# Screening report Croatia

**Chapter 28 – Consumer and health protection** 

# **Date of screening meetings:**

Explanatory meeting: 8 - 9 June 2006 Bilateral meeting: 10 - 11 July 2006

#### I. CHAPTER CONTENT

The *acquis* under the Consumer and Health Protection chapter consists of horizontal policy instruments, including financial support, regulatory and governing measures as well as vertical policies. These describe in detail the mechanisms, on the one hand, for the protection of the consumer's safety and his/her economic interests and, on the other hand, human public health.

The *acquis* in the area of **consumer protection** includes the following instruments: a general financing framework and rules for the governing of consumer protection at the Community and Member State level, including injunctions and access to justice. It also covers aspects related to the consumer's general product safety, such as dangerous imitations, liability for defective products and the Community's Rapid Alert System (RAPEX), as well as topics like sale of consumer goods and associated guarantees, unfair contract terms, price indications, doorstep selling, distance selling, distance marketing of financial services, consumer credits, misleading and comparative advertising, unfair commercial practices, timeshare, package travel and rights of flight passengers.

The *acquis* in the area of **public health** comprises measures as regards the general financing framework and measures for governing this area. It also deals with issues related to tobacco, communicable diseases, blood, tissues and cells, mental health, socio-economic determinants of health, health inequalities, alcohol, cancer as well as health and environment.

Member States need to transpose the *acquis* into national legislation. The implementation and enforcement of consumer and health protection policies require adequate administrative capacities and infrastructure at national, regional and local level. As regards consumer protection, this refers to effective market surveillance and appropriate independent judicial and out-of-court dispute resolution mechanisms. It is also necessary to raise public awareness, consult with the public and involve consumers actively in effective policy implementation, thus informing and educating the consumer and ensuring a role for consumer associations.

# II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

This part summarises the information provided by Croatia and the discussion at the screening meeting. Croatia indicated that it can accept the *acquis* regarding consumer and health protection. It indicated that it does not expect any difficulties to implement the *acquis* by accession.

#### **II.a.** Consumer protection

# Horizontal aspects

Croatia has prepared a National Consumer Protection Programme 2005–2006 stemming from and driven largely by its engagement with the EU. This Programme currently provides Croatia's Consumer Policy Framework as regards the principles, goals, priorities, timetable for activities, finances for the implementation and support of consumer associations in order to establish a comprehensive and efficient consumer protection mechanism.

As regards the legal framework, the *acquis* in the field of consumer protection is mainly transposed into Croatian legislation through the Consumer Protection Act (CPA - 2003) and the Civil Obligation Act (COA - 2005). Croatia is also currently in the process of drafting a new CPA the adoption of which is foreseen for the first quarter of 2007. In addition, the product safety issues are transposed through the General Product Safety Act (GPSA - 2003).

As far as the EU *Directive on Injunctions* is concerned, Croatia plans to transpose this horizontal piece of the *acquis* – covering 14 vertical Directives – into its national legislation through the new CPA.

Concerning the institutional framework, the main actors are the Consumer Protection Department of the Ministry of Economy, Labour and Entrepreneurship (MoELE) for assuring the compatibility of the Croatian legislation with the *acquis* and the Consumer Protection Department of the State Inspectorate which is the main market surveillance authority. In order to strengthen the legal and administrative capacity of the latter, a new regulation on the internal organisation of the State Inspectorate has been adopted. As a consequence, six new departments have been established to support the market inspectors in their daily inspection work. Furthermore, the Consumer Protection Council acts as an advisory body to the Minister of Economy, Labour and Entrepreneurship and represents all stakeholders in consumer protection, such as the Chamber of Commerce, the Chamber of Craftsmen, the Employers' Association and the Union of Consumer Protection Associations. Currently, 21 non-governmental bodies are registered as consumer associations and receive public financial assistance. Four Consumer Counselling Centres have been established to provide special technical expertise at regional level.

As regards the EU Regulation on Cooperation between National Authorities responsible for the Enforcement of the Consumer Protection Laws and the Regulation on the Conformity Checks on Safety of Products imported from Third Countries, Croatia stated that the plan is to make changes in legislation and working procedures of the State Inspectorate, thus becoming one of the competent authorities with the single liaison office, by accession.

