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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the Member States' transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011

1. Introduction and legal framework

The falsification of medicines is a serious threat to public health. Falsification affects a wide range of medicines, such as cancer, sexual dysfunction and Hepatitis C treatments. Falsified medicines can and do penetrate the legal supply chain, as seen with the discovery in 2014 of falsified vials of the cancer treatment Herceptin (trastuzumab) in multiple EU markets[1].

In 2011, the European Parliament and the Council adopted Directive 2011/62/EU[2] (the Falsified Medicines Directive) to amend Directive 2001/83/EC[3] and address increasing concerns regarding falsified medicines in the legal supply chain.

The Falsified Medicines Directive introduces mandatory safety features on prescription medicines from February 2019 (unless explicitly exempted), strengthens good distribution practices and requirements for wholesale distributors, reinforces rules on importation, controls and inspections of active substances and their manufacturers, and establishes an EU-wide logo to allow the identification of legal online retailers of medicines (applicable from 1 July 2015).

In order to ensure effective enforcement of these provisions, Article 118a of Directive 2001/83/EC requires Member States to 'lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and [to] take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive'. Such rules are to address *inter alia*:

- 'the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well the sale of falsified medicinal products at a distance to the public by means of information society services;
- non-compliance with the provisions of the Directive on manufacturing, distribution, import and export of active substances; and
- non-compliance with provisions of the Directive on the use of excipients.

Where relevant, the penalties should take into account the risk to public health presented by the falsification of medicinal products'.

Member States were to notify the Commission of their measures by 2 January 2013. Article 118a also requires the Commission to submit a report to the European Parliament and the Council 'giving an overview of the transposition measures of Member States as regards [the] Article, together with an evaluation of the effectiveness of those measures'.

This report provides an overview of the Member States' transposition measures and a qualitative assessment of their effectiveness. The Commission was aided in its assessment by the TRANSPOSE study conducted by an external contractor[4]. The study provided an overview of transposition measures based on information provided by Member States under Article 118a and from legal experts in the 28

1 https://www.researchgate.net/publication/303445021_Operation_Volcano_-_The_Herceptin_Case

2 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).

3 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

4 *Study on the transposition measures of Member States in relation to the pharmaceutical legislation* (TRANSPOSE) – SANTE/2016/B4/052

Member States. This was complemented by a qualitative assessment of current penalties relating to falsified medicines, active substances and excipients. The Commission also consulted Member State competent authorities, through the Expert Group on the delegated act on safety features for medicinal products for human use, for further information on penalties in force[5].

2. Overview of the transposition of Article 118a in the Member States

A total of 26 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) have introduced changes to their legislation in relation to penalties for the falsification of medicines, active substances and excipients[6] in order to transpose Article 118a. Hungary made changes to its Criminal Code as a result of the Council of Europe Medicrime Convention[7]. Finland has not changed its legislation, as penalties were already in place before the entry into force of Article 118a.

Bodily harm or personal injury is covered by general criminal law in all Member States. Member States also impose general administrative sanctions for unlawful conduct involving medicines. These sanctions are complemented by specific penalties for the falsification of medicinal products, active substances and excipients, as outlined in Article 118a.

Current penalties for the falsification of medicines, active substances and excipients are imprisonment (criminal penalties), fines (criminal or civil penalties) and/or administrative sanctions (e.g. the revocation of licences or seizure/withdrawal of unlawful products from the market).

Falsification of medicines

In all Member States, at least some activities relating to the falsification of medicinal products are a criminal offence. In 21 Member States (AT, BE, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LU, MT, NL, PT, SI, SK, UK), the manufacturing, distribution, brokering, import, export and sale at a distance of falsified medicines all attract criminal penalties.

