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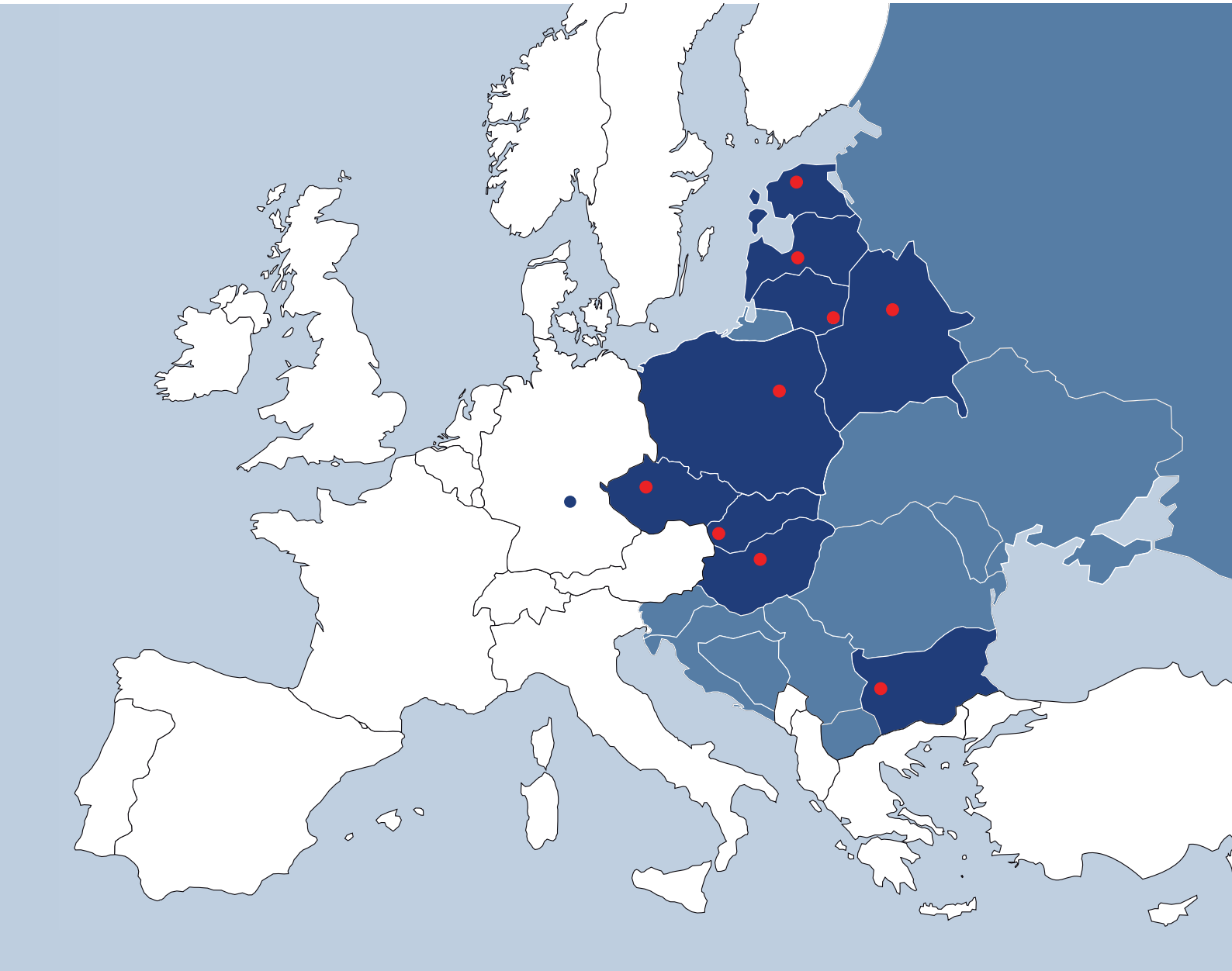
EFPIA DISCLOSURE CODE

The Central and Eastern European Approach

2015/2016



BRATISLAVA BUDAPEST MINSK NÜRNBERG PRAHA RIGA SOFIA TALLINN VILNIUS WARSZAWA

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Content

Introduction

Development of new medicines cannot be imagined without collaboration between healthcare professionals and healthcare organizations on the one hand and the pharmaceutical industry on the other. However, the financial relationship between pharmaceutical companies and healthcare organisations and professionals often suggests conflict of interest, lacks transparency and thus leads to disclosure initiatives.