As for the consumers' access to justice, consumer disputes in Croatia can be settled before regular courts and before institutions devoted to out-of-court procedures. The Civil Procedure Act is applied in disputes which are brought before regular courts, whereas in out-of-court procedures other regulations are applied, such as the Arbitration Act for arbitration and the Mediation Act for mediation. Since 1989, most of the consumer disputes have been solved by the Court of Honour at the Croatian Chamber of Economy. Nearly 40% of all disputes are being resolved through such settlements, and if no agreement is reached, the procedure is continued before a court council. The council members are independent legal experts or retired judges. Consumer representatives are not members of the court's councils. However, in the draft of the new Consumer Protection Act, a solution is inserted according to which the court's councils will have a consumer representative.

## Product safety related issues

The General Product Safety Act (GPSA) aims at transposing the EU *Directive on General Product Safety*. Inspectors from the State Inspectorate are empowered and have the necessary legal instruments to carry out efficient market surveillance.

Croatia indicated that the rules for the EU system on Rapid Exchange of Information on Dangers arising from the Use of Dangerous Products (RAPEX) have been transposed into Croatian legislation through the "Ordinance on System of Exchange of Information concerning Products that represents Risk for Consumers' Health and Safety". The State Inspectorate working together with other bodies is designated to be the RAPEX contact point.

As regards EU rules on *Dangerous Imitations*, the transposition is scheduled for the fourth quarter of 2007 through an amendment of the GPSA. Nonetheless, already now the general provisions of the GPSA prohibit the production, import, export and placing on the market of

unsafe products misleading consumers, especially children. Both legal and natural persons can be fined for the violation of this prohibition.

According to Croatia, the EU *Directive on the Liability for Defective Products* is fully transposed through the Civil Obligation Act (COA).

# Non-safety related issues

Croatia indicated that the EU *Directive on Certain Aspects of the Sale of Consumer Goods and Associated Guarantees* is transposed into Croatian legislation through the COA.

As regards the EU *Directive concerning Unfair Terms in Consumer Contracts*, Croatia indicated that it is transposed into Croatian legislation through the CPA and that it is mostly in compliance with the EU terms. The State Inspectorate is in charge of supervising the enforcement. The courts of law are to be addressed in the event of disputes between a consumer and a professional.

The CPA also aims at transposing the EU *Directive on Price Indications*. Full alignment with EU requirements is foreseen with the adoption of the new CPA. The State Inspectorate is in charge of market surveillance. Penalties are imposed for infringements; individual persons can be fined, as well as both natural and legal persons in charge of the legal persons. It has been noted that more than half of the infringements observed by the State Inspectorate were related to price indications.

Croatia indicated that the EU *Directive on Contracts negotiated away from the Business Premises (Doorstep Sale)* is transposed into Croatian legislation through corresponding articles in the CPA and that the transposition is mostly *acquis* compliant. Full alignment with EU requirements is foreseen with the adoption of the new CPA. The current competences of the State Inspectorate in market surveillance should allow an efficient market surveillance concerning the enforcement of the EU requirements. Violations of the rules can be fined.

For the EU *Directive on Distance Sales* transposition has been partly achieved. Further work is required to include the rules laid down by the two amendments to the Directive. Full alignment with EU requirements is foreseen with the adoption of the new CPA.

Also transposition of the EU *Directive on Distance Marketing of Financial Services* is foreseen with the adoption of the new CPA.

The CPA and one additional ordinance form the basis for a partial alignment with the EU *Directive on Consumer Credits* relating to contracts between business and consumers. The State Inspectorate is the institution in charge of dealing with consumer complaints.

At present, the CPA and the Act of Trade provide the Croatian legal basis for transposition of the rules laid down by the EU *Directives on Misleading / Comparative Advertising* as regards the business to consumer relation. However, the EU approach on the "court versus administrative" procedure and the organisation of protection in the context of the business to consumer relation will be taken into account with the adoption of the new CPA.

Concerning the EU *Directive on Unfair Commercial Practises (UCP)* Croatia has only a piecemeal approach to certain rules e.g. in its food legislation and in the Medical Products Act. However, according to Croatia, the new CPA will provide a transparent alignment with the UCP in all areas. As indicated above, the business to consumer relation will be included and blacklists on misleading acts and aggressive commercial practises will be established. It

is anticipated that the State Inspectorate will become the enforcement body in the context of the "court versus administrative" procedure approach.

Basic alignment with the EU *Directive on Timeshare* has been achieved through the existing CPA.

For the EU *Directive on Package Travel*, the COA provides the legal basis for alignment with the EU rules. Although the COA does not specify a body or authority competent for the enforcement and market surveillance, the enforcement and market surveillance of the rules regarding the package travel are provided through the provisions of Articles 66–74 of the Tourist Activities Act.