In the seven remaining Member States, some activities are covered by civil penalties (such as fines) rather than criminal penalties. In Bulgaria, criminal penalties apply only to the import or export of falsified medicinal products; the remaining activities are covered by civil penalties. In Finland, there are no specific penalties for brokering or export, but these are covered by more general provisions. In Latvia, criminal penalties cover manufacturing, distribution and brokering; there are civil penalties for import and export. In Romania, import and export are covered by civil rather than criminal penalties. In Poland and Sweden, criminal penalties do not cover export, but this is covered by civil penalties. In Lithuania, import is covered by civil penalties.

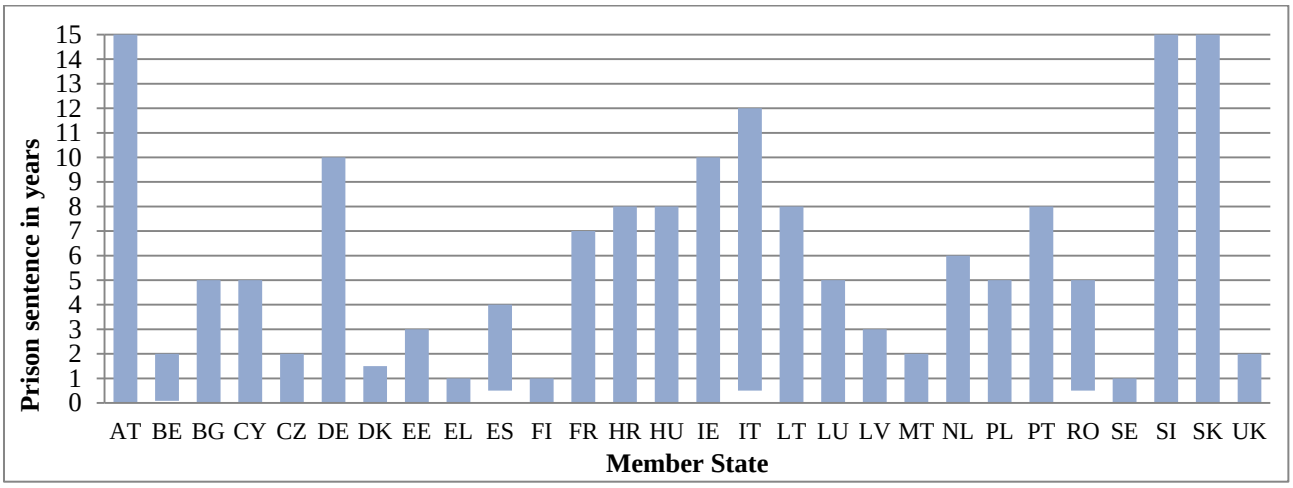
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5 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1); http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2719

6 Article 1(3b) of Directive 2001/83/EC defines excipients as 'any constituent of a medicinal product other than the active substance and the packaging material'.

7 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No.211).

Figure 1: Prison sentences for the falsification of medicinal products[8]



Maximum prison sentences range from one to 15 years (Figure 1).

All Member States apply criminal or civil fines in relation to the falsification of medicines (Table 1). Eight Member States (BE, FI, FR, IE, IT, LU, MT, UK) have criminal fines only. Seven (AT, CZ, HU, LT, RO, SI, SK) have civil fines only. The 13 remaining Member States (BG, CY, DE, DK, EE, EL, ES, HR, LV, NL, PL, PT, SE) have both criminal and civil fines. Maximum fines range from EUR 4 300 in Lithuania to EUR 1 million Spain[9].

Table 1: Maximum fines for the falsification of medicines (EUR)

* For non-euro Member States, an approximate euro amount is given.