The EFPIA Code on Disclosure of Transfers of Value from pharmaceutical companies to healthcare professionals and healthcare organizations requires its members to disclose any direct payments or other forms of support. The Code affects not only the 33 European countries in which EFPIA has national member associations plus direct corporate EFPIA members but also other countries where pharmaceutical industry associations and companies that are not EFPIA members decide to voluntarily implement the Code. This may well lead to significant changes in marketing and compliance policies in all pharmaceutical companies.

As the first public disclosure by 30 June 2016 (for the period 1 January – 31 December 2015) is just around the corner, the Pharma subgroup of our Industry & Regulatory Practice Group has examined how far countries in Central and Eastern Europe ("CEE") have come in their implementation and how they have chosen to achieve the aim of transparency. The differences in progress of implementation quite surprised us.

In addition, the ways chosen for implementation differ considerably from country to country. Pharmaceutical companies are therefore well advised to compare national systems, noting the following in particular: national deviations from the EFPIA Code, differences in publication requirements and data to be disclosed, national data protection issues raised by the disclosure obligation and other matters having an impact on pharmaceutical companies' business in the countries concerned.

This bnt | attorneys-at-law survey EFPIA TRANSPARENCY CODE - THE CENTRAL AND EASTERN EUROPEAN APPROACH is a systematic overview of the regulatory framework in CEE. It covers the main issues of national pharmaceutical industry codes in CEE and also aims to show that in some countries the obligation to disclose actually derives from statutory requirements and is not based solely upon membership in the pharmaceutical industry association. The Survey will therefore be of use to any pharmaceutical company doing business or planning to do so in the CEE region as well as any healthcare organisation or healthcare professional having their principal practice or physical address in one of the CEE countries where we operate.

Vilnius, 15 October 2015

Yvonne Goldammer

Head of the Industry & Regulatory Practice Group

Note that this Survey was prepared based on the laws in effect on 15 October 2015. Later changes have not been reflected. Note also that, despite having been prepared diligently, the Survey and the information in it are not to be understood as legal advice, which should be sought from a pharma law specialist for each specific case.

Bulgaria

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EFPIA disclosure code

Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation		• The EFPIA Disclosure Code is implemented by the Code for Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Health Organizations. This code was adopted by the Bulgarian Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM). The code was adopted in November 2013 and has been in force since January 1st 2014. • Deviations: the Bulgarian code does not provide substantial deviations.
2. How does publication of data take place?		• Disclosure should be made on the website of the pharmaco, a link to which should be published on www.arpharm.org or on a dedicated information website in Bulgarian to which access is unrestricted and public. Disclosure should be made in Bulgarian.
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?		• Responsibility not determined. • The pharmaco must establish a link to its website where publication is accessible. The data itself will be published on a standardized template which is already established (in Bulgarian).
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical		• Disclosure should be made under the national code of the country where the recipient has its physical address. If a member company is not resident or does not have a subsidiary or an affiliate in the country where the recipient has its physical address, the member company should disclose the

