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The WHO Protocol to Eliminate Illicit Trade in Tobacco Products: A Next Step in International Control of Tobacco Products

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The WHO Protocol to Eliminate Illicit Trade in Tobacco Products: A Next Step in International Control of Tobacco Products

Lukasz Gruszczynski*

This report discusses the main provisions of the recently adopted WHO Protocol to Eliminate Illicit Trade in Tobacco Products. While recognizing the remarkable achievement of the global community in its efforts to curb illicit trade in tobacco products at the international level, the report also highlights those aspects of the Protocol that may undermine its effectiveness in the long-term perspective. In this context the enforcement capabilities of developing countries are cited as a main concern.

Introduction

The Framework Convention on Tobacco Control (FCTC or the Convention) is an international treaty adopted under the auspices of the World Health Organization. It entered into force on 27 February 2005 and currently has 176 signatory Parties. The aim of the Convention is to protect human life and health from the consequences of tobacco use and exposure to tobacco smoke, by establishing certain international standards to be implemented by the Parties (Art. 3). Since the obligations contained in the Convention are of a general character, the Parties, acting as the Conference of the Parties (CoP), are granted a mandate to approve non-binding guidelines that will help them in the implementation of specific provisions of the Convention.¹ In addition, pursuant to Art. 33 of the FCTC, Parties may also adopt

additional protocols in order to build upon and complement the obligations provided by the Convention. Contrary to guidelines, a protocol is binding on the Parties which accept it and has an equal legal status to the Convention. The Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol) is the first document of this kind.

Illicit trade in tobacco products is a serious challenge for all governments. Not only does it undermine an important source of state revenues, it also weakens national health policies aimed at the suppression of tobacco consumption. The scientific studies available assess that annual losses in tax revenues resulting from the illicit trade in cigarettes alone amounts to USD 40.5 billion, with illegal products constituting about 11.6% of the global market (in some countries the market share is well above 50%).² It is also estimated that elimination of illicit trade in tobacco products could save as many as 164,000 lives in 2030 and annually thereafter (by reducing the availability of cheap and frequently low quality products).³ The Protocol is the most recent and most ambitious attempt to address these concerns at the international level.

The aim of this report is to provide readers with an overview of the basic obligations of the Protocol and its potential impact on global illicit trade in tobacco products. The report proceeds as follows: The first part gives a brief summary of the negotiating process that led to the adoption of the Protocol. The second part concentrates on the specific mechanisms established by the Protocol (i.e. preventive measures, improvement of law enforcement, and international cooperation). The last section, while appraising the remarkable achievement of the global community, also highlights those aspects of the Protocol which may undermine its success in the long-term perspective.

I. The negotiation process

The FCTC as such is rather general when it comes to dealing with illicit trade in tobacco products. Apart from defining the term, it only includes in its Art. 15 some broadly formulated obligations. It was clear from the beginning that this set of rules would be insufficient to tackle the problem of illicit trade. As a consequence, the first CoP decided to set up an expert group assigned with the task of preparing a template for a future additional protocol.⁴ This template

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1 Although guidelines are non-binding instruments, they may be considered as international standards under the WTO Agreement on Technical Barriers to Trade and enjoy a quasi-normative status. For more details, see Lukasz Gruszczynski, "The WHO Framework Convention on Tobacco Control as an International Standard under the TBT Agreement?", 5 *TDM Journal* (2012).

2 Luk Joossens, David Merriman, Hana Ross and Martin Raw, "The Impact of Eliminating the Global Illicit Cigarette Trade on Health and Revenue", 105 *Addiction* (2010), pp. 1640–1649, at p. 1645.

3 *Ibidem*, p. 1646.

4 Conference of the Parties to the WHO FCTC, First Session (6–17 February 2006), *Decisions and Ancillary Documents*, COP/1/2006/CD, p. 57.

was indeed produced in 2007 and served as the basis for initiating negotiations between the Parties.⁵ The inspiration for specific mechanisms included in the template came from various different sources, such as the United Nations Convention against Transnational Organized Crime⁶ (e.g. methods of international cooperation), or settlement agreements concluded in 2004–2010 between the European Union and major tobacco manufacturers (e.g. mechanisms ensuring that products are sold only to legitimate clients and a tracking system for cigarettes).⁷