Some principles on passenger rights as laid down by EU Regulations on Rights of Flight Passengers can be found in the Croatian legislation. However, full alignment has not been achieved yet and no enforcement body has been designated or set up yet.

#### II.b. Public health

## Horizontal aspects

Croatia has adopted a National Healthcare Development strategy as well as a Healthcare Plan and Programme, forming its Public Health Framework as regards maintaining and promoting the health of its entire population and environment. Having an ageing population and a negative natural population growth rate, chronic non-communicable diseases and injuries predominate in national pathology. However, the modern health promotion policy applied is also directed at the prevention of other diseases and the proclamation of healthy lifestyles.

The Croatian Health Care Act forms the legal platform not only for the implementation of Croatia's public health policy together with the Health Insurance Act, but it also provides the main basis for the transposition and implementation of the *acquis*.

Concerning the institutional framework, Croatia has already established the necessary infrastructure for the enforcement of the *acquis* at central, county and local level. The main actors are the Ministry of Health and Social Welfare (MoH) and the subordinate Croatian National Institute of Public Health (CNIPH), Institutes of Public Health in each of the twenty counties and the Croatian Institutes of Occupational Health, Transfusion Medicine, Toxicology (CNIT), Radiation Protection (SIRP) and Mental Health as well as of Health Insurance. This system is also supported at field level through primary to tertiary health care services.

In more detail, the Croatian National Institute of Public Health covers all aspects of communicable and non-communicable diseases, social medicine, school medicine, drug addiction prevention, environmental health and microbiology as well as risk assessments in all of these areas.

#### Tobacco

Tobacco is produced in Croatia on around 7 000 ha, and around 12 000 tons of tobacco are harvested every year.

Croatia indicated that the *acquis* on tobacco has been partly transposed into Croatian legislation through the Act on Restriction of Tobacco Product Use, the Food and Objects of Common Use Safety and Surveillance Act and a corresponding ordinance, the Media Act,

the Occupational Safety and Health Act and one additional ordinance regarding conditions and methods for informing consumers about alcoholic beverages and tobacco products.

A national action plan on tobacco control has been drafted covering the outline for further alignment of Croatia's national legislation in order to achieve full compliance with the *acquis*. A timetable for the additional work on harmonisation is part of the national plan.

The ban on tele-shopping of tobacco products and the ban on sponsoring of TV programmes by undertakings with the principal activity of the manufacture or sale of tobacco products as laid down by the EU *Directive on TV without Frontiers* have still to be transposed into Croatian legislation.

The WHO *Framework Convention on Tobacco Control (FCTC)* was signed by Croatia on 2 June 2004, but has not yet been ratified.

Many enforcement authorities are involved in the control of the rules on tobacco. In Croatia, the different aspects are subject to inspection by the sanitary, health, occupational safety, school, catering and tourism authorities. A multi-disciplinary Government Anti-smoking Committee, appointed by the Ministry of Health and Social Welfare, takes a leading role in planning, initiating and monitoring of the tobacco control programme.

# Communicable diseases

The Croatian Health Care Act, the Croatian Communicable Diseases Control Act and eleven related ordinances represent the current state of play of legal alignment in this area. A new Act on the Protection of the Population form Communicable Diseases should be adopted in 2007.

Although already compatible with the *acquis* to a great extent, modifications of the national legislation are still necessary as regards the EU *List of Communicable Diseases and Case Definitions*; they are foreseen in the course of 2007.

Croatia indicated that the current Croatian networks on communicable diseases surveillance and control including the early warning and response system are mostly compatible with those of the EU and are operational for reporting to the World Health Organisation's (WHO) Centralised Information System for Infectious Diseases (CISID). Disease-specific features are already incorporated into the Croatian reporting system, so the system could easily be adapted for full integration into the EU networks. Eleven of the EU dedicated surveillance networks are operated by the Croatian National Institute of Public Health, whereas the twelfth on anti-microbial resistance is managed by the Infectious Diseases Teaching Hospital, Zagreb. Croatia also operates other surveillance networks, such as for vaccination coverage and vaccination side effects and nosocomial infections.

Reporting of communicable diseases has a long history in Croatia and is based on the work of specially trained and organised epidemiological services at communal and county level under the co-ordination of the Croatian National Institute of Public Health. The reporting networks also comprise healthcare related disciplines such as the veterinary services (zoonoses control), co-ordinated by the National Committee for co-ordinated activities and health threats. Supervision of the disease surveillance networks lies with the Ministry of Health and Social Welfare, in particular with a view to the protection of personal data. Statistics about the development of Poliomyelitis, Rubella, Hepatitis A, AIDS, active Tuberculosis, and other diseases in Croatia have been presented.