EFPIA disclosure code

address / code of the country where the pharmaco is located?	transfer of value in a manner consistent with the national code to which it is subject.
5. Does the national disclosure code cover all pharmaceutical companies?	• The national disclosure code covers only member companies. However, most pharmacos operating in Bulgaria are represented in ARPharM.
6. How about those companies that are not covered by implementation?	• Withdrawal from application of the code is possible by terminating membership. • No special benefits accrue from membership besides public confidence and a better chance to protect/lobby interests before the government or other stakeholders.
7. Data protection – problems and solutions • Legal basis for disclosure • Period of disclosure • What kind of data according to local data protection laws will be disclosed? • Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?	• The code indirectly imposes an obligation on companies to obtain disclosure consent from recipients. • Period of disclosure is one year. • Except as expressly provided for by the code, each member company should disclose individually for each clearly identifiable recipient the amounts attributable to transfers of value to the recipient in each reporting period. • The HCP may revoke its consent at any time.
8. Procedure • Person / Authority responsible for monitoring • Who decides about penalties and the amount (Arbitration board)? • If there is a kind of arbitration procedure – who is allowed to complain?	• The ethics committee on the advertising of medicines established by ARPharM monitors compliance with the code and imposes penalties. A decision of the committee may be appealed before the extended composition of the committee. • Any party is entitled to complain.
9. Sanctions and penalties • Types of penalty set in the code / other national legal acts	• The ethics committee can impose fines of BGN 2 000 to 7 000 (EUR 1 = BGN 1.95583). For repeated misconduct, twice the amount can be imposed. Administrative expenses and fees (BGN 600) are borne by the infringing party. • Decisions of the ethics committee or extracts thereof should be published on the ARPharM website. Depending on the nature and seriousness of the violation, the ethics committee considers whether the published decision contains the name of the company that violated the code and details of the case.

Czech Republic

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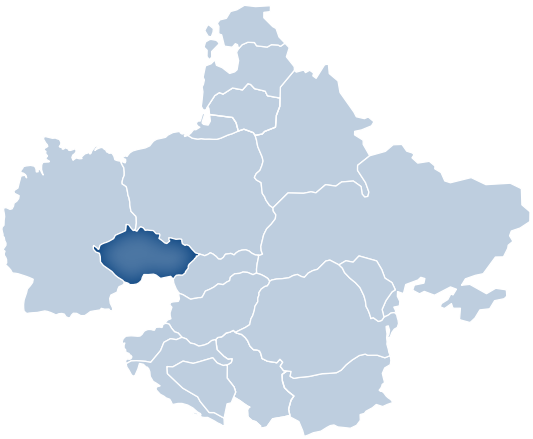
EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation	• Basic regulation similar to the EFPIA Code is in-tended to be implemented in the Act on Regulation of Advertising. However in April 2015 the bill was rejected (for basic amendments) by the House of Representatives.	• The EFPIA Disclosure Code was implemented by an association called AIFP (Asociace inovativního farmaceutického průmyslu), which is a voluntary self-regulation association operating in the Czech market. • The code was adopted on 23 May 2014. Deviations: There are no substantial deviations within Czech implementation.
2. How does publication of data take place?		• Information should be published centrally on the website of the AIFP and also individually by each member company (although the concrete method of publication is in the discretion of the member).
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?		• The central publication platform should be operated by AIFP. • Each member should provide data to AIFP within 6 months after the end of every year. • A template for data provision is set as an annex to the code. However, the annex has not yet been approved.
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?		• Relevant data should be published on the website of the member company but no special regulation is set for foreign recipients. Thus each AIFP member company should not distinguish between foreign or local HCP/HCO as to the publication procedure. Other questions (e.g. personal data protection) should be regulated under the law of the country of the respective HCP/HCO.

EFPIA disclosure code

5. Does the national disclosure code cover all pharmaceutical companies?

- The code applies only to AIFP member companies, of which there are 30.

6. How about those companies that are not covered by implementation?

- Only AIFP has implemented the transparency code (the other pharmaceutical associations not) although we expect that most companies have implemented similar rules within their internal compliance programmes.

7. Data protection – problems and solutions

- Legal basis for disclosure
- Period of disclosure
- What kind of data according to local data protection laws will be disclosed?
- Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?

