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NOTE

From:	General Secretariat of the Council
To:	Delegations
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Subject:	Counterfeiting: medicrime and approximation of national legislation - Compilation of replies by Member States

Further to the informal meeting of Justice Ministers on 29 January 2021, the Presidency presented a paper on the issue of "Counterfeiting: accession to the Medicrime Convention and approximation of national legislation" at the COPEN meeting on 7 May 2021 (8183/21).

The paper contained several questions. After a first discussion in the said meeting of the COPEN Working Party, the Presidency invited the Member States to reply to the questions in writing.

Delegations will find in the Annex a compilation of the replies as received by the General Secretariat.

Contents

AUSTRIA

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Austria has significantly and actively participated in the elaboration of the MEDICRIME Convention and has signed it at the earliest moment, i.e. on 28 october at the Moscow Conference.

   Furthermore, has Austria fully transposed the criminal provisions regarding medicinal products in 2013 (see Sec. §§ 82b, 82c Arzneimittelgesetz - AMG).

   The transposition regarding medical devices is under preparation, but will face some delay due to complexity, necessary coordination between the Ministries of Health and Justice, limited resources (i.a. due to the COVID 19-Pandemic).

   Austria is fully committed to the Convention and will proceed to the ratification when the implementation is about to be concluded.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

We think that it would be premature to answer these questions. However, we would like to react through the following more general remarks:

1. After the negotiations on the 2006 proposal on a directive on criminal measures aimed at ensuring the enforcement of intellectual property rights, COM(2006) 168, had failed, the competent Working Party had deployed "the lack of a pertinent and up-dated study on the situation of the Intellectual property legislation in the Member States" and requested the Commission "to proceed to a synthesis of the state of play on the measures taken against infringements of intellectual property rights, on the basis of studies elaborated by international organisations" (see document 10714/07).

Later, it was known that such a study had been achieved by Salomé and Daniel Lachat, but the Commission had never communicated that study to the Member States.

Austria recommends that the current work could perhaps build on that study. So the Commission is kindly asked to share this study with the Member States.

We are **not convinced**, at this stage, that there is a real need to harmonize criminal law provisions in the field of (all) **intellectual property rights**.

2. However, we feel that **counterfeiting of medicinal products (or even medical products)** could be a field where harmonised criminal law provisions could be necessary and useful. We have experienced that before the relevant legislation on counterfeiting of medicinal products had entered into force (in 2013), perpetrators had used Austria as a kind of "safe haven" for their activities.

We also point out that relevant legislation harmonizing the Union policy already exists, for medicinal products see Directive 2001/83 on the Community code relating to medicinal products for human use (as amended by Directive 2011/62 – see provision on sanctions in Art. 118a), for medical devices see Regulation 2017/745 (provision on sanctions in Art. 113). This legislation should be regarded as "harmonisation measures" in the sense of Art. 83 paragraph 2 TFEU.

3. We note that currently the **Commission is preparing legislative work** in substantive criminal law in many fields, such as:

a. hate crime (recent public consultation, view to add to the list of eurocrimes under Art. 83 paragraph 1 TFEU);

b. violence against women (recent public consultation);

c. organised crime (current study on FD 2008/841);

d. environmental crime (recent workshop on revision of Directive 2008/99);

e. trafficking in human beings (revision of Directive 2011/36);

f. confiscation (revision of Directive 2014/42: see EC Strategy on Organised Crime)

g. corruption ("lisbonizing" the 1997 Convention and FD 2003/568: see EC Strategy on Organised Crime).

This possible wave of legislative proposals in the field of substantive criminal law raises (first the question why DROIPEN has just been abolished, but primarily) **fundamental questions**, like:

- necessity of increased criminalisation (and possible additional minimum requirements of sanctions)
- priority in relation to other fields of possible legislative activity, like on cooperation (where the patchwork of FDs, Directives and Regulations is detrimental and where daily practise and ECJ judgements show deficits)
- setting of priorities with respect to limited ressources of Member States.

As mentioned in last CATS under AOB, we think that a discussion on strategy on these and neighbouring questions should take place (in CATS).

BELGIUM

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Belgium has already signed and ratified the MEDICRIME Convention.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   The Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights provides a solid foundation for enforcing intellectual property rights in the internal market. However, the measures, procedures and remedies concerning an infringement of an intellectual property right laid down by this Directive are of the civil and administrative nature.

   In order to tackle the risks posed by counterfeiting activities related to cross-border and organised crime, civil and administrative measures and procedures may not be sufficient. Proceedings on the criminal law level and appropriate sanctions are important to combat counterfeiting, and especially with regard to the new challenges posed by counterfeiting during the Covid-19 crisis.

b) Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?