Subsequent negotiations concerning the Protocol were channelled through the special Intergovernmental Negotiating Body (INB) that was created at the same 2007 session of the CoP. Participation in the INB was open to all Parties to the Convention. The work of the INB was very closely followed, not only by the majority of governments but also by representatives of civil society (e.g. international non-governmental organizations), as well as tobacco industry. The first official session of the INB was held in Geneva on 11–16 February 2008, and was followed by three additional meetings.⁸ Since the INB was not able to agree on certain provisions of the future Protocol (e.g. some specific legal mechanisms for controlling the supply chain, financing the operation of the Protocol, or provisions on mutual legal assistance, enforcement, and extradition), the CoP decided at its 4th session to establish an informal working group to break the deadlock in negotiations.⁹ This group met twice – in July and September 2011 – and was able to agree to a new wording of those articles that were mired in controversy. The draft was eventually approved by the INB at its meeting in March/April 2012 and subsequently submitted to the CoP, which formally adopted the Protocol at its session held in Seoul on 12 – 17 November 2012, with more than 140 Parties to the Convention voting in favour.

The Protocol is open for signature by the Parties to the Convention for a period of one year, starting from 10 January 2013 (Art. 43 of the Protocol), and will enter into force 90 days following the date of deposit of the 40th ratification (Art. 45 of the Protocol). The Protocol is binding only on those Parties that decide to sign it (Art. 33.5 of the FCTC).

II. The Protocol

The Protocol repeats the very broad definition of “illicit trade” included in the Convention, understood

as “any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase, including any practice or conduct intended to facilitate such activity.”¹⁰ Consequently, it goes beyond the common meaning of the term and covers such acts as manufacturing or complicity in various illicit activities. Note also that this definition – and as a consequence the Protocol itself – is not limited to international illicit trade only, but also encompasses purely domestic acts. In practice, when one speaks about illicit trade, the following activities are the most common: large scale smuggling of tobacco products between different jurisdictions (with respect to either genuine or counterfeit products); bootlegging (illegal reselling in high-tax jurisdictions of tobacco products legally purchased in low-tax jurisdictions), which is one of the recent forms of smuggling; manufacturing of counterfeit tobacco products; simulated export with subsequent reintroduction of products to the original market.¹¹

Probably the most important reason that led to the adoption of the Protocol is the fact that illicit trade in tobacco products undermines a number of the FCTC provisions. In particular, it compromises price and tax measures adopted by the countries with the aim of suppressing the demand for tobacco products. It may lead to avoidance of packaging and labelling requirements enforceable in a particular jurisdiction, or facilitate sales to minors (since illicit products are frequently traded on the black market). It makes

5 Conference of the Parties to the WHO FCTC, Second Session (30 June – 6 July 2007), *Decisions and Ancillary Documents*, CIO/2/2007/CD, p.28.

6 United Nations Convention against Transnational Organized Crime, signed on 15 November 2000, entered into force on 29 September 2003, 2225 UNTS 209.

7 Neil Boister, “Recent Progress in the Development of A Protocol on the Illicit Trade in Tobacco Products”, 5 *Asian Journal of WTO & International Health Law & Policy* (2010), pp. 53–86, at p. 59. The European Union concluded four agreements with Philip Morris International, Japan Tobacco, British American Tobacco, and Imperial Tobacco Limited. For the full texts of these agreements, see: <http://ec.europa.eu/anti_fraud/investigations/eu-revenue/cigarette_smuggling_en.htm> (last accessed on 07 January 2013).

8 These sessions were held in Geneva in October 2008, June 2009 and March 2010.

9 Conference of the Parties to the WHO FCTC, Fourth Session (15–20 November 2010), *Decisions and Ancillary Documents*, FCTC/COP/4/REC/1, p.58.

10 Art. 1(6) of the Protocol, repeating Art. 1(a) of the FCTC.

11 Transcrime (Joint Research Centre on Transnational Crime), *Analysis of the Draft Protocol to Eliminate Illicit Trade in Tobacco Products*, Milan: 2012, p. 8.

tobacco products more accessible to users and undermines applicable rules relating to the technical qualities of products (e.g. permissible ingredients, emission standards). Illicit trade therefore clearly contributes to an increase in the health problems posed by tobacco use. In addition, it also results in significant losses in state revenues and diverts portion of those funds to black market operators and organized crime.