- Under Czech law, the explicit and fully informed consent of the data subject is necessary. The data subject is entitled to withdraw its consent any time.
- The period of disclosure is 3 years.
- So far not determined (the annex to the code has still not been approved).
- They can refuse to disclose this information.

8. Procedure

- Person / Authority responsible for monitoring
- Who decides about penalties and the amount (Arbitration board)?
- If there is a kind of arbitration procedure – who is allowed to complain?

- The code itself does not regulate procedures. However, in these cases the rules of the AIFP Code of Ethics should be used.
- The AIFP Code of Ethics sets a detailed procedure policy based on arbitration proceedings.

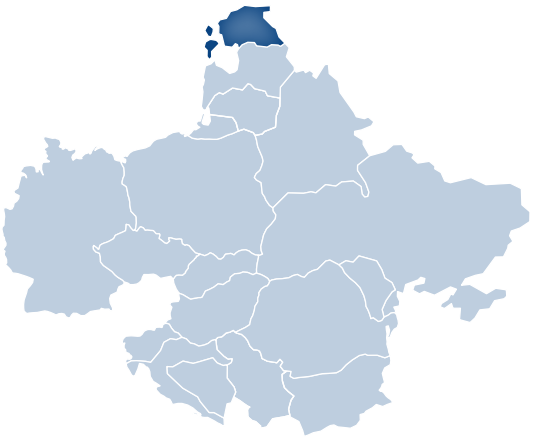
9. Sanctions and penalties

- Types of penalty set in the code / other national legal acts

- The code itself does not regulate penalties and sanctions or their amount. However, breach of its rules is punishable under the AIFP Code of Ethics.
- The AIFP Code of Ethics contains a detailed proceedings and penalties system (including financial penalties, temporary suspension of membership or permanent exclusion from the association).

Estonia

EFPIA disclosure code



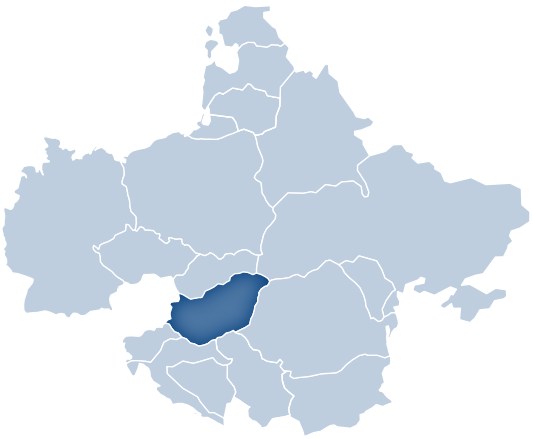
Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation	• According to the website of "Eesti ravimitootjate liit" (APME, the Association of Estonian Pharmaceutical Manufacturers) the EFPIA code has been "transferred into State law", but clearly no such official transfer has taken place yet.	• The EFPIA Disclosure Code was implemented in the APME Code of Ethics without deviations.
2. How does publication of data take place?		• Disclosure should be "made on the website of APME member companies in Estonian and if necessary in English".
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?		• Responsibility not determined. • APME member companies must disclose these transfers themselves on the APME website in Estonian and if necessary in English. • Method of data provision not set.
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?		• Not determined. • No regulation at all.

EFPIA disclosure code

5. Does the national disclosure code cover all pharmaceutical companies?	• The code applies to all pharmaceutical companies.
6. How about those companies that are not covered by implementation?	• n/a.
7. Data protection – problems and solutions • Legal basis for disclosure • Period of disclosure • What kind of data according to local data protection laws will be disclosed? • Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?	• The Estonian code directly obliges companies to "disclose transfers of value as set by the EFPIA". • Fees disclosed should be kept available on the website of APME member companies for at least 3 years after initial disclosure.
8. Procedure • Person / Authority responsible for monitoring • Who decides about penalties and the amount (Arbitration board)? • If there is a kind of arbitration procedure – who is allowed to complain?	• Breaches of the code are handled by the pharmaceutical manufacturers' ethics committee established under the APME. • The ethics committee.
9. Sanctions and penalties • Types of penalty set in the code / other national legal acts	• For a first breach, the ethics committee may issue a warning, along with an order to terminate the breach immediately. For a serious first breach, the ethics committee may impose a penalty of up to EUR 1 300, to be transferred to the APME bank account within 10 working days. • For repetitive and malicious breaches of the APME code, the ethics committee may impose a penalty of up to EUR 6 391 and require the violator to terminate the breach immediately and compensate any damage.

