

LAW N. 376 OF 14 DECEMBER 2000

**REGULATION OF HEALTH STANDARDS IN SPORTS
ACTIVITIES AND THE FIGHT AGAINST DOPING**

Section 1 - Health standards in sports activities, prohibition of doping

1. The aim of sport is to promote individual and collective health and thus sporting activities must be governed by the ethical principles and educational values set forth in the Anti-Doping Convention, and relative appendix, opened in Strasbourg on 16 November 1989 and ratified pursuant to Law N° 522 of 29 November 1995. Sporting activity shall therefore be monitored according to the provisions established by the legislation in force regarding the protection of health and the legality of competitions and may not be undertaken using techniques, methodologies or substances of any type which could present a risk to the psycho-physical integrity of the athletes involved.
2. Doping consists in the administration or taking of drugs or substances which are biologically or pharmacologically active, and the adoption of - or the participation in - medical practices which are not justified by pathological conditions and may change the psycho-physical or biological conditions of the organism and thus alter the performance of the athletes.
3. For the purposes of this law, the administration of drugs or substances which are biologically or pharmacologically active, and the adoption of medical practices which are not justified by pathological conditions and which may - and indeed intend to - modify the results of monitoring of the use of the drugs, substances and practices mentioned in Subsection 2 here in above, shall also be deemed to constitute doping.
4. Should an athlete suffer from a pathological condition which has been regularly documented and certified by a physician, he or she may be prescribed specific treatment provided such treatment is administered according to the procedures set forth in the relative and specific European or Italian decree of registration and the dosages comply with those established for the specific therapy. Providing the athlete makes the relevant documentation available to the authorities responsible, he or she may participate in sporting competitions, in accordance with the rules of the game, as long as such activity does not present any risk to the athlete's psycho-physical integrity.

Section 2 – Classification of doping substances

1. All drugs or substances which are biologically or pharmacologically active, as well as any medical practices whose use is deemed to constitute doping pursuant to Section 1, and in accordance with the Sections of the Strasbourg Convention, ratified pursuant to Law N° 522 of 29 November 1995 and the indications of the International Olympic Committee (IOC) and the international organisations responsible for the sports sector, shall be classified into classes of drugs, substances or medical practices approved by decree of the Minister of Health, in agreement with the Minister for Cultural Heritage and Activities, according to the proposal put forward by the Commission for the Monitoring and Control of Doping and the Protection of Health in Sports Activities of which in Section 3.
2. The classification of drugs or substances which are biologically or pharmacologically active is determined on the basis of their respective chemical and pharmacological characteristics; the classification of medical practices is determined on the basis of their respective physiological effects.
3. The classes shall be revised on a regular basis every six months or sooner and any variations shall be made according to the procedures set forth in Subsection 1.
4. The decree of which in Subsection 1 shall be published in the *Official Gazette*.

Section 3 - Commission for the Monitoring and Control of Doping and the Protection of Health in Sporting Activities

1. A Commission for the Monitoring and Control of Doping and the Protection of Health in Sporting Activities (hereinafter the “Commission”) shall be instituted at the Ministry of Health for the purpose of undertaking the following activities:
 - a) Establishing the classes of which in Section 2, Subsection 1, and revising such classes according to the procedures set forth in Section 2, Subsection 3;
 - b) Determining, in compliance with the indications of the IOC and other relative organisations and institutions, the cases, criteria and methodologies for anti-doping control and identifying the competitions and sporting activities for which health checks shall be conducted by the laboratories of which in Section 4, Subsection 1, on the basis of the characteristics of the competitions and sports activities involved;
 - c) Performing anti-doping controls and checks on the health of the athletes during and outside competitions, availing itself of the laboratories of which in Section 4 as well as physicians specialised in sports medicine; preparing

research programmes into drugs, substances and medical practices which may be used for doping in sporting activities;

d) Identifying means of co-operating with National Health Service structures in order to implement anti-doping controls;

e) Maintaining working relationships with the European Union and international organisations and guaranteeing participation in anti-doping programmes;

f) Promoting information campaigns for the protection of health in sporting activities and the prevention of doping, especially in all state and private schools of every type and level, in co-operation with public authorities, the Italian National Olympic Committee (CONI), national sports federations, affiliated sports clubs, public and private organisations for the promotion of sports, and availing itself of physicians specialised in sports medicine.

