Commission (ISO/FTC) tests are useful for providing information to regulators, they cannot provide meaningful information to consumers. Because of multiple mechanisms of 'compensation', the total human exposure to toxic chemicals is high even in the case of products labelled to be low in tar and nicotine content by machine testing (see Box

### Box 7.3 Why is 'mild' not mild when it comes to tar and nicotine levels?

When nicotine levels are reduced in 'low tar–low nicotine' cigarettes, smokers tend to compensate in many ways to obtain their accustomed dose of 'nicotine fix'. Indeed, receptors in the throat respond even to puff by puff variations of nicotine dose. The smoker learns to inhale more deeply, smoke more cigarettes per day or push the filter back into the mouth to get unfiltered smoke. The health effects of smoking such cigarettes, therefore, ultimately are no different from those of smoking cigarettes with higher levels of tar and nicotine. Nevertheless, regulators must try to progressively lower the levels of as many harmful chemicals as possible, because of the potential for eliminating highly toxic chemicals (e.g. nitrosamines).

7.3). This is because consumers' beliefs and behaviours act as powerful modifiers in the pathway between cigarette yield and human consumption of toxic chemicals. An erroneous impression that cigarettes with 'lower' levels of tar and nicotine are 'safer' for human health leads to altered consumption patterns that may have adverse health effects on populations as well as individuals. Non-smokers, especially the youth, may be tempted to use tobacco products in the mistaken belief that they are safe. Smokers may abandon their efforts at cessation since the new product may act as a 'cessation decoy' through the false promise of safety. Smokers who have quit may return to the habit because they no longer fear the health consequences. Active smokers may even increase the volume of consumption of so-called 'safe' cigarettes, apart from using other compensatory mechanisms for obtaining their desired level of nicotine intake. All of these have adverse consequences on health, which are well documented in the following studies that provided the rationale for SACTob's recommendations.

In 2001, the US National Cancer Institute (NCI) completed its evaluation of the scientific basis for the relationship between FTC methods and the health effects of smoking, as well as the effects of marketing claims (e.g. 'reduced tar' and 'light') that are supported by the information derived from these methods. The NCI Monograph (Number 13, 2001) *Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine* presented the following five main conclusions:<sup>8</sup>

1. Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the past fifty years.
2. For spontaneous brand-switchers, there appears to be complete compensation for nicotine delivery, reflecting more intensive smoking of lower-yield cigarettes.
3. Widespread adoption of lower-yield cigarettes in the US has not prevented the sustained increase in the incidence of lung cancer among older smokers.
4. Many smokers switch to lower-yield cigarettes out of concern for their health, believing these cigarettes to be less risky or a step toward quitting. Advertising and marketing of lower-yield cigarettes may promote initiation and impede cessation—more important determinants of smoking-related diseases.
5. Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different brands of cigarettes.

Currently, there are two major issues of concern about the health claims based on the ISO/FTC methods: (i) machine measurements are not valid estimates of the exposure to smoke or nicotine received by smokers when they smoke different brands of cigarettes,<sup>9,10</sup> and (ii) many smokers currently believe that lower-yield or light cigarettes deliver less tar, produce lower rates of disease and are therefore 'safer'.<sup>11–14</sup> Because of these misconceptions, smokers believe those cigarettes marked as lower-yield or light and ultra-light are a reasonable intermediate step or alternative to cessation and may defer or avoid the one change in smoking behaviour proven to actually reduce their disease risk—cessation.