The competent authority for the *Rapid Alert System for Biological and Chemical Agents Threats* (RAS BICHAT) is the Ministry of Health and Social Welfare, which is also in charge of a potential crisis and emergency management. The Croatian National Institute of Public Health, the Croatian Institutes of Occupational Health, Transfusion Medicine, Toxicology and the Radiation Protection (SIRP) are involved in handling the emergency depending on the type of threat.

# Blood, tissues and cells

As regards the *Directive on quality and safety of blood and blood components*, Croatia adopted an Act on Blood and Blood Components in June 2006. Additional by-laws for the transposition and implementation of the three additional implementing Commission Directives are foreseen for full harmonisation with the *acquis* by the end of 2007.

Croatia is self-sufficient in terms of blood components and currently operates 24 full blood transfusion services (BTS) at hospitals, including the national centre (CITM). Furthermore, 13 blood banks at hospitals and one plasma fractionation centre serve patients only. Statistics on blood collection, processing and testing in Croatia for 2005 have been presented. The enforcement of the transposed *acquis* is expected to have a knock-on effect on BTS in Croatia as regards the need for a technical upgrade to the required EU standards. In this context, Croatia plans to restructure its BTS and to establish a new network by accession. Already a member of the EU Haemovigillance, Croatia reports on relevant data in this field.

The Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes and eleven additional ordinances, in force as of 30 June 2006, aim at full harmonisation with the two EU *Directives on Human Tissues and Cells*. The scope of the Croatian legislation is already broader than that of the EU, as Croatia includes organs as well. However, it is expected that the full enforcement of the transposed *acquis* will have an effect on the operation of the current seven tissue banks in Croatia concerning compliance with EU standards. Accreditation for banks holding bones, skeletal muscle tissues, skin, valves, cornea, umbilical cord, blood and stem cells will be organised under the rules laid down by the Act on Explantation and transplantation of parts of the human body for therapeutic purposes and the Ordinance on the activities and inspections of the hospitals or a part of hospitals with the tissue banks. Statistics on transplants have been presented.

# Mental health, socio-economic determinants of health, health inequalities, alcohol, cancer and health and environment

As regards mental health, Croatia has started drafting a National Mental Health Strategy, also involving a public debate. This Strategy is expected to be adopted by the Croatian parliament in 2007 and should cover the EU policy and provisions on *Community Mental Health Actions, Depression, Mental Illness* and the *Promotion of Mental Health*. At present, this field is covered by five Croatian Acts. The current objectives are in accordance with those of the EU, especially regarding the rights of patients, aspects of institutionalisation and strategies on de-institutionalisation. As regards enforcement, Croatia has about 9.8 specialists per 100 000 of population working in the mental health services and about 94.3 beds in psychiatric wards and hospitals. The overall co-ordination and planning to protect and promote mental health is with the Croatian Mental Health Institute. Procedures for the classification of patients, statistics on mental disorders, hospitalisation rates, homes, half-way homes, de-institutionalisation and results of treatments have been presented.

In line with the EU policy on *Drug Abuse Prevention*, Croatia has adopted a National Drug Abuse Prevention Strategy for the period 2006–2012 and a concrete action plan for the suppression of Drug Abuse for the period 2006–2009. The Croatian health services have various starting points and strategies for the prevention of and the fight against drug abuse and subsequent health related problems, such as drug related infectious diseases. School programmes focus on health promotion and the prevention of drug related risk behaviours, including information on condom use and on harm reduction activities such as needles and syringes exchange programmes. Croatia operates twenty centres for drug prevention and treatment in the county institutes of public health. Different drug substitute treatments, such as Methadone Substitution Treatment, are used in the medically assisted treatments of drug-addicted adolescents. Statistics from the register of drug abusers in relation to their drug dependence and treatment were presented.

For enforcement of the Council *Conclusions in June 2005 on Obesity, Nutrition and Physical Activity*, Croatia has drafted a national strategy and action plan for the period 2007–2011, focusing on the prevention of obesity. A National Action plan for food and nutrition is under preparation, too.

Croatia has only partially harmonised its legislation with the EU *Conclusion on Healthy Lifestyles* and EU policy and *Resolution on Health Determinants*. Nevertheless, Croatia has carefully analysed the health and inequalities situation of its population. Thus, Croatia is prepared to establish a sound programme for targeted vulnerable groups. Relevant statistical data have been forwarded to the EC, in particular on the interrelationship between socioeconomic status and mortality as well as socio-economic status and health of children and adolescents.