The Protocol consists of three broad categories of provisions. The first category includes detailed rules on preventive measures to be taken by the Parties to control illegal trade in tobacco, tobacco products, and manufacturing equipment. The second category is concerned with the improvement of law enforcement, while the third deals with international cooperation.¹² These are supplemented by a set of provisions relating to reporting obligations and dispute settlement mechanism. The section below summarizes the most important obligations in each of the categories.

1. Preventive measures: Supply chain controls

The Protocol requires the adoption of specific control measures over the supply chain. Firstly, the Protocol establishes a mandatory licensing requirement for key participants in the supply chain (manufacturers, importers and exporters of tobacco products or manufacturing equipment), and allows for a possible extension of the licensing obligations to other actors, such as wholesalers or retailers of tobacco products (Art. 6.1–2). In this context, the Protocol provides detailed instructions on information that needs to be included in a licensing application, operation of the licensing system, and its supervision. Second, it requires certain operators engaged in the supply chain to perform customer identification and verification procedures (together with a due diligence), and to monitor subsequent sales (Art. 7). The provision does not set any *de minimis* threshold. Third, the Protocol requires the establishment of a tracking and tracing system for all tobacco products and establishes its parameters (e.g. scope of relevant information and rules on access to this information). In this context, the Protocol distin-

guishes between national and global tracking and tracing systems. The former covers tobacco products that are manufactured in or imported onto the territory of an individual Party. The latter is supposed to connect national systems into one network, and its implementation is to be phased-in over for a period of five years from the Protocol's entry into force. As a part of a tracking and tracing system, each Party is expected to introduce unique, secure and non-removable identification markings on all unit packets and packaging, as well as on the individual packaging of cigarettes and other tobacco products. These can take the form of codes or stamps (Art. 8). Fourth, the Parties need to guarantee that all entities in the supply chain of tobacco, tobacco products, and manufacturing equipment comply with certain record-keeping obligations. The extent of required information depends on the type of an actor (e.g. a licensed or non-licensed entity), and covers such information as quantities of tobacco products and equipment in their possession; shipment data, including identification of contractors, transaction details, and the intended market for retail sales (Art. 9). Fifth, the Parties are expected to require all entities that are subject to licensing obligations to introduce measures preventing the diversion of legal tobacco products into illicit trade channels. This task is to be accomplished through various reporting obligations (e.g. with respect to "suspicious" transactions), restrictions on acceptable methods of payment, and requirements to supply tobacco products only in an amount necessary to satisfy the demand in the intended market of retail sale (Article 10). Sixth, each Party has to implement control measures on the manufacturing of tobacco and tobacco products (and related transactions) in free zones (Art. 12.1), as well as control and verification measures with respect to international transit and any transfer of tobacco products and manufacturing equipment that takes place on its territory (Art. 12.3).

2. Penalization, investigation and prosecution

The Protocol requires Parties to make certain activities connected with the illicit trade of tobacco, tobacco products and manufacturing equipment unlawful. The catalogue is broad and includes, among the other things, acts such as manufacturing or selling tobacco products without the payment of applicable duties

¹² *Ibidem*, p. 13.

or taxes; failure to comply with applicable marking and labelling requirements; producing tobacco products with false markings or fiscal stamps; and misdeclaring on official forms the description, quantity or value of tobacco or tobacco products in order to evade payments of duties or taxes. At the same time, the Protocol leaves the Parties with the discretion as to which of these activities are to be considered as criminal offences under domestic law (Art. 14). Besides penalization, each Party needs to provide in its legal system for possibility of making legal entities liable for such acts (either in the form of criminal, administrative, or civil liability) (Art. 15).

The above acts, as well as other acts connected with the illicit trade of tobacco products as identified by the Parties, must be subject to effective, proportionate, and discouraging sanctions of either a criminal or non-criminal character (including monetary sanctions). Illegal products (e.g. tobacco products or manufacturing equipment) which are confiscated are subject to destruction (Art. 18). The Protocol also encourages the use of special investigative techniques, such as controlled deliveries or undercover operations, leaving however final decisions in this respect to each individual Party (Art. 19).