Hungary

EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation		• The EFPIA Disclosure Code has been implemented by the Association of Innovative Pharmaceutical Manufacturers (AIPM). • The AIPM implemented the EFPIA Disclosure Code as self-regulation at the end of 2013. It came into force on 1 January 2015. • Deviations: Hungarian implementation does not deviate from the EFPIA Disclosure Code substantially, only structurally. Some aspects are more clarified, for instance, the procedural rules.
2. How does publication of data take place?		• The pharmaco may publish information on its website or on the website of a subsidiary or of its affiliated companies.
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?		• n/a.
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?		• Disclosure should be made in accordance with the national code of the country where the company has its physical address, irrespective of the nationality of the recipients (HCP or HCO).

EFPIA disclosure code

5. Does the national disclosure code cover all pharmaceutical companies?

- The AIPM Transparency Code applies to AIPM member companies and their subsidiaries or affiliates and any other pharmaceutical manufacturer, wholesaler or distributor that is a signatory to the AIPM code and has accepted the code as binding in a declaration of adherence.

6. How about those companies that are not covered by implementation?

- n/a.

7. Data protection – problems and solutions

- Legal basis for disclosure
- Period of disclosure
- What kind of data according to local data protection laws will be disclosed?
- Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?

- Under Hungarian regulation, the data in question can be qualified as personal data. Under Act CXII of 2011 on the Right of Informational Self-Determination and on Freedom of Information (Privacy Act) personal data can be processed when the data subject has consented or when it is mandatory by law. No law makes disclosure mandatory. Therefore, the personal data in question can be disclosed only upon the clear, voluntary and informed consent of the data subject.
- Relevant data must remain on a website for at least 3 years, unless a shorter period is set by law or the data subjects (recipients) revoke their consent.
- Under the AIPM Transparency Code, a transfer of value must be disclosed, specifying the name of the recipient (HCP or HCO).
- Annex 1 to the AIPM Transparency Code contains all the data that must be disclosed: full name, business address, country of principal practice, address of principal practice. Optionally, identification of the recipient (seal number, registration no. etc.) can be disclosed. Annex 1 corresponds to Schedule 2 of the EFPIA Disclosure Code.
- Under the Privacy Act, the leading principle is that personal data can be processed only for specified and explicit purposes, must be important for the purpose they were collected for and must be suitable to serve that purpose. Additionally, the data in question must be treated as personal as long as the data subject remains identifiable through them. Accuracy, completeness and up-to-datedness must be ensured.
- HCOs and HCPs may revoke their consent to disclosure. In that event, the data concerned cannot remain disclosed.

8. Procedure

- Person / Authority responsible for monitoring

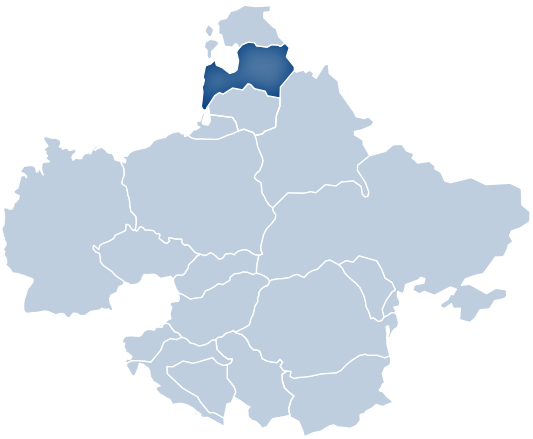
- The companies set up a transparency committee to oversee compliance with the transparency code, defining its functions and its rules of procedure for handling conduct infringing the transparency code.