As regards the EU policy and *Conclusion and Recommendation on Alcohol*, Croatia has also identified problems arising from alcohol consumption (e.g. "alcopops") by young people. At present, a number of different Croatian acts form an instrument to fight this threat, setting rules for the distribution of alcohol, for drivers (zero-tolerance enforced since 2003), for under-aged youth and the treatment of alcohol-addicts and their rehabilitation, as well as related research. All this will be supported by a Croatian Action plan on alcohol which is being drafted by the Ministry of Health and Social Welfare. In addition, based on available Croatian statistics for the alcohol consumption and related harm, preparatory work on the Croatian Alcohol Strategy will start in 2007, to be adopted in 2009.

Likewise, Croatia has prepared an early detection programme for breast cancer which will be harmonised with the EU *Recommendation on Cancer Screening*. The national programme, the legal provisions and the enforcement structure provided through the County Public health institutes form the framework for the application of the *acquis* in Croatia. The existing Malignant Disease programme of Croatia also covers cervical and colorectal cancer. Statistics indicate that the mamma in female and the trachea/lung in male are the most common cancer sites in Croatia over the last 25 years. Breast cancer screening covering women aged 50 to 69 started national wide in the second half of 2006.

Croatia indicated that alignment with the EU *Recommendation on Electromagnetic Fields* has been achieved with the enforcement of the Croatian Non-ionising Radiation Protection Act and a corresponding Ordinance in 2004. The competent authorities for the inspection and control arrangements are the Sanitary Inspection of the Ministry of Health and the State Inspectorate for radio and telecommunication equipment. The adoption of an additional ordinance on the occupational protection of workers against non-ionising radiation is foreseen for 2007.

#### III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY

Overall, Croatia has already reached a good level of alignment with the *acquis*. It needs to finalise its transposition process on quite a number of EU measures in both parts of the chapter. It also needs to strengthen its administrative capacity for *acquis* enforcement and apply EU technical standards, in particular in the area of public health.

# III.a. Consumer protection

# **Horizontal** aspects

Croatia is undertaking all efforts to develop a consumer protection system in line with the EU Consumer Protection strategies and values. A Consumer Policy Framework and legal measures, as well as important infrastructure, have already been introduced in Croatia and are forming an efficient basis for the full alignment and completion of the transposition, implementation and enforcement of the *acquis* in Croatia.

For an efficient transposition of the *acquis*, Croatia has chosen three pillars, the Consumer Protection Act, the Civil Obligation Act and the General Product Safety Act. Croatia is aware of further alignment needs as a result of a gaps analysis report made in 2006. Besides the necessary refinement of current legal texts, Croatia still needs to align with six EU measures in this subchapter. They concern the *acquis* on the cooperation between national authorities, injunctions – access to justice, dangerous imitations, distance marketing of financial services, unfair commercial practises and rights of flight passengers. In addition, Croatia needs to continue to prepare for the participation in the RAPEX system. For all of this work, Croatia has adopted a clear time schedule.

# Product safety related issues

In the field of general product safety, further harmonisation is required as regards some definitions, including the definition of producer as well as the definition of recall and withdrawal. The administrative capacity of the State Inspectorate needs to be strengthened, in particular with a view to the model of supervision, sampling and testing, to financial, technical and IT resources, as well as to training and continuous professional developments.

#### Non-safety related issues

In the field of the *acquis* related to certain aspects of the sale of consumer goods and associated guarantees, further alignment is necessary as regards the scope, compliance of the definitions and the inclusion of minor defects; the terminology used needs to be re-checked as well as the full inclusion of warranties and hierarchy of remedies. The provisions of the Directive have to be enforced by the market surveillance authority.

As regards the *acquis* on timeshare, further harmonisation will have to cover a revision of the Croatian terminology and scope as well as the inclusion of certain mandatory rules.

# Administrative capacity

The Consumer Protection Department of the Ministry of Economy, Labour and Entrepreneurship is not only the competent body for the preparation of legal alignment but also involved in monitoring the achievements of the National Consumer Protection Programme, the management of the National Information System, the activities of the consumer counselling centres and consumer protection organisations.

