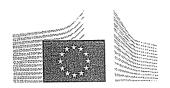
## **EUROPEAN COMMISSION**



Brussels, 18.7. 2013 C(2013) 4564 final

Dear President,

The European Commission would like to thank the Narodno Sabranie for its Reasoned Opinion on the proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products {COM(2012)788 final}.

The Commission would like to make the following remarks.

The Commission welcomes the Narodno Sabranie's support for the aims of the proposal.

The Narodno Sabranie expresses doubts as to Article 114 TFEU as legal basis for the Proposal. The Commission would like to point out that the current Directive largely pursues the same aims as foreseen under the proposal for its revision. The legality of the current Directive has been confirmed by the European Court of Justice (ECJ) (see Case 491/01, BAT [2002] ECR I-11453, paras 177-185 on subsidiarity). Moreover, the Commission recalls that the legal base of the proposal is Article 114 TFEU, the choice of which has also been confirmed by the ECJ with regard to the current Directive. This legal base is appropriate to update the existing level of harmonisation, to remove obstacles to the internal market due to divergent regulatory developments in the Member States, and to prevent circumvention of internal market rules. It thus either updates or extends regulations to ensure the functioning of the internal market, or provides rules that could not be effectively adopted at national level, such as on tracking and tracing and distance sales.

The Narodno Sabranie furthermore considers that the increased size of health warnings might impair intellectual property rights, might impact negatively on the quality of tobacco, and might lead to an increase in illicit trade. It also questions whether the increased size of health warnings would lower the number of smokers in the EU. The Commission would like to point out that it has provided scientific evidence showing the effectiveness of pictorial health warnings. Moreover, according to the Eurobarometer survey 2012, 76% of EU citizens are in favour of using pictorial warnings, and in 17 Member States pictorial health warnings attract the highest level of support among all possible tobacco control measures. In the view of the Commission, the proposed rules on packaging would not increase the risk of illicit trade. During the public consultation, no evidence was presented to substantiate any such claims. In any event, the proposal foresees effective measures against illicit trade, including a security feature and a

Mr Mihail Raykov MIKOV President of the Narodno Sabranie 2, Narodno Sabranie Square BG – 1169 SOFIA tracking and tracing system for tobacco products. The Commission is therefore of the view that its proposal would reduce illicit trade. The Commission would also like to recall that requirements in the current Directive already restrict the use of trademarks, which was confirmed as legal by the Court of Justice. Restrictions to the use of trademarks can be justified provided that the measure is proportionate. Under the proposal, manufacturers of tobacco products would be able to continue to use their trademarks on the non-regulated surface of the package, which would correspond to approximately 30% of the total surface area. This will allow tobacco companies to distinguish their goods from those of other companies. Consumers will also be able to differentiate between different brands.

The Narodno Sabranie further claims that there is no impact assessment on the benefits of the proposed changes for citizens as well as on the economic effects on producers, wholesalers and retailers. The Narodno Sabranie also considers that the rules on traceability would require further justification and would place an undue burden on economic operators. The Commission would like to note that the proposal is accompanied by a thorough analysis of the economic, market, social and health impacts in the publicly available Impact Assessment (SWD(2012) 452 final), and that extensive stakeholder consultations have been conducted. This Impact Assessment and the Explanatory Memorandum of the proposal also lay out the rationale for the provisions on traceability, which would protect the legal trade in tobacco products, facilitate market surveillance and law enforcement and empower consumers to detect illicit products. Moreover, the tracking and tracing system is designed to be fully compatible with the provisions of Article 8 of the recently adopted Protocol to Eliminate Illicit Trade in Tobacco Products.

The Narodno Sabranie considers that the proposed delegation of powers in the proposal would not meet the requirements laid down by Article 290 TFEU. However, the Commission considers that in order to make this Directive fully operational in the view of technical, scientific and international developments in the tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU is necessary. The delegations of power in the proposal provide for clear and concise criteria, giving limited discretion to the Commission. The Commission would involve Member States in the preparation of these acts and would ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

The Commission hopes that these clarifications address the comments and concerns raised in the Reasoned Opinion submitted by the Narodno Sabranie and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

Maroš Šefčovič Vice-President