EFPIA disclosure code

• Who decides about penalties and the amount (Arbitration board)? • If there is a kind of arbitration procedure – who is allowed to complain?	• The transparency committee conducts a procedure (ex officio or in response to complaints) in the event of a violation of the AIPM Transparency Code. • Complaints can be lodged by companies with a disclosure obligation and recipients (HCO, HCP). The transparency committee will not institute proceedings lodged by anonymous complainants.
9. Sanctions and penalties • Types of penalty set in the code / other national legal acts	• The AIPM Transparency Code includes procedural rules on penalties and sanctions. The code does not impose monetary penalties. • The transparency committee can apply the following sanctions (or a combination of sanctions) for any violation of the AIPM Transparency Code: – written warning; – issue a cease and desist order and require alignment of conduct with the AIPM Transparency Code by a given deadline and in a defined manner and to notify the committee in writing about restored compliance; – resolutions about violations can be published on the website of the AIPM or the transparency committee mentioning the name of the company until the conduct is remedied, but for no more than one year from the issuance of a resolution. • in the event of very serious or repeated infringements, a company can be excluded from the AIPM and its name can be published among the 'Non-Transparent Pharmaceutical Manufacturers' on the website of the AIPM / transparency committee until the conduct is remedied. The publication can be seen by anyone.

Latvia

EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation	• Not direct implementation, but similar obligations are implemented in Governmental Regulation No.378 (2011, last amended in 2014, the amendments entered into force on 1 January 2015), governing advertising of medicines (under the law advertising covers any activity aimed at facilitating prescription, distribution or use of medicines, including organizing and sponsoring advertising or scientific events, financially or other support of the HCO etc). • Under Regulation No. 378 the marketing authorization holder, its representative or other advertiser or distributor of advertisement ("advertisers") organizing or sponsoring the above events or providing support to the HCO for participation by the HCP in these events must disclose certain information. • Regulation No.378 also allows NGOs (including professional associations) to adopt codes of ethics corresponding to law and	• The EFPIA Disclosure Code is implemented jointly by the disclosure code agreed upon by two Latvian associations - SIFFA (Association of International Research-based Pharmaceutical Manufacturers) and PMA (Latvian Generic Medicines Association). This code is binding on their members. • The code was approved by SIFFA on 22 September 2014 and by PMA on 30 September 2014. • The code entered into force on 1 January 2015. • Deviations: the Latvian code does not provide substantial deviations.

EFPIA disclosure code

	international codes of ethics.	
2. How does publication of data take place?	• Data are published on the website of the health inspectorate.	• Both options are provided. Publication takes place once a year through (i) a central platform (database) established by (a) both SIFFA and PMA or (b) governmental or other regulatory authorities or other relevant professional bodies (if the authorities or other bodies establish such a platform); or (ii) on the member's website. If the member publishes data only on its webpage, it must within a month after the publication date notify the ethics committee of the SIFFA and PMA of the respective web page address.
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?	• The Advertiser must send data to the Health Inspectorate in writing (including electronic use of the system of the state site www.latvija.lv) annually by 31 March of the following year.	• If publication is through a central platform the provider must publish data on a standardized template (in Latvian; English can also be used). • Detailed instructions on the process for sending data have not yet been elaborated.
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?	• Regulation No. 378 applies to any advertisement (i.e. event or support) provided in Latvia, regardless of the residence of the recipient.	• The code of the country where the recipient has its physical address or is registered must be applied. However, if a member, its affiliate or a contracting party are not residents of the country where the recipient has its physical location or is registered, the member must publish the data in accordance with the Latvian code.
5. Does the national disclosure code cover all pharmaceutical companies?	• Yes.	• The national disclosure code covers only members of SIFFA and PMA. However, most pharmacos operating in Latvia are represented in SIFFA and PMA. • In case of discrepancies between the code and the applicable law to which the member is subject (e.g. foreign law) and which would make adherence in full to the code not reasonably possible, the member must comply with the laws of its own country. • In turn, members operating under Latvian law are bound only by the Latvian code (N.B. the Latvian text of the code differs from the quoted English text – the Latvian version states that members bound by Latvian law must comply only with the Latvian code). • Non-members that decide to voluntarily implement the code must ensure that despite their legal status they will comply with all provisions of the code.