A study by the Health Education Authority in the UK<sup>15</sup> and several other studies have revealed that the tar and nicotine ratings, as displayed by the industry, are not clearly understood by consumers.<sup>16,17</sup> Due to the advertising and packaging methods adopted by the industry, smokers see these terms not as technical descriptors but as implying health benefits.<sup>18–20</sup> These advertising and marketing approaches have contributed to consumers' using lower-yield cigarettes in an attempt to reduce their health risks, or as a step towards or an alternative to smoking cessation.<sup>21,22</sup> A number

of reputed bodies have therefore recommended banning terms such as 'light', 'mild', etc.<sup>23,24</sup>

Based on the existing science, SACTob made the following conclusions and recommendations in 2002:

1. Tar, nicotine and carbon monoxide (CO) numerical ratings based upon current ISO/FTC methods, and presented on cigarette packages and in advertising as single numerical values are misleading and should not be displayed.
2. All misleading health and exposure claims should be banned.
3. The ban should apply to packaging, brand names, advertising and other promotional activities.
4. Banned terms should include light, ultra-light, mild and low tar, and may be extended to other misleading terms. The ban should include not only misleading terms and claims but also names, trademarks, imagery and other means of conveying the impression that the product provides a health benefit.

### Obligations of WHO Member States under the FCTC (as relevant to tobacco product testing and regulation)

Three articles in the FCTC address regulation of tobacco products in terms of their permitted content, testing methods, industry disclosures to government, consumer information and public disclosure.<sup>25</sup>

Article 9: Regulation of the contents of tobacco products

**Article 9** requires testing of product contents and emissions, through recommended methods, as well as placing of regulatory limits on those contents and emissions.

Article 10: Regulation of tobacco product disclosures

**Article 10** obligates each Party to ensure adequate disclosure, by the industry to the

government and also, via government directed mechanisms, to the public.

Article 11: Packaging and labelling of tobacco products

**Article 11** requires the Parties to prevent packaging and labelling from being used as vehicles for false or misleading information or impressions and to provide the consumers information on relevant constituents and emissions, as defined by national authorities.

It is worth noting that Article 11.2 does not specifically require the Parties to provide quantitative information on the levels of toxic chemicals in the constituents and emissions of tobacco products. Mere listing of some of these toxic chemicals would satisfy the requirements of Article 11.2. Statements such as 'this product contains nitrosamines which cause cancer and nicotine which is addictive' should suffice to meet this requirement.

National authorities may wish to enact legislation to mandate the disclosure of the levels of these chemicals (such as tar, nicotine, carbon monoxide [CO] and nitrosamines) but the FCTC itself does not impose such an obligation. Since SACTob has previously expressed its view that providing consumers with such quantitative information may lead to false perceptions of 'relative safety' of some products, the wording of Article 11.2 enables Member States to avoid such quantitative communications to consumers, if they choose to do so, while providing relevant information on the presence of toxic chemicals in the product and/or its emissions. The regulator would then ensure that the levels of the chemicals are no higher than the prescribed upper levels (to attempt limitation of harm) while avoiding public disclosure of those levels to the consumer (since there is no available proof of relative safety of that product).

Does the FCTC require countries to establish or strengthen 'independent' tobacco product testing laboratories?

Countries who become Parties to the FCTC could fulfil all of their obligations under Articles 9, 10 and 11 by any of the following mechanisms, for tobacco product testing, content regulation and disclosure:

- Use government-run laboratories;
- Use government-accredited 'independent' laboratories which provide commercial service to multiple users;
- Use government-recognized research laboratories located in academic institutions, if they undertake to perform periodic testing, as per the requirements of the National Regulatory Authority (NRA);
- Depend on information provided by the tobacco industry which may generate that information from laboratories it owns or contracts.

One or more of the above mechanisms could be utilized, provided that any laboratory which generates the required information follows the guidelines prescribed under Article 9 (to be provided by the Conference of Parties [COP] and further legislated by the concerned Member State).

### **Why should India use an independent laboratory?**

Despite the fact that the FCTC does not impose a specific obligation on them to use independent testing laboratories for tobacco product regulation, developing countries such as India should invariably use such laboratories. Whether such laboratories are government operated or government accredited and situated within the country or accessible from other locations is not of much importance, provided they are clearly demonstrated to be free from the influence of the tobacco industry.