3. International cooperation

The provisions on international cooperation constitute an important part of the Protocol. The aim of these obligations is to improve enforcement capabilities with respect to transnational acts of illicit trade by establishing communication channels among the Parties, facilitating information exchange, simplifying or creating necessary procedures, and providing necessary technical assistance. The relevant rules provide for:

- general information sharing (reporting in aggregated form on seizures of tobacco, tobacco products, and manufacturing equipment, and their import, export or transit) (Art. 20);
- information sharing on enforcement if necessary for the detection or investigation of illicit trade in tobacco (e.g. records of investigations and prosecutions, payments for import, export, or duty-free sales of tobacco) (Art. 21);
- assistance and cooperation with respect to training, provision of technical assistance, and cooperation in scientific, technical and technological matters (transfer of relevant expertise or tech-

nology in areas such as protection of personal data, electronic surveillance, forensic analysis) (Art. 23);

- assistance and cooperation with respect to the investigation and prosecution of offences (Art. 24);
- law enforcement cooperation (enhancing cooperation among the competent national authorities responsible for enforcement activities) (Art. 27);
- mutual administrative assistance with respect to information required for proper enforcement of customs and other laws relevant to the prevention, detection, investigation, or prosecution of acts of illicit trade (Art. 28);
- mutual legal assistance in investigations, prosecutions and judicial proceedings in relation to acts penalized by the Protocol (e.g. executing searches and seizures, identifying or tracing the proceeds of crime) (Art. 29);
- extradition rules applicable to persons charged with the criminal offences envisaged by the protocol (subject to strict conditions) (Art. 30).

4. Other provisions

The Protocol imposes on the Parties certain reporting obligations with respect to implementation of its provisions (Art. 32). It also contains a dispute settlement clause, which refers back to the relevant rules provided in the FCTC. As a consequence, any dispute between the Parties concerning the interpretation or application of the Protocol is to be resolved through diplomatic means, and if such means fail, through compulsory *ad hoc* arbitration (subject to the consent of each Party upon ratification, acceptance, and approval).¹³

IV. Impact of the Protocol on the global market for tobacco products

The adoption of the Protocol is generally seen as a positive development that may significantly assist governments in their fight against illegal trade in tobacco products. For example, the WHO Director General has stated that “[t]he protocol gives the world an orderly rules-based instrument for countering and

¹³ Art. 27 of the FCTC.

eventually eliminating a sophisticated international criminal activity that costs a lot, also for health.”¹⁴ Other international and governmental officials have described the Protocol as a landmark development and a historical achievement of the international community. Indeed, the Protocol is a real revolution. It introduces control standards to the field of international tobacco trade that are characteristic of other highly controlled domains, such as prevention of money laundering, arms trade, or drug trafficking. It also constitutes an important step forward compared to the rules on illicit trade that are included in the Convention. As a consequence, it has a significant potential for improving the transparency of the market and making illicit transactions more difficult. In particular, one of the important innovations introduced by the Protocol is to make manufacturers and exporters responsible for the supply chain (e.g. due diligence requirement, record-keeping, tracking and tracing, and restrictions on payments). As the historical data shows, transnational tobacco companies (TTCs) were in the past frequently, directly or indirectly, involved in the smuggling of their own products. For example, in 2008 Rothmans and Imperial Tobacco were found guilty of complicity in tobacco smuggling between 1989 and 1994.¹⁵ The settlement agreements concluded by the European Union with some of the TTCs were also connected with large-scale smuggling with the participation of the tobacco industry.

The European experiences show that proper implementation of mechanisms envisaged in the Protocol can have a huge impact on diminishing illicit trade, leading to both an increase in governmental

revenues as well as a decrease in the size of the market for illegal tobacco products (e.g. developments in Italy and Spain).¹⁶ Of course the effectiveness of the Protocol will depend in the first instance on the level of its acceptance. The higher the number of ratifications, the greater are the chances that the Protocol will really redefine the global market for tobacco products. Fortunately, considering that more than 140 Parties voted in favor of the Protocol, one may expect that ratification rate will be high.