2. Within ninety days of the coming into force of this law, the Minister of Health, in agreement with the Minister for Cultural Heritage and Activities and with the approval of the relevant Parliamentary Commissions, shall issue a decree confirming the regulation establishing the ways and means in which the Commission shall be organised and shall function,

3. The Commission shall be composed of:

a) Two representatives from the Ministry of Health, one of whom shall be appointed chairman;

b) Two representatives from the Ministry for Cultural Heritage and Activities;

c) Two representative from the Conference of Chairmen of Regions and Autonomous Provinces;

d) A representative from the Higher Institute of Health;

e) Two representatives from CONI;

f) A representative chosen by trainers and coaches;

g) A representative chosen by athletes;

h) A legal toxicologist;

i) Two physicians specialised in sports medicine;

l) A paediatrician;

m) A pathologist;

n) A biochemist;

o) A pharmacologist;

p) A representative chosen by sports promotion bodies;

q) An expert in pharmaceutical legislation.

4. The Commission members of which in letters f), g) and p) of Subsection 3 shall be proposed by the Minister for Cultural Heritage and Activities; the members of which in letters h) and n) of Subsection 3 shall be proposed by the National Federation of Associations of Chemists; the members of which in letters i), l) and m) of Subsection 3 shall be proposed by the National Federation of Associations of Physicians and Dentists; the members of which in letters o) and q) of Subsection 3 shall be proposed by the National Federation of Associations of Pharmacists.

5. The members of the Commission shall be appointed by Decree of the Minister of Health, in agreement with the Minister for Cultural Heritage and Activities, and shall hold office for a non-renewable period of four years.
6. Remuneration of the members and the budget for the functioning and operations of the Commission shall be set, pursuant to the regulation of which in Subsection 2, within a maximum limit of Lit. 2 billion per annum.

Section 4 – Laboratories performing health controls regarding sporting activity

1. Health controls regarding the competitions and sporting activities identified by the Commission, pursuant to Section 3, Subsection 1, letter b), shall be performed by one or more laboratories accredited by the IOC or other international organisation recognised by the international regulations in force, on the basis of a convention signed by the Commission. Charges deriving from the convention shall not exceed a maximum limit of Lit. 1 billion per annum. The services provided by the accredited laboratories may not be charged to the National Health Service or to the State budget. The laboratories of which in this Section shall be supervised by the Higher Institute of Health, according to ways and means set forth in the Decree of the Minister of Health, after consultation with the Director of the Institute, to be issued within ninety days of the coming into force of this law.
2. The laboratories of which in Subsection 1 shall complete the following tasks:
 - a) Perform anti-doping controls according to the rules approved by the Commission pursuant to Section 3, Subsection 1, letter b);
 - b) Conduct research into drugs, substances and medical practices which may be used for the purpose of doping in sporting activities;
 - c) Cooperate with the Commission in defining the requisites of which in Subsection 3 of this Section.
3. Control of competitions and sporting activities other than those identified pursuant to Section 3, Subsection 1, letter b) shall be performed by laboratories with the organisational and functional requisites set forth in a Decree of the Minister of Health, after consultancy with the Commission, within 120 days of the coming into force of this law.
4. As from the date of signing of the conventions of which in Subsection 1 and in any case as from the 180th day following the coming into force of this law CONI shall cease all activities regarding control of the analysis laboratory which is being active in the CONI itself.

Section 5 – Responsibilities of the Regions

1. The Regions shall plan Anti-doping and health protection initiatives with regard to sporting activities, identifying the services responsible and availing themselves of prevention departments as part of the regional health plan. The Regions shall also coordinate the activities of the laboratories of which in Section 4, Subsection 3.

Section 6 – Integration of the regulations of sporting organisations

1. CONI, sports federations, affiliated sports clubs, sporting associations and public and private organisations for the promotion of sport shall adjust their regulations to encompass the provisions of this law. They shall provide sanctions and disciplinary procedures to regulate their members in the case of doping or refusal to submit to testing.
2. Being legally recognised as autonomous, the national sports federations may establish sanctions to discipline the administering or taking of drugs or of biologically or pharmacologically active substances and the adoption of - or participation in - medical practices which are not justified by pathological conditions and may change the psycho-physical or biological conditions of the organism and thus alter performance of the athletes, regardless of whether such practices are classified in the classes of which in Section 2, Subsection 1 or otherwise, on condition that such drugs, substances or practices are considered as to constitute doping by other international regulations in force.
3. The organisations of which Subsection 1 shall also prepare all the documentation necessary in order to comply with the rules governing the protection of health set forth in this law.
4. Athletes shall comply with the rules of which in Subsection 1 and shall confirm their full awareness and acceptance of the terms and conditions therein.
5. CONI, national sports federations and organizations for the promotion of sport shall ensure that all managers, technical staff, athletes and health care personnel are kept up to date with regard to problems related to doping. The activities of which in this Subsection shall not result in any further charges to public finance.