EFPIA disclosure code

6. How about those companies that are not covered by implementation?		• Pharmaceutical companies that are not members of SIFFA and PMA are invited to accept and implement the code. Non-members that decide to voluntarily implement the code must ensure that despite their legal status they will comply with all provisions of the code. • Withdrawing from application of the code is possible by terminating membership of SIFFA and/ or PMA. • There are no special benefits because of membership, beside public confidence and a better possibility to protect or lobby interests before the government or other stakeholders.
7. Data protection – problems and solutions • Legal basis for disclosure • Period of disclosure • What kind of data according to local data protection laws will be disclosed? • Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?	• Under the Personal Data Protection Law (2000) disclosure is based on requiring the data controller to perform the duties assigned by law (i.e. the advertiser as data controller must disclose information under Regulation No. 378). • The period of disclosure is not regulated. • The name, specialization (profession), participation in the event supported and/or or the value (in money) of the support received by the HCP should be disclosed. • The HCO and HCP cannot influence disclosure.	• In this case under the Personal Data Protection Law personal data may be processed (including disclosure) only (i) with the consent of the data subject (i.e. a recipient- HCP) or (ii) if processing is required according to a contractual obligation of the data subject (i.e. under a contract between the member and HCP). • Relevant data must be accessible for at least three years from initial disclosure on the respective platform or website unless a shorter period is set by Latvian law (current law sets no limit) or the recipient has revoked consent under the applicable law (of the country governing data processing). • Under the code the name, address of the practice and the value (in money) of support received from the HCP should be disclosed. • The HCP may revoke its consent at any time.
8. Procedure • Person / Authority responsible for monitoring • Who decides about penalties and the amount (Arbitration board)? • If there is a kind of arbitration procedure – who is allowed to complain?	• The health inspectorate monitors compliance with Regulation No. 378 and imposes penalties. • Any party may complain (the further status of the complainant in the proceedings will depend on the complainant's legitimate interest). Anonymous complaints may not be considered but may informally push the inspectorate to start an examination on its own initiative.	• The ethics committee on advertising medicines established by SIFFA and PMA monitors compliance with the code and imposes penalties. A decision of the committee may be appealed to a joint meeting of the boards of SIFFA and PMA. • Any party may complain. Anonymous complaints may not be considered but the complainant may ask the head of the committee that the name of the complainant is not disclosed either to the defendant or other members of the committee, or to third parties.

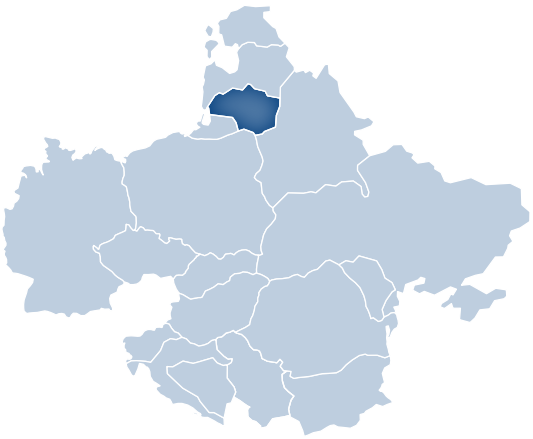
EFPIA disclosure code

9. Sanctions and penalties

- Types of penalty set in the code / other national legal acts
  - The inspectorate may impose a penalty for violations of Regulation No. 378 up to EUR 700 for individuals and from EUR 400 to 14 000 for legal entities.
  - The inspectorate may also issue a warning (setting a certain term for the elimination of violations) to the pharmaco. If the violations are not eliminated, the inspectorate may close down the operation of the company.
  - Only a public rebuke is provided for violating the code - the committee publishes the information on a particular violation on the webpage/s of SIFFA and PMA as well as in the mass media, announcing a summary of facts. The name of the committer cannot be disclosed for a minor violation but may be disclosed only for severe or recurrent violations (at least two violations established in one calendar year).
  - In addition, the committee may send information on established violations to the state authorities (e.g. the health inspectorate).