The most compelling reason for urging developing countries to use such independent laboratories is the dismal duplicitous record of the tobacco industry in consistently concealing relevant scientific information from the regulatory authorities as well as the consumers and public. This has become increasingly

evident, through repeated revelations of such conduct in developed countries, during legislative or judicial review. It would be a folly to depend solely on data furnished by the tobacco industry, without having the ability to subject those data to independent verification.

The capacity for independent verification is integral to a competent regulatory process. Without that capacity, the regulator may mandate a testing procedure or prescribe limits for levels of toxic chemicals but would lack the assurance that these mandated measures are being strictly adhered to by an industry which has not been reputed for scrupulous conduct.

### **Which products need to be tested and for what physicochemical characteristics of the constituents and emissions?**

The FCTC does not specify the chemicals and physical properties which are to be tested for, but does state that both contents and emissions of tobacco products need to be tested and regulated. The COP would be called upon to provide guidelines, which are to be developed in consultation with relevant international bodies (Article 11). It is generally expected that the WHO would undertake this task, with the help of expert committees such as SACTob. Ultimately it is the COP which will approve and recommend the testing guidelines to the Member States who are Parties to the FCTC. Each Party is expected to enact suitable national legislation and undertake measures to implement the testing and regulatory provisions in accordance with those guidelines. The language of Article 11 does not make it clear as to whether these guidelines are prescriptive or merely recommendatory, and to what extent each Party must undertake the testing or require tests to be performed by the industry. These issues would need to be addressed and resolved by the COP.

SACTob recommends the following list of analytes for testing purposes. This list is an initial minimum list for product content and emissions. It is not exhaustive and will require regular updating. These results will be reported per cigarette or per unit of any other smoked product.

### Product content

- Nicotine/free nicotine (smokeless products)
- Ammonia/ammonium ion
- Metals (arsenic, cadmium, chromium, lead, mercury, nickel, selenium)
- Nitrosamines (N-nitrosornicotine [NNN], 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone [NNK], N-nitrosoanatabin [NAT], and N-nitrosoanabasin [NAB])
- Menthol

### Emissions (mainstream and sidestream)

- Nicotine/free nicotine
- Tar
- CO
- Ratio of nicotine-free dry particulate matter to nicotine yield
- Polynuclear aromatic hydrocarbons: benzo[a]pyrene
- Volatiles: benzene, 1,3-butadiene, formaldehyde, acetaldehyde
- Nitrosamines: NNN, NNK, NAT, NAB
- Metals: arsenic, cadmium, chromium, lead, mercury, nickel, selenium
- Gas phase compounds: nitrogen oxide, hydrogen cyanide

This list is subject to addition and revision. It is considered optimal to expand this list to include other toxins in the profile. These additional compounds have been commonly called the Canadian list and include other semi-volatiles, additional polynuclear aromatic hydrocarbons, other volatiles, nitrosamines, etc.

A limitation of the laboratory methods available so far is that they have not been standardized for testing smokeless tobacco products. The abundance of a variety of smokeless tobacco products in India makes it essential that they be tested and regulated. Their constituents (ingredients and additives) would also need to be tested. Emissions are difficult to define, since there are no pyrolytic products.

Similarly, nicotine replacement products (NRPs) as well as other products vying to be recognized

as ‘harm reduction’ products are also likely to require regulatory testing. Research laboratories should be encouraged to test such products before they enter the regulatory pathway.

### What are the levels that must be set?

These would vary over time, with the goal of periodic lowering of the permitted upper level for each chemical. India has not yet set the upper levels for nicotine and tar, the two chemicals which need to be regulated under its law.

In 2001, the European Union decreed that from 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in Member States shall not be greater than:

- 10 mg per cigarette for tar;
- 1 mg per cigarette for nicotine;
- 10 mg per cigarette for CO.

As regards cigarettes to be exported, these rules will apply from 1 January 2007 onwards.