Being an independent central body of state administration – amongst many other areas – the State Inspectorate is in charge of supervising the fields covered by the Consumer Protection Act and the General Product Safety Act, thus presenting the main governmental institution for market surveillance concerning consumer protection. The State Inspectorate was already strengthened through the establishment of a special Department for Consumer Protection. It is supported locally by market inspectors in five regional units and 38 branch offices throughout Croatia. Regarding market surveillance, both methods, proactive and reactive, are used by the State Inspectorate. With the envisaged further strengthening of this institution, focussing particularly on working procedures (EU good practices) and continuous professional development of present and additional human resources, Croatia has already got a solid and powerful structure for enforcing the *acquis*, underlined by statistics provided on inspection results for 2005.

This view is also supported by good co-ordination with and between all of the institutions involved in market surveillance and inspection, such as customs, sanitary, veterinary and phyto-sanitary, etc. In addition, the planned introduction of a special IT system for market surveillance will increase the efficiency of the work of the State Inspectorate together with the scheduled upgrading of its laboratory capacity.

Croatia's non-governmental consumer protection organisations are financed out of the State budget. Their current role is not only to assist, educate and train consumers in protecting their rights but also to provide information to the Ministry of Economy, Labour and Entrepreneurship regarding consumer problems noted and work performed in the counselling centres. In conclusion, Croatia has by now established a strong consumer movement backed by continuous information through flyers, brochures, TV programmes, seminars, workshops etc. with the goal of raising consumer awareness. Areas of consumers' greatest concerns are related to services provided by telecommunication companies and suppliers of water, gas and electricity.

Croatia also prepares for the consumers' better access to justice and alternative settlement of consumer disputes. The main goal regarding the latter aspect is to establish an independent body for out-of-court settlements.

#### III.b. Public Health

With its national Public Health Framework, its legal measures, its current administrative structures and available infrastructure, Croatia has established a good platform for the completion of legal alignment with the *acquis* and its enforcement. However, it is advisable that Croatia extends, revises and fine-tunes the existing legislation towards full transposition, in particular in the field of tobacco, blood, tissues and cells.

#### Tobacco

As indicated by Croatia, the transposition of the Tobacco Advertising Directive and Tobacco Products Directive is incomplete.

Further harmonisation is necessary to tighten rules against tobacco advertising in media (TV, information society services) and sponsorship of events and to take into account the provisions of general and additional warnings, a ban on misleading product description, the obligation for manufacturers and importers to submit annually a list of all tobacco products' ingredients and their quantities, including the toxicological data and dissemination of those data to consumers, as well as the rules for yields and batch labelling.

As regards the EU *Directive on the Manufacture, Presentation and Sale of Tobacco Products*, the transposition is incomplete. The same goes for the EU *Directive on Tobacco Advertising*. As regards the latter, currently, the legal alignment does not include rules on the sponsorship of events and on information society. Problems of indirect advertising and internet sales are not either sufficiently addressed.

The ratification and enforcement of the WHO *Framework Convention on Tobacco Control* (*FCTC*) still needs to be carried out. It requires further alignment as regards measures to control illicit trade, support of alternative crops, protection of the environment in respect of tobacco cultivation and manufacture, legal actions dealing with liability and certain other requirements.

It would be advisable to have legislation to remove tobacco products from self-service displays in retail outlets, to prohibit the sales of sweets/toys which resemble tobacco in the context of the prevention of tobacco sales to children and adolescents, to introduce the use of price measures to discourage tobacco product consumption and to introduce measures to protect against exposure to second-hand smoke as part of the implementation of the EU Recommendation on the Prevention of Smoking and Initiatives to improve Tobacco Control.

# Blood, tissues and cells

As regards the Directive on quality and safety of blood and blood components, Croatia adopted an Act on blood and blood components in June 2006. Additional by-laws for the transposition and implementation of the three additional implementing Directives are foreseen to be adopted and implemented by the end of 2007. Some elements also need further harmonisation, such as a quality assurance system applicable to the transfusion services, as well as labelling of each blood product and traceability from donor to recipient and vice versa, foreseen for 2007.

For full compliance with the *acquis* on tissues and cells, further adaptations of the existing Croatian legislation are necessary, in particular for the inclusion of EU rules on reproductive cells and reporting of serious adverse events and reactions.

As regards the enforcement of the *acquis*, particularly concerning the facilities for handling blood, blood components, tissues and cells it is expected that upgrading and restructuring is required in order to meet the EU technical standards.

Some further efforts are needed in the field of communicable diseases and mental health. Croatia has presented a time schedule for achieving harmonisation of its national legislation with the *acquis*. In the field of mental health, the intention of adopting a National Mental Health Strategy during 2007 is welcomed.