The Kingdom of Belgium is not opposed to the discussion on the further development of EU legislation which adds added value at EU level, but which remains in line with international instruments in the areas of law in which an international instrument already exists. The Kingdom of Belgium believes that the MEDICRIME Convention provides a solid basis for any further discussion related to the harmonization of substantive criminal law to tackle the counterfeiting of medical products and similar crimes according to Article 83 (2) TFEU.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

The Kingdom of Belgium believes that in the area of counterfeiting, the importance of the fight against counterfeiting of medical products and similar crimes has been intensified by the COVID-19 crisis.

BULGARIA

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Bulgaria recognizes the gravity of the problems arising from the counterfeiting of medical products and medical devices and its threats to the public health, the health and social systems as well as to the economy of the Member States.

   Bulgaria is one of the countries which has not signed and ratified the MEDICRIME Convention. Before signing the Convention, a more detailed analysis is needed to assess the Convention's provisions and their effect on the national framework. The analysis will allow us to define the criminal response to this phenomenon, taking into account that most of the offences covered by the MEDICRIME Convention are already subject to robust administrative regime and sanctions. Strengthening corporate liability is another question which should be subject to further assessment in light of the requirements of the Convention.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      As the internal discussions on the issue are still ongoing, at the present moment we are not in a position to provide a definitive answer.

b) Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?

Bulgaria is open to discuss proposals and further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, with a focus on counterfeiting crimes which pose a threat to public health and safety.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

As mentioned above, Bulgaria is open to discuss the need for strengthening the legal framework with regard to counterfeiting of medical products at Union level. However, we think it is premature to establish the specific types of counterfeiting that should preferably be addressed by such rules and to decide whether these debates should be focused only on the criminalization of the counterfeiting of medical products and crimes which threaten the public health and the health systems of the Member States.

CZECH REPUBLIC

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   The Czech Republic is one of the countries that have neither signed nor ratified the MEDICRIME Convention and currently we are not considering signing or ratifying the Convention. One of the obstacles for us is that the Convention requires the imposition of criminal sanctions for some of the acts listed therein, even in relation to offences of a lesser gravity, for which we consider administrative sanctions to be more appropriate and effective. The Convention also requires the criminalization of certain acts as such, that is regardless of a certain possible consequence or harm that would justify imposition of criminal sanctions, such as actual endangering of life or health for example. In other words, criminal sanctions would have to be applied also to cases of less serious illegal activity, which is to certain extent punished by means of administrative law within the framework of the Czech legal system.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

   c) **If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?**

If we are to consider the common criminal law response to counterfeiting at EU level, we are of the opinion that a thorough analysis of the necessity and proportionality of such a legal instrument should be carried out before any possible proposals for the approximation of substantive criminal law are made. This analysis should also include the context of judicial cooperation as well as the assessment of individual forms of counterfeiting.

In this respect, we shall bear in mind that harmonization in the area of criminal law should take place only at a stage when specific problems caused by a lack of harmonization are clearly identified and that possible harmonization should take place only in relation to the most serious cases in line with ultima ratio principle.

In our view, Member States should have the choice whether they apply the means of administrative or civil law on one hand or criminal law on the other hand as far as the area of counterfeiting and enforcement of intellectual property rights is concerned. This would ensure that there is a sufficient room for an appropriate national response to specific situations, also bearing in mind that substantive criminal law is relatively sensitive and distinctive area, which is based on different systems of respective Member States.

FINLAND

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   The Council of Europe MEDICRIME Convention is a wide-ranging and an important international instrument in its field. Finland has signed the Convention but has not acceded to it yet. We have commenced national evaluation related to the ratification of the convention and accordingly, our legislation is, for the most part, in line with the obligations deriving from the Convention.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      Finland would like to remind that there are also other measures, procedures and remedies to tackle risks posed by counterfeiting, than those listed in the aforementioned directive. Examples of these are: directives related to medicinal products for human use (2001/83/EC) and the prevention of the entry of falsified medicinal products into the legal supply chain (2011/62/EU).

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

When approximation of criminal law through the adoption of common minimum rules is considered, the already existing means to combat the harmful activity and the possibilities to make those means more effective should be given a priority. There are for example directives related to medicinal products for human use (2001/83/EC) and the prevention of the entry of falsified medicinal products into the legal supply chain (2011/62/EU).