Section 7 – Drugs containing doping substances

1. On an annual basis, the producers, importers and distributors of drugs included in the pharmacological classes prohibited by the IOC as well as those included in the classes of which in Section 2, Subsection 1, shall provide the Ministry of Health with

data confirming the amounts produced, imported, distributed and sold to pharmacies, hospitals or other authorised facilities, for each pharmaceutical speciality.

2. The packaging and instruction sheet of the drugs of which in Subsection 1 shall show a special mark to be determined by the Commission. Furthermore, comprehensive details of “Precautions for those practising sports” shall be provided in a specially dedicated paragraph of the instruction sheet.
3. The Ministry of Health shall monitor compliance with the regulations of which in Subsection 2 regarding the packaging of drugs on application for national registration or on application for variation or on completion of 5 year revision of registration.
4. Galenical, officinal or magisterial preparations containing active ingredients or excipients included in the classes of prohibited drugs or substances established by the IOC as well as those of which in Section 2, Subsection 1, may only be prescribed in writing on a non-repeatable basis. The dispensing pharmacist must conserve the original prescription for six months.

Section 8 – Reporting to Parliament

1. The Minister of Health shall present Parliament with an annual Report on the state of implementation of this law and the activities completed by the Commission.

Section 9 – Penalties

1. Unless a more serious crime is constituted, whomsoever should obtain drugs or biologically or pharmacologically active substances included in the classes of which in Section 2, Subsection 1, which are not justified by pathological conditions and which may change the psycho-physical or biological conditions of the organism and thus alter the performance of athletes on behalf of a third party, or administer, take or encourage the use of the aforementioned substances or substances which may - and indeed intend - to modify the results of monitoring of the use of the drugs, shall be punished by imprisonment for between three months and three years and a fine of between Lit. 5 million and Lit. 100 million.
2. Unless a more serious crime is constituted, the penalties of which in Subsection 1 shall be applied to whomsoever shall adopt - or participate in - any medical practices included in the classes of which in Section 2, Subsection 1, which are not justified by pathological conditions, may change the psycho-physical or biological conditions of the organism and thus alter the performance of athletes, or may -and indeed intend to- modify the results of monitoring of the use of such practices.

3. The penalties of which in Subsection 1 and 2 shall be increased:
 - a) Should the health of any party be harmed by the criminal act;
 - b) Should the criminal act be committed against a minor;
 - c) Should the criminal act be committed by a member or employee of CONI or any national sports federation, club, association or organisation recognised by CONI.
4. Should the criminal act be committed by a professional figure operating in the health care sector, the guilty party shall be punished with the aforementioned penalties and temporarily suspended from exercising his/her profession.
5. In the case of which in Subsection 3, letter c), the guilty party shall also be permanently banned from the offices of CONI or any national sports federation, sports clubs, association or sports promotion organisation recognised by CONI.
6. Issue of a sentence of guilt shall automatically result in confiscation of the drugs, pharmaceutical substances and other items used to perpetrate the crime.
7. Whosoever shall trade in the drugs and biologically or pharmacologically active substances included in the classes of which in Section 2, Subsection 1, other than through retail pharmacies, hospital pharmacies, retail dispensaries and other facilities in which pharmaceuticals are stored for use on patients, shall be punished with imprisonment of between two and six years and a fine of between Lit. 10 million and Lit. 150 million.

Section 10 – Financial coverage

1. As from the year 2000, CONI shall be responsible for any charges deriving from implementation of Section 3, assessed as standing at Lit. 2 billion per annum, and Section 4, assessed as standing at Lit. 1 billion per annum. The amount corresponding to the aforesaid expenses shall be paid by CONI to the Revenue Office of the Budget and Economic Planning Department by 31 March of each year and, on presentation of the first application, within 60 days of the date of coming into force of this law.
2. The amount paid to the Revenue Office of the Budget and Economic Planning Department pursuant to Section 1 shall be reassigned to a specific basic budget item of the budget of the Ministry of Health.
3. The Ministry of the Treasury, Budget and Economic Planning shall be authorised to effect the necessary variations to the budget by its own decree.