AT	**BE**	**BG**	**CY**	**CZ**	**DE**	**DK**	**EE**
50 000	240 000	25 500	85 000	775 000	25 000	not specified	32 000
EL	**ES**	**FI**	**FR**	**HR**	**HU**	**IE**	**IT**
200 000	1 000 000	not specified	750 000	20 000	not specified	300 000	15 600
LT	**LU**	**LV**	**MT**	**NL**	**PL**	**PT**	**RO**
4 300	20 000	14 000	116 469	450 000	not specified	180 000	6 500
SE	**SI**	**SK**	**UK**				
not specified	120 000	25 000	unlimited				

In 24 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, LT, LV, NL, PL, PT, RO, SE, SI, SK, UK), there are specific administrative sanctions for the falsification of medicinal products.

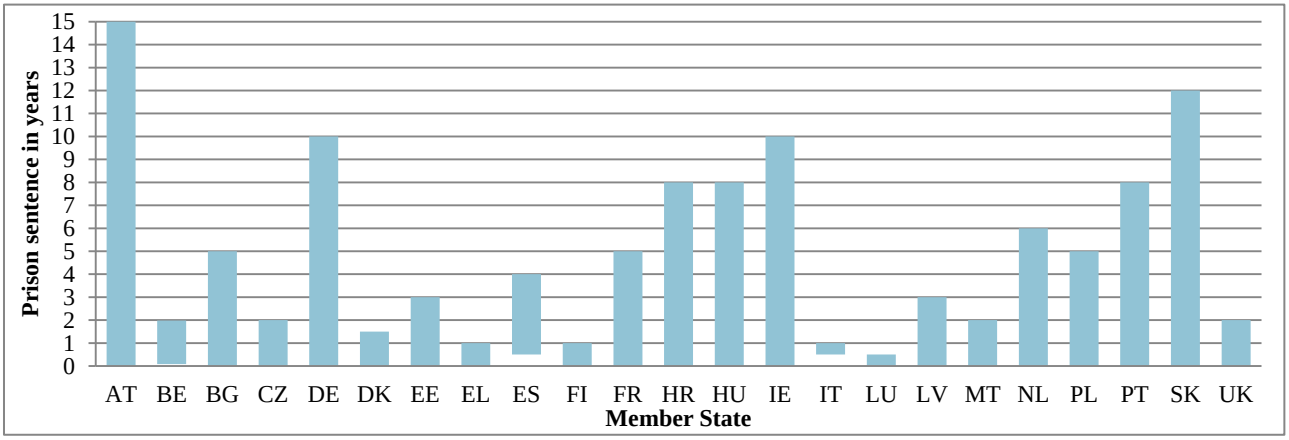
8 In the United Kingdom, offences under the Trade Marks Act, which may apply to the falsification of medicines, carry a maximum prison sentence of 10 years.

9 In Spain, the level of the fine depends on the severity of the offence. A fine of EUR 1 million would apply in the case of a 'very serious' offence.

Misconduct involving active substances

In 23 Member States (AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, PL, PT, SK, UK), misconduct in relation to active substances is a criminal offence.

Figure 2: Prison sentences for misconduct with respect to active substances



In 17 of those Member States, misconduct in the manufacturing, distribution, import and export of active substances are all covered by criminal penalties. In Bulgaria, criminal penalties only apply to misconduct in the import or export of active substances; the remaining activities are covered by civil penalties. In Finland, Poland and the United Kingdom, there are no specific penalties covering the export of active substances. In Latvia and Malta, criminal penalties only cover manufacturing and distribution of active substances, but Latvia imposes civil penalties to misconduct involving the import and export of active substances. Maximum prison sentences imposed range from six months to 15 years (Figure 2).

A total of 26 Member States (BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) apply criminal or civil fines in relation to active substances (Table 2). Seven Member States (BE, FI, IE, LU, MT, PL, UK) have criminal fines only. Seven (CY, CZ, LT, RO, SE, SI, SK) have only civil fines. The 12 remaining Member States (BG, DE, DK, EE, EL, ES, FR, HR, IT, LV, NL, PT) have both criminal and civil fines. The maximum fines for misconduct involving active substances range from EUR 1 500 in Lithuania to EUR 1 million in Spain.