Brazil also enacted legislation during 1996–2001 to regulate tobacco products. The maximum limits for tar, nicotine and CO levels have been specified for multistage reduction. The notification of March 2001 provides an 18-month period by which a maximum of 10 mg, 1 mg and 10 mg, respectively, of tar, nicotine and CO levels would have to be attained for each cigarette. These levels are to be printed on cigarette packages, followed by a statement ‘There aren’t safe levels for consumption of these substances.’ An NRA has been established and efforts are under way for strengthening independent laboratory capacity for regulatory testing. The revenue model for such a laboratory would involve a levy of user charges to be paid by tobacco manufacturers whose products are to be tested.

South Africa too has enacted legislation which mandates that tar and nicotine yields of cigarettes marketed in South Africa should not exceed 15 mg and 1.5 mg, respectively, with effect from 1 December 2001. These would need to be further downscaled to 12 mg and 1.2 mg per

cigarette, for tar and nicotine, respectively, from 1 June 2006. The availability of independent laboratories for conducting tobacco product testing needs to be ascertained.

### Laboratory capacity: Research and testing

SACtob has, in a recent report (2004), identified the needs of establishing laboratory capacity for tobacco product testing. Laboratory capacity refers to the physical and human resources needed to conduct research, develop standards for product performance, develop product testing methods and conduct product testing. The Institute of Medicine report on tobacco harm reduction summarizes the scientific basis for testing the physical attributes of tobacco products that contribute to addiction, morbidity and premature mortality.<sup>26</sup> It is useful to distinguish two main types of laboratory capacity required to enable implementation of Articles 9–11 of the FCTC: research and testing.

*Research:* The main goals of research are to better understand the nature of tobacco products, how they work, their effects and how they might be modified to alter their effects (e.g. by new ingredients and designs). This can include molecular, *in vitro*, animal and human research, addressing topics such as the relationship between tobacco-specific nitrosamines (TSNAs) and lung cancer risk, the relationship between ingredients and addiction risk, and the relationship between particle size and lung retention of cigarette smoke toxicants. Research on human patterns of use and how they interact with product characteristics is also essential.

*Testing:* Repetitive examination and evaluation of products according to standardized methods to assess product performance is generally referred to as testing. This can occur at several stages. To help inform regulation, it can be useful to test products on a standardized protocol to characterize their delivery of substances such as for CO, nicotine and nitrosamines.

Laboratory research and testing must be

coordinated. Although research, testing and development of performance standards may be distinguished for conceptual and organizational purposes, they are not mutually exclusive. Indeed, they must be interactive. Performance standards require testing of a broad range of product characteristics, conducting research to determine which toxicity-reducing goals are feasible and developing standardized testing protocols. This process will continually evolve and rapidly expand to address the challenges raised by existing products. As the number of new products in the pipeline increases, it is reasonable to assume that the need for developing performance standards will similarly expand. Research and testing needs include developing assays of physical characteristics, chemical composition, performance of products, *in vitro* and *in vivo* toxicology testing, and assessment of human-use patterns to determine the interactions between behaviour and product characteristics as well as actual human exposures.

### Establishing laboratory capacity

The following principles are recommended for consideration in establishing laboratory capacity, whether through contracting mechanisms to existing laboratories or developing new laboratories:

1. The primary goal of establishing laboratory capacity is to provide a scientific basis for improving public health through tobacco product regulation.
2. Both research and testing laboratory capacity must be supported, developed, maintained and altered as conditions dictate. Research and testing operations have overlapping but distinct missions that must be recognized.
  - *Research laboratories:* A major characteristic of research endeavours is the presence of considerable flexibility to pursue the process of scientific discovery and analysis.
  - *Testing laboratories:* A major characteristic of testing operations is the capability of adhering to reliable, standardized, high-throughput protocols.