Having said this, it needs to be acknowledged that the current version of the Protocol is considerably less stringent than its earlier drafts (in particular the document prepared by the special expert group). In the course of the negotiations, a number of initial proposals were criticized as being too costly, impracticable, or overly interfering with the sovereign rights of the states (e.g. mandating that certain “key inputs” be subject to regulation; providing for broad personal scope of the licensing requirement; and the mandatory criminalization of certain activities).¹⁷ The final version of the Protocol, to the disappointment of many anti-tobacco activists, either omitted some issues, softened the applicable requirements, or added legal qualifiers (e.g. “as appropriate”, “subject to the basic principles of its domestic law”, “in accordance with their domestic law”). Some of these compromises probably went too far. For example, some argue that the failure of the Parties to agree on a list of unlawful acts that have to be criminalized may undermine the effectiveness of the Protocol. The text as it stands now gives absolute freedom to the Parties to decide whether to qualify specific acts enumerated in Art. 14 as criminal offences. This may lead to a lack of consistency between the Parties and result in both over- and under-criminalization (i.e., either too many acts will be criminalized, which may result in the inoperability of the system; or some acts, despite their gravity, will not be considered as crimes in some jurisdictions). This heterogeneity can complicate cooperation among the Parties, as the applicability of certain mechanisms are reserved only for criminal activities.¹⁸ It should also be noted that the extent of implementation of Art. 14 will directly affect the operation of the whole Protocol, since a number of obligations are activated only with respect to criminalized acts (e.g. the liability of legal entities, use of special investigative techniques, and mutual legal assistance and extradition). Consequently, as summarized by a group of the researchers with respect to the earlier version: “[t]

14 Dr. Margaret Chan Director-General of the World Health Organization, *Address to the Fifth Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control*, Seoul, Republic of Korea, 12 November 2012, available on the Internet at <http://www.who.int/dg/speeches/2012/tobacco_control_20121112/en/index.html> (last accessed on 07 January 2013).

15 Cf., Boister, *supra* note 7, p. 57. See also, Kelley Lee and Jeff Collin, “Key to the future”: British American Tobacco and cigarette smuggling in China”, 3(7) *PLOS Medicine* (2006), p. 228 *et seq.*; Eric Legresley, Kelley Lee, Monique Muggli et al., “British American Tobacco and the ‘insidious impact of illicit trade’ in cigarettes across Africa”, 17 *Tobacco Control* (2008), pp. 339–346.

16 See generally, Luk Joossens and Martin Raw, “Progress in Combating Cigarette Smuggling: Controlling the Supply Chain”, 17 *Tobacco Control* (2008), pp. 399–404.

17 For a good overview of the earlier drafts, see, Boister, *supra* note 7, pp. 65–81.

18 Transcrime, *supra* note 11, p. 20.

he current provision leaves such discretion to State Parties, [that it] may deprive the Draft Protocol of its potential in practice.”¹⁹ Another problem relates to the exclusion of so-called “key inputs” (i.e. major components of cigarettes other than tobacco, such as cigarette papers or filters) from the scope of the Protocol. Despite numerous calls for extending the provisions on licensing, costumer identification and verification to include key inputs, this was eventually rejected by the INB. Since there was no agreement between the Parties as to what should be considered as a “key input”, the final version of the Protocol only asks the Parties to identify, within the period of five years after its entry into force, existing key inputs and assess the effectiveness of different control mechanisms with relation thereto. Such an assessment will subsequently form the basis for further actions (Art. 6.5). Some non-governmental organizations argue that this omission may compromise the overall effectiveness of the Protocol.²⁰

The impact of the Protocol on the global tobacco market will significantly depend on its actual enforcement at the national level and the quality of cooperation among the Parties. This may be particularly challenging for developing countries, where legal enforcement in general remains relatively poor. As some commentators indicate, factors such as “under-resourced customs, law enforcement, and criminal justice agencies; lack of capacity to enact, monitor and enforce legislation and regulations; weak governance systems; corruption; and lack of technological capacity”²¹ may significantly limit the practical importance of the Protocol. At the same time, various studies show that low and middle-income states are actually the main victims of the illicit trade in tobacco products. According to Joossens and others, about 56 % (i.e. USD 22.9 billion) of total annual revenue loss occurs in those countries, with as many as 132,000 avoidable deaths annually.²² It should also be noted that the Protocol may involve significant implementation costs (e.g. connected with the introduction of a licensing scheme, tracking and tracing system, use of innovative investigation techniques, and establishment of methods to assure compliance with verification requirements). Those costs relate not only to necessary investments in technical equipment, but also cover expenses connected with human resources (i.e. hiring of additional staff and providing them with necessary training). Although some of those costs can be shifted to the tobacco industry or recovered through the higher tax revenues which will

result from the elimination of illicit products from the market, the high initial investment remains an obstacle, perhaps not for the developed countries, but certainly developing states may have difficulties in establishing fully operational mechanisms. This aspect was highlighted number of times during the course of the negotiations, with several Parties stressing the need for technical assistance and capacity building.²³ Although, the Protocol includes a set of rules dedicated to this issue, they are formulated in very general language and it is difficult to predict how they will operate in practice. One may hope that the global nature of illicit trade (which requires a coordinated international response) will force developed countries to dedicate sufficient resources for the provision of technical assistance to less developed countries.