Table 2: Maximum fines for misconduct involving active substances (EUR)

* For non-euro Member States, an approximate euro amount is given.

BE	**BG**	**CY**[10]	**CZ**	**DE**	**DK**	**EE**	**EL**
240 000	10 000	42 000	775 000	25 000	not specified	32 000	100 000
ES	**FI**	**FR**	**HR**	**IE**	**IT**	**LT**	**LU**
1 000 000	not specified	375 000	20 000	300 000	100 000	1 500	10 000
LV	**MT**	**NL**	**PL**	**PT**	**RO**	**SE**	**SI**
14 000	11 647	450 000	not specified	180 000	6 500	not specified	120 000
SK	**UK**						
35 000	unlimited						

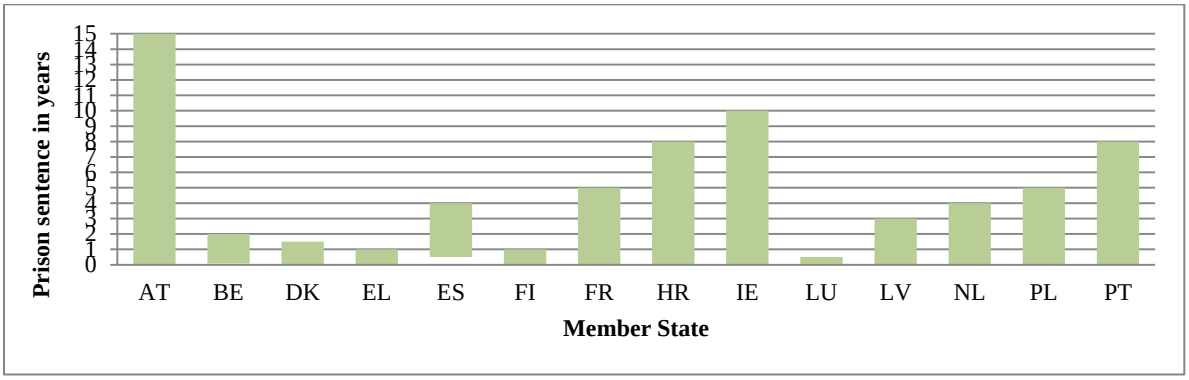
[10] In Cyprus, the fine may be increased by EUR 341 for each day the violation continues.

In 21 Member States (BG, CY, CZ, DE, DK, EE, ES, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK), there are specific administrative sanctions in place for misconduct in relation to active substances.

Misconduct involving excipients

In 14 Member States (AT, BE, DK, EL, ES, FI, FR, HR, IE, LU, LV, NL, PL, PT), misconduct in relation to excipients is a criminal offence.

Figure 3: Prison sentences for misconduct with respect to excipients



In nine of those Member States, misconduct in the manufacturing, distribution, import and export of excipients are all covered by criminal penalties. In Finland, misconduct in relation to the export of excipients is not covered by criminal penalties. In Ireland, only misconduct in relation to the manufacturing of excipients is covered by criminal penalties. In Latvia and Poland, criminal penalties only cover misconduct in the manufacturing and distribution of excipients; however, Latvia has civil penalties for import and export involving excipients. In Luxembourg, criminal penalties cover misconduct in the manufacturing and import of excipients. Maximum prison sentences for misconduct in relation to excipients range from six months to 15 years (Figure 3).

A total of 20 Member States (BE, CY, CZ, DK, EL, ES, FI, FR, HR, IE, IT, LU, LV, NL, PL, PT, RO, SE, SI, SK) also apply criminal or civil fines in relation to misconduct with excipients (Table 3). Five Member States (BE, FI, IE, LU, PL) have only criminal fines for misconduct with excipients. Seven (CY, CZ, IT, RO, SE, SI, SK) have only civil fines. The eight remaining Member States (DK, EL, ES, FR, HR, LV, NL, PT) have both criminal and civil fines. The maximum fines range from EUR 2 200 in Romania to EUR 1 million in Spain.