Lithuania

EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation	• No direct implementation. However, a very similar provision exists in Art. 51 para. 9 of the Lithuanian Law on Pharmacy. This obliges the registrant of a medicinal product or their representative to collect and submit to the State Medicines Control Agency information on financed professional or scientific events and the personal data of health care or pharmaceutical professionals whose participation was financed in the events.	• The EFPIA Disclosure Code was implemented by an association called IFPA (Inovatyvios farmacijos pramones asociacija – Association of Innovative Pharmaceutical Industry) on 26 November 2013 and an association called VGA (Vaistu gamintoju asociacija – Association of Pharmaceutical Manufacturers) on 16 January 2015. Respective provisions are contained in Annex D of the Code of Ethics for Pharmaceutical Marketing. • No substantial deviations in the national code.
2. How does publication of data take place?	• The State Medicines Control Agency publishes information on its website by 31 March of each year. Data are accessible for 3 years.	• Information must be published on the website of the member company or its mother company. On a special website for the code (www.vaistukodeksas.lt) a reference must be given to data published on company websites.
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?	• Each provider is responsible for the accuracy of data submitted. • Yes, data must be submitted annually, by 1 February, electronically.	• n/a

EFPIA disclosure code

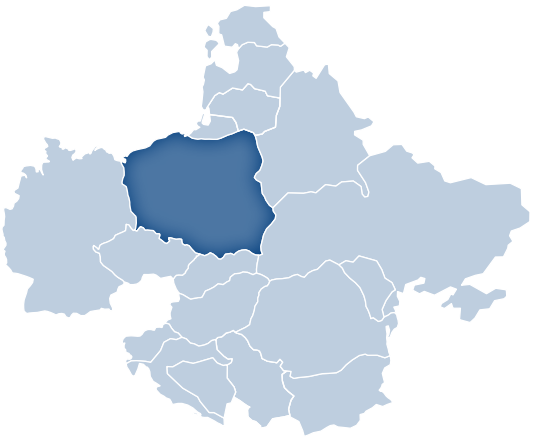
4. Regulations regarding foreign recipients • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?	• n/a.	• Information must be published on the website of the member company, its subsidiary or affiliated company under the rules of the code of the country where the recipient has its physical address. • If there is no company, subsidiary or affiliated company where the recipient is physically located, the member company must disclose the information under the national code of the recipient. The national code does not regulate disclosure where the recipient has its physical address in a country that is not a member of EFPIA.
5. Does the national disclosure code cover all pharmaceutical companies?	• The above mentioned provision of the Law on Pharmacy applies to all MA holders of the medicinal product or their representatives in Lithuania.	• The code applies to (i) companies engaged in pharmaceutical marketing in Lithuania, (ii) their representatives and (iii) member companies of the Code of Ethics for Pharmaceutical Marketing associations or other legal arrangements or their structural units. • Currently, the code applies to 40 member companies: 17 IFPA and 23 VGA members.
6. How about those companies that are not covered by implementation?	• See question 5.	• Most companies not covered by this code are covered by other codes, e.g. if they are corporate members of the EFPIA. • Upon termination of membership in either IFPA or VGA, the obligation to disclose expires. However, the obligation to disclose under the Law on Pharmacy remains. • No special benefits accrue from membership other than public confidence.
7. Data protection – problems and solutions • Legal basis for disclosure • Period of disclosure • What kind of data