The lack of necessary funds for implementation of the Protocol may have another unexpected consequence. The tobacco industry itself appears to be very interested in financing different enforcement activities undertaken by governments against illicit trade. To some extent this can be explained by real concerns on the part of tobacco companies with the growing market for counterfeit goods. However, this is only a part of the story. As noted in the literature, this willingness may also result from purely image-related considerations. The tobacco industry wants to “re-invent itself as a ‘responsible’ [actor] selling a risky product, rather than a moral pariah knowingly selling a harmful and addictive product.” In this context, illicit trade is seen as “an area where it can portray itself as a ‘partner’ in a joint struggle – the ‘legitimate’ companies ‘working together’ with governments and intergovernmental agencies against

19 *Ibidem*.

20 Framework Convention Alliance, “Briefing Note: Fourth Session of the Intergovernmental Negotiating Body on an Illicit Trade Protocol”, 24 February 2010, available on the Internet at: <http://www.fctc.org/index.php?option=com_docman&task=doc_download&gid=407&Itemid=159> (last accessed on 07 January 2013).

21 Jonathan Liberman, Evan Blecher, Alejandro Ramos Carbajales and Burke Fishburn, “Opportunities and risks of the proposed FCTC protocol on illicit trade”, 20 *Tobacco Control* (2011), pp. 436–438, at p. 437.

22 Joossens et al., *supra* note 2, pp. 1646–47.

23 Conference of the Parties to the WHO FCTC, *Report to the fifth session of the Conference of the Parties of the Chairperson 1 of the Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products*, FCTC/COP/5/7, 11 May 2012, p. 4.

‘illegitimate’ counterfeiters, smugglers and organised criminals.”²⁴ Indeed British America Tobacco agreed to pay, under its 2010 cooperation agreement with the EU, a sum of 200 million USD over a period of 18 years to fund enforcement activities against illicit trade.²⁵ This may be a tempting option for many governments looking for additional funds, notwithstanding the instruction of Article 5.3 of the FCTC and corresponding guidelines which explicitly prohibit partnering with the tobacco industry. Although funds provided by the industry may help to limit the size of illicit trade in tobacco products, such funding also creates its own costs that are difficult to assess (i.e. socially normalizing the image of industry).

In conclusion, it seems that an assessment of the practical significance of the Protocol will be possible only after several years. Although most of the obligations introduced by the Protocol seem to provide effective tools for eliminating or suppressing illicit trade in tobacco products, what will really matter is how (and whether) they are actually enforced by the Parties.

Substantial Amendment of the EU Regulatory Framework on Medical Devices and International Trade Implications

Ignacio Carreño*

I. Introduction

On 26 September 2012, the European Commission published two proposals for the substantial amendment of the regulatory framework on medical devices: a ‘*Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009*,¹ and a ‘*Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices*’² (hereinafter, IVD). The reasons for the recast of the EU regulatory framework on medical devices are four-fold: 1) there has been enormous technological and scientific progress in the past 20 years; 2) EU Member States do not always interpret and implement the current rules (set out in directives) in the same way; 3) it is not always possible to trace medical devices back to their supplier (i.e., rules on traceability are needed), and 4) supervision of the independent conformity assessment bodies (the so-called “notified bodies”) by EU Member States needs to be strengthened to ensure that all bodies have the necessary competence to carry out the pre-market assessment of medical devices. In addition, the IVD proposal clarifies the scope in respect to genetic tests, companion diagnostics and diagnostic services offered at a distance.

II. Background

Medical devices include products such as sticking plasters, contact lenses, dental filling materials, x-ray machines, pacemakers, breast implants or hip

24 Liberman et al., *supra* note 21, at p.437.

25 The agreement is available at the Commission webpage: <http://ec.europa.eu/anti_fraud/documents/cigarette_smug/2010/bat_main_agreement.pdf> (last accessed on 07 January 2013).

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1 COM(2012) 542.

2 COM(2012) 541.