3. International coordination and facilitation of emerging laboratory capacity to implement certain provisions of the FCTC require at least two discrete expert considerations:
  - *Administrative issues* such as how to develop, fund and contract for laboratory capacity must be addressed. Mechanisms for funding may need to vary to meet differing needs on a country- or region-specific basis.
  - *Scientific issues* such as the prioritization and sequencing of potential targets of tobacco product design and ingredients must be addressed, and a mechanism for international sharing of knowledge and coordination implemented.
4. In view of the vast number of potential targets for study and testing, as well as the need for funding and developing standardized protocols, priorities and a timetable for their implementation in light of the FCTC must be developed to guide the sequencing. Priorities must be driven to the greatest extent possible by the existing scientific basis and public health needs, following review by appropriate scientific advisory groups, to provide oversight and guidance. WHO and its advisory committees shall identify the means whereby such priorities are established. In this regard, there are provisions in the FCTC that call on the Parties to cooperate in the scientific, technical and legal fields, and in the provision of related expertise.
5. The vital public health importance of product regulation necessitates the development of laboratory capacity as quickly as possible. However, the Study Group recognizes that the large magnitude of the need for research and testing capacity necessitates gradual development of laboratory capacity as funding is obtained, expertise is developed and laboratory facilities are established. The development pace should consider the critical importance of ensuring that high standards of integrity and quality of science are preserved.
6. Research and testing laboratories must develop mechanisms to share information, both nationally and internationally, and collaborate as necessary to ensure that the emerging scientific basis guides all. Mechanisms for sharing methods and results to ensure standardization of testing protocols are vital.
7. Transparency in operations is necessary to provide regulatory authorities and the public with confidence in the integrity of laboratory operations and findings.
8. The overall laboratory testing needs must be dictated largely by risk to humans as documented in human studies and animal models; therefore, laboratory capacity must enable physical, chemical and biological testing, together with the ability to modify and correct procedures following the findings by actual human-use assessments.
9. Surveillance of the health effects and changes in individual and population patterns of tobacco use, for example, as a function of changes in marketing messages are essential to guide the process and provide an objective basis for changing and improving the priorities for research and protocols for testing.
10. The laboratories must provide mechanisms for training new scientists and building the greatly expanded base of expertise and human capacity needed to fully implement the FCTC in the future.
11. Funding must be predictable, sustained and long term, with gradual growth potential provided as needed to enable laboratories to keep pace with emerging product issues, and the emergence of broader technical expertise that will enable laboratory expansion. Examples of such funding approaches include a surcharge on tobacco products as has been done in other areas of product regulation.
12. Regardless of the mechanism for funding, there should be assurance that the independence and integrity of research and testing operations are not compromised or inappropriately influenced.
13. Laboratory capacity addressed by these principles does not include the regulation

- of non-tobacco nicotine products (smoking cessation medicines) but it is urged that regulation of tobacco products and medicines be mutually informed so that there are no inappropriate inconsistencies in regulation.
14. Existing independent laboratories serving the tobacco industry provide potential laboratory capacity, but if they are to be used to serve public health regulation, provisions must be put into place to assure independence of operations and credibility. Appropriate 'firewalls' must be developed in the drawing up of contracts for such laboratories.
  15. The need to provide for flexible adaptation to altered or novel tobacco products is critical as the changing cigarettes and smokeless products have already led to the problem of inadequacy of the ISO/FTC protocol. Recent years have witnessed even more radical changes in the design of cigarettes and novel cigarettes as well as smokeless products, and further changes need to be anticipated. Therefore, it is critical that the research and testing capacity anticipate rapid evolution of products and have the capacity to adjust.
  16. For countries with little or no existing laboratory capacity and insufficient resources for establishing them, such as in many developing countries, it is vital that networks be established to enable resource sharing and collaborative efforts to achieve the recommended laboratory capacity.
  17. It is urged that all new tobacco products and modified existing products be subjected to pre-market review by regulatory authorities. Rigorous pre-market review is especially critical when claims such as 'harm reduction' are made or anticipated.
  18. Pre-market review and product evaluation, which would be required by effective implementation of certain articles of the FCTC, are neither intended nor capable of assuring the safety of the products.