Table 3: Maximum fines for misconduct involving excipients (EUR)

* For non-euro Member States, an approximate euro amount is given.

BE	**CY**[11]	**CZ**	**DK**	**EL**	**ES**	**FI**	**FR**
240 000	42 000	775 000	not specified	100 000	1 000 000	not specified	375 000
HR	**IE**	**IT**	**LU**	**LV**	**NL**	**PL**	**PT**
20 000	300 000	18 000	10 000	14 000	450 000	not specified	180 000
RO	**SE**	**SI**	**SK**				
2 200	not specified	120 000	25 000				

[11] In Cyprus, the fine may be increased by EUR 341 for each day the violation continues.

In 15 Member States (CZ, DK, EE, ES, FR, HR, HU, IT, LT, LV, PL, PT, RO, SI, SK), there are specific administrative sanctions in place for misconduct in relation to excipients.

Overall transposition

All 28 Member States apply criminal penalties in the form of imprisonment for the falsification of medicines. One Member State (LV) penalises falsification that causes physical harm or death (harm crimes) and two Member States (ES, PT) falsification that causes a risk or danger to the health of a person or public health (concrete endangerment). Four Member States (EL, LT, RO, SI) penalise falsification that is shown to be generally dangerous, i.e. the falsified medicine contains insufficient active ingredients or harmful substances (concrete-abstract endangerment). In the remaining 21 Member States, falsification *per se* is penalised, without the need to prove that the product is dangerous to health (abstract endangerment). For active substances, 23 Member States apply criminal penalties. For excipients, 14 Member States apply criminal penalties.

Where criminal penalties apply for the falsification of medicines, the maximum prison sentence is at least three years in 20 Member States (AT, BG, CY, DE, EE, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK). A prison sentence of at least three years means that the crime falls under the European Investigation Order[12].

As outlined above, all Member States apply fines for the falsification of medicines. For active substances, 26 Member States apply fines. For excipients, 20 Member States apply fines. Fines may take the form of criminal or civil penalties, although maximum levels vary across Member States.

All Member States except Finland, Luxembourg and Malta have introduced additional administrative sanctions for the falsification of medicines, active substances and/or excipients.

3. Effectiveness

It is difficult to measure the effectiveness of specific national penalties due to a lack of exhaustive data on incidents in the Member States and the inherent illegal nature of the activities. Many of the national legal experts consulted as part of the TRANSPOSE study were unable to provide estimates of the effectiveness of specific penalties in relation to falsified medicines, active substances and excipients[13].

Experts in 10 Member States provided estimates of the effectiveness of national penalties in preventing falsified medicines from penetrating the legal supply chain (i.e. manufacturers, parallel importers, wholesale distributors and pharmacies). They considered that all of the penalties in place (criminal, civil and administrative) had at least some effect in reducing the presence of falsified medicines in the legal supply chain. Overall, administrative sanctions were rated as effective more often. Eight experts provided estimates of the extent to which the presence of falsified medicines in the legal supply chain had been reduced since the introduction of Directive 2011/62/EU. Six experts

[12] See Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters (OJ L 130, 1.5.2014, p. 1). The European Investigation Order is based on mutual recognition, which means that Member States are obliged to recognise and act on each other's requests for evidence in the same manner as they would act on a request from their own authorities.

[13] Seventeen experts did not provide any replies regarding the effectiveness of penalties in the legal supply chain. Fifteen experts did not provide any replies regarding the effectiveness of penalties in the illegal supply chain.

considered a reduction of more than 25 % had occurred, whereas two considered a reduction of less than 5 % had occurred.

For the illegal supply chain (e.g. purchases of medicines from illegal online pharmacies), experts in 12 Member States provided estimates of the effectiveness of national penalties. Six considered that the criminal penalties had at least some effect in reducing the presence of falsified medicines in the illegal supply chain. Two experts considered that civil penalties had a small effect and three considered administrative sanctions to have had at least some effect. Overall, criminal penalties were rated as effective more often. Four experts considered that the presence of falsified medicines in the illegal supply chain had been reduced by at least 25 % since the introduction of Directive 2011/62/EU; seven estimated the reduction at less than 25 %.

In general, the study noted that Member States should introduce both criminal penalties and administrative sanctions in order to safeguard the legal supply chain and tackle the illegal sale of falsified medicinal products. Criminal penalties are effective and dissuasive for actors in both the legal and illegal supply chains. Administrative sanctions are useful in addressing misconduct in the legal supply chain (where operators are dependent on licences), but cannot adequately address operators in the illegal market, who already act without authorisations, i.e. illegally. However, administrative sanctions are generally easier to enforce than criminal penalties.

As regards criminal penalties, the study noted that it is easier to enforce broader provisions that do not require proof of direct harm to patients, but rather cover medicinal products that are dangerous or falsified. For example, in many Member States falsification *per se* is penalised, without the need to prove that the product is dangerous to patients' health.

Applying maximum prison sentences of at least three years can also facilitate the sharing of evidence through a European Investigation Order[12], which may be relevant if crimes have been committed across multiple Member States. In any case, cooperation is necessary to ensure that evidence is shared for crimes with cross-border relevance.

The effective enforcement of existing penalties is crucial in addressing the falsification of medicines, active substances and excipients. It is important to ensure that enforcement officials are well trained and given adequate resources to investigate pharmaceutical crimes.

The Working Group of Enforcement Officers[14] (established by the Heads of Medicines Agencies network) is an important forum to ensure cooperation and sharing of best practices between medicines agencies and enforcement authorities in the European Economic Area. Interpol also works to support international cooperation, provide training and encourage the exchange of information between police, customs, medicines authorities, scientists and industry[15].

Member States should monitor enforcement to ensure that penalties are effectively applied. For example, since 2015 Germany has been collecting more detailed crime statistics on the falsification of

14 http://www.hma.eu/wgeo.html
15 https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime

medicines and related offences[16]. This should allow in future for a clearer understanding of the effectiveness of penalties.

4. Conclusions

Member States' transposition of Article 118a of Directive 2001/83/EC is satisfactory. To further reinforce measures in place and strengthen their overall effectiveness, certain Member States could consider introducing additional criminal penalties or administrative sanctions in relation to falsified medicines, active substances or excipients.

Member States should ensure that adequate resources and personnel are allocated to enforcing penalties in place (e.g. by training new enforcement officers). Increased monitoring and data collection could allow for more accurate assessment of the effectiveness of specific national provisions, especially given the difficulties in obtaining accurate estimates of the extent of falsification in the EU market.

The falsification of medicines is a serious threat to public health. The Falsified Medicines Directive has introduced a number of measures to protect the legal supply chain of medicines from falsification in the EU. This includes mandatory safety features on prescription medicines, strengthened GDP requirements, reinforced rules on importation of active substances, and an EU-wide logo for online pharmacies.

The Commission will continue to support Member States' implementation of the Falsified Medicines Directive, in particular the medicine authentication system which becomes applicable in the Member States in February 2019. The system is designed to ensure that medicines in the legal supply chain are genuine, safe and of high quality. The EU logo for online pharmacies should ensure that consumers do not unknowingly buy medicines from illegal suppliers and should assist Member States in their enforcement efforts.

Discouraging the falsification of medicines through suitable penalties will only be possible on the basis of continued cooperation, sharing of best practices and effective monitoring of the legislation in place.

[16] Polizeiliche Kriminalstatistik [police crime statistics] [Germany] 2015, p. 122; https://www.bka.de/DE/AktuelleInformationen/StatistikenLagebilder/PolizeilicheKriminalstatistik/PKS2015/pks2015_node.html