It is especially good to keep in mind the recent Communication from the Commission (25 november 2020; Com [2020] 760:) including an intellectual property action plan. There are no criminal law measures in that plan, but many other measures meant for the protection of the intellectual property rights and for the fight against counterfeiting of products and other infringements of such rights are in place.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

FRANCE [1]

1. If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?

We do not need to reply to this question as France has already signed (28 October 2011) and ratified (21 September 2016) the Medicrime Convention.

2. In the light of the above, in particular the information provided by Eurojust and Europol:

a) Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?

From the perspective of the judicial authority and as pointed out in the document submitted, the lack of harmonisation in substantive criminal law (minimum maximum sentences) may theoretically create difficulties in terms of intra-EU judicial cooperation when offences relating to infringement of intellectual property rights – which are by nature often transnational – are in certain countries subject only to administrative penalties.

For instance, it is possible to refuse to execute a European Investigation Order (EIO) if the act giving rise to the EIO does not constitute a criminal offence. However, the grounds for refusing to execute an EIO are restrictive. The general philosophy of intra-EU cooperation based on mutual trust is always to execute as many requests as possible. We therefore do not find there to be any particular operational difficulty in this regard.

[1] Original: French. Translation provided by the General Secretariat of the Council.

b) Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?

There is no proven need for such a development from an operational perspective. The main issue seems to be rather **the effective and harmonised implementation of the existing provisions**. In a report entitled '*The fight against counterfeiting – organisation and tools to better protect consumers and industrial property rights*', published in February 2020, the French Court of Audit highlighted the fragmented landscape of the fight against counterfeiting in Europe, in terms of the harmonisation of national rules in the wake of Directive 2004/48/EC and in terms of the means employed (disparity in customs controls despite the coordination mechanisms put in place by the European Commission) – see page 50 et seq. of the report.

In addition, before considering any change to the legislative framework, it is worth first examining the relevant initiatives under way, whether in relation to the applicable provisions of the DSA, the political and operational objective of the EMPACT cycle, or the Commission's announcement of recommendations in 2022 which will serve as a toolbox in this area.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

French criminal law criminalises counterfeiting broadly, whatever the product or intellectual property right protected, and has gradually approximated the penalties for each protected right (trademarks, copyright, designs, etc.). Only medicinal products and raw materials for pharmaceutical use are specifically protected, due to their nature, by the Public Health Code. If the principle of harmonising substantive criminal law concerning respect for intellectual property rights were to be adopted, a broad approach would seem to be more appropriate for French law than an approach based on the type of product concerned.

As regards the products covered, it may however be worth noting that, in addition to the counterfeiting of medicinal products, which raises real public health issues, the counterfeiting of cigarettes/tobacco appears to us to be a particular fiscal or even public order issue (street sales and link with organised crime).

GERMANY

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Germany signed the MEDICRIME Convention on October 28, 2011. The ratification is currently in preparation.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

   c) **If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?**

   Generally speaking, counterfeiting is not a declining phenomenon and not a stagnant one, it is a steadily growing problem. Therefore, we agree that additional, EU-coordinated efforts need to be made to win the fight against counterfeiting. In this context we understand that we also have to reflect on our existing legal framework including Directive 2004/48/EC and our criminal rules. Before considering new legal measures especially common minimum rules in the context of criminal law, we should first start with a thorough stocktaking of existing legal differences and possible prosecution gabs within the EU.

This stocktaking exercise is now included in the current draft version of the Council Conclusions on IP Policy:

"27. To help ensure that more effective measures can be taken against IPR infringements, CONSIDERS it necessary to encourage reflections on the prevention of and fight against criminal violations of IP rights, in particular counterfeiting and piracy and their connection with international economic and financial crime, due to the involvement of organised criminal groups, including on the possible need to conduct a stocktaking exercise on existing legal differences between the Member States' criminal law frameworks, on possible criminal and prosecution gaps and on legal and practical obstacles to cross border cooperation within the EU;".

IRELAND

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Ireland is not currently in a position to sign or ratify the MEDICRIME Convention. While Ireland has not ratified the Convention, it does have robust criminal legislation and operational measures to combat the counterfeiting of medical products and similar crimes involving threats to public health.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

      In response to 2a) and 2b), Ireland is open to proposals and efforts made to harmonise an EU response to Intellectual Property Crime.

   c) **If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?**

ITALY

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Italy intends to ratify the MEDICRIME Convention but I am unable to specify the timing. The Ministry of Foreign Affairs has already activated the ratification process, at the moment the Ministry of Foreign Affairs is waiting to receive information from other Ministries, therefore the bill authorizing the ratification will be prepared. Therefore, we will soon be able to provide a more precise answer on the timing.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      Counterfeiting activities linked to cross-border and organized crime are likely to require broader criminal protection.

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

      Yes

   c) **If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?**

      The most serious forms of counterfeiting that endanger individual and public health (drugs, food supplements, protective products) as evidenced during the pandemic.

LATVIA

We would like to draw attention to the fact that Latvia has neither signed nor ratified the Medicrime Convention. At the same time, it is necessary to point out that a comprehensive assessment was carried out in 2010 on the possibility of signing and ratifying the relevant convention, but it was concluded that the signing and ratification of the Medicrime Convention would require significant changes in the regulatory framework of a number of sectors, as well as disproportionate administrative and financial resources. The Management Committee of the Ministry of Justice therefore decided not to endorse the signature and ratification of the Medicrime Convention.

Although the sectoral regulatory framework has not changed since the assessment was carried out, the conclusions reached are consistent with the current system. Pending the relevant amendments to sectoral legislation in order to bring them closer to the scope of the Medicrime Convention, it is not possible, in the meantime, to provide the Criminal Law with responsibility for the criminal offences provided for in the Medicrime Convention.

At the same time, there is a similar situation at European Union level. It is not possible to develop a European Union instrument intended to criminalise the criminal offences referred to in the Medicrime Convention, while there is no harmonised regulation at European Union level applicable to the medical and pharmaceutical sector. As an example, the term “counterfeiting” of the Medicrime Convention is used in a much wider context, as is currently the case in criminal law, including offences not related to intellectual property rights. Thus, if a criminal law instrument was created before the regulation of the medical and pharmaceutical sector was developed, an instrument would be established which would be impossible to apply in practice.

In conclusion, we would like to point out that the European Commission has carried out an evaluation of all the Council of Europe conventions with a view to determining which conventions the European Union should accede to jointly. The European Commission concluded that the Medicrime Convention does not need to be joined by the European Union together, but Member States may decide themselves to accede to the Medicrime Convention.

POLAND

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Poland is planning to become a party to the MEDICRIME Convention – the works are being carried out in the Ministry of Health of the Republic of Poland and in the Chief Pharmaceutical Inspectorate.

   Falsified medical products poses a real risk for public health, thus an accession to the above-mentioned agreement is key for the right to safe access to medicines of appropriate quality.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      Directive 2004/48/EC on the enforcement of intellectual property rights does not contain any provisions on criminal liability.

      Poland does not see the need to amend this directive. Under the current legal framework, intellectual property rights are sufficiently protected under national provisions and on the basis of international conventions and agreements implemented into the Polish legal system. Thus, adding criminal sanctions provisions to the directive 2004/48/EC will not present any added value.

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

Any decision to supplement Article 83(2) TFEU should be made after exhaustive and in-depth examination of the area and scope of the proposed criminal activity to be included. In case of counterfeiting activities (especially in context of counterfeited medicinal products) such examination should not be limited to infringements of intellectual property rights, but rather focus on threats such crimes pose to public health and safety.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

Poland agrees that initiating a debate to identify potential areas for improvement through establishment of common minimum rules in the fight against counterfeiting could be useful, however at this point we cannot prejudge the outcome of such debate, nor express support for such minimum rules set.

ROMANIA

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   In Romania, the competence in the field is shared between different ministries, therefore inter-institutional consultations and evaluations are ongoing with respect to the next steps to be taken.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   In Romania, the protection of industrial property rights (trademarks, patents, designs, industrial models) as well as of copyrights is ensured including through means of criminal law.

   We are of the opinion that the civil and administrative measures stipulated in Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights, in addition to national criminal law, are sufficient at this stage.

   In this respect, the Directive is without prejudice to national provisions in force in the Member States concerning criminal proceedings and penalties applicable to infringements of intellectual property rights (Article 2 (3) (c)).

b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

We consider that the intervention in criminal matters could be taken into account as *ultima ratio* solution.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

To the extent that harmonization of minimum standards in criminal matters is considered necessary, we believe that the most serious forms of counterfeiting should be taken into account.

SLOVAK REPUBLIC

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Slovakia has not signed the Council of Europe Convention on the counterfeiting of medical products and similar crimes (MEDICRIME Convention) yet. Recently, a thorough review of the text of the Convention by all interested governmental entities has been initiated by the Ministry of Justice and is underway. The aim is to determine whether the existing domestic laws are in line with the provisions of the Convention or further legislative changes are necessary to fully implement it. Based on the outcomes of this process the Slovak authorities will make the decision on further steps towards the ratification of the Convention.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      The final position on this question is not finalised yet and is subject of national consultation due to complexity of the question. However, we can indicate that the Criminal Code already criminalises the crime of counterfeiting of Medicines and Medical Devices (Section 170b), violation of Rights to Trade Marks, Indication of the Origin and Business Name (Section 281), violation of Industrial Rights (282) and violation of Copyright (Section 283) where the commission of those crimes as a part of dangerous group[2] is considered un aggravating circumstance and is reflected in the severe sanction.

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[2] A dangerous group shall mean a criminal group, or a terrorist group. A criminal group shall mean a structured group of at least three persons, which exists during a certain period of time and acts in coordination with the objective of committing one or more crimes, the criminal offence of money laundering or any of the criminal offences of corruption for the purpose of direct or indirect procurement of financial or other advantages.

b) Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?

Preliminarily we can consider the necessity for a minimum rules in the fights against counterfeiting. However, the study and step by step approach would be welcomed.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

Preliminarily we would propose to consider the scope of Medicrime Convention.

SLOVENIA

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Amendments of Slovenia's Criminal Code are under preparation in order to implement certain provisions of the Convention. As soon as amendment is adopted in Parliament (by the end of 2021), Slovenia will immediately commence the procedures for ratification.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      Organised crime is not covered by the Directive 2004/48/EC. The directive lays down administrative and civil measures only and says nothing on criminal offences and sanctions. Nevertheless, the Directive also mentions the TRIPS Agreement that contains criminal provisions. Therefore, not only the Directive but the whole system that it covers should be evaluated in this regard.

      Due to the fact that the organised crime exploits the lack of coordination between the Member States, Slovenia is firmly convinced, that the existing legal framework should be fully implemented and its impacts assessed before new instruments are designed on the EU level.

b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

We consider that further exploring of such possibilities could be appropriate. Nevertheless, before the activities aimed at the new rules would take place, current legislation, actual extent of criminal activity, its forms and its dangers for society, as well as the tools that are already available to combat the counterfeiting should be objectively evaluated.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

We consider that the counterfeiting activities that result in danger for health and lives of people and other living beings or the environment, or results in heavy losses for the injured parties/big profits for the organised crime groups should be addressed first.

SPAIN

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Spain signed the Medicrime Convention on 8 October 2012 and ratified it on 5 August 2013, without making any reservations. Its provisions have been incorporated into our Penal Code by a reform in 2015.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

      Directive 2004/48/EC contains minimum measures for the protection of intellectual property rights, which can be extended by legislation at national level, including by means of criminal law. This combined protection seems to us to be sufficient

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

      Regarding the possibility of harmonising criminal protection of intellectual property rights at the European level, we are cautious. We believe that it could be appropriate only in those cases in which counterfeiting, regardless of the degree of infringement of intellectual property rights, harms other relevant legal interests, such as public health and the integrity of persons.

c) If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?

Counterfeiting of medical products seems to us to be an area where criminal harmonisation could make sense, especially after the extent of the phenomenon that we have seen during the pandemic. However, this is not the only possibility, since ratification of the Medicrime Convention by the Member States, and even by the EU as such, is another solution to be considered.

SWEDEN

1. **If your Member State has not yet signed and ratified the MEDICRIME Convention, do you intend to do so? In the affirmative, when do you plan to start this process/where are you in this process?**

   Regarding ratification of the Medicrime convention, Sweden has no position in this moment, but we welcome the discussion.

2. **In the light of the above, in particular the information provided by Eurojust and Europol:**

   a) **Do you consider that measures, procedures and remedies provided for by Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights are sufficient to tackle the risks posed by counterfeiting activities related to cross-border and organised crime?**

   b) **Do you consider that it would be appropriate to further explore the possibility of adopting common minimum rules in the fight against counterfeiting, defining criminal offences and applicable sanctions, in accordance with the conditions laid down in Article 83(2) TFEU?**

   c) **If so, do you think there are specific types of counterfeiting that should preferably be addressed by such rules?**

      Sweden thinks it is too early to answer these questions and if an approximation of criminal law at EU-level is the right way to go. As noted in the Working Party of Intellectual Property during the process of drafting Council conclusions, a first step would rather be to investigate possible legal differences between the Member States' existing criminal law frameworks in this area, and if, and to what extent, these differences result in legal and practical problems in cross-border investigations and judicial cooperation in criminal matters within the EU.

Sweden looks forward to working together with other Member States to prevent intellectual property infringements, first of all through the actions that have been presented in the IP Action Plan.