### Development of laboratory capacity in India

India is now in the process of developing laboratory capacity for regulatory testing of tobacco products. In addition, it also needs to consider methods to develop research laboratories. At present, it has no dedicated laboratory of either kind which can perform the range of testing recommended by SACTob, though there are some laboratories capable of performing some tests (Table 7.5).

It is essential that India develop adequate laboratory capacity for both testing and research. The range of products to be tested must also include all major categories of tobacco products consumed in India: cigarettes, *beedis* and

**Table 7.5** Tobacco testing facilities in India

Testing institutes/laboratories		Product	Constituents	Standard used
Government	Central Tobacco	Cigarettes	Tar, nic and CO	ISO
	Research Institute (CTRI), Rajamundry (Ministry of Agriculture)	Leaf	Nic TSNA, sugar, chloride	BIS Nil
Medical	Tata Memorial Hospital	Cigarettes	Tar and nic	Nil
Government	Bidi Tobacco Research Station (BTRS), Anand (Ministry of Agriculture)	<i>Beedis</i>	Tar, nic CO	BIS Nil
		Leaf	Nic	BIS
Industry		Cigarettes	Tar, nic and CO	ISO
		<i>Beedis</i>	Tar and nic	–

Nic: nicotine; CO: carbon monoxide; TSNA; Tobacco-specific nitrosamines; BIS: Bureau of Indian Standards; ISO: International Standards Organization

chewed tobacco products such as *gutka*. The capacity must also extend to the testing of purported ‘harm reduction’ products (such as herbal *beedis*), which are burgeoning in the Indian market. Both independent testing laboratories (with government control or affiliation) and research laboratories (in academic/research institutions) need to be established for regulatory purposes.

Establishment of such laboratory capacity also requires the development of human resources (technical training) and financial resources (for equipment and operations). International collaboration with reputed laboratories (such as the tobacco testing laboratory at the Centers for Disease Control and Prevention, Atlanta, USA) will help in the development of technical capacity. For financing the laboratory in a sustainable manner, the Brazilian model of compulsory testing of tobacco products with levy of a user fee appears to be the best. If every brand of a tobacco product was to require compulsory testing every year for being permitted market operations, and if a fee was charged by the government for conducting such tests in a government-owned/accredited

laboratory, the financial resources required for running a high-quality laboratory would be readily available on a sustainable basis.

### Establishment of an NRA

For regulatory restraints on tobacco to be successful, it is essential that a strong NRA be established, with a clearly defined mandate, and adequate resources to monitor and discipline the tobacco industry. The NRA has to be linked to the testing as well as research laboratories on the one hand and to the administrative ministries on the other. The NRA would need to regulate on issues related to testing methods, upper limits of constituents and emissions of tobacco products, packaging and labelling as well as health claims. The authority of the NRA may also be extended to other areas covered under the Indian law. The NRA and the regulatory laboratories affiliated to it should be empowered to access all relevant information from the tobacco product manufacturers including details of raw material analysis, industrial processes, consumption by product, age of consumer and other factors which influence the population harm potential.

## 7.2 TOBACCO PRODUCT REGULATION, TESTING AND LABORATORY STRENGTHENING

### KEY MESSAGES

- The regulation of tobacco products aims to progressively reduce the levels of harmful chemicals and alter their physical characteristics.
- A Scientific Advisory Committee on Tobacco Product Regulation (SACtob), established by the WHO in 2002, provides technical guidance on matters related to tobacco product regulation—limitations of testing methods, setting up of upper limits for toxic ingredients and their emissions.
- India needs to develop laboratory capacity for regulatory testing of tobacco products (both smoking and chewed tobacco products).
- To monitor and discipline the tobacco industry, it is essential to develop a National Regulatory Authority with a clearly defined mandate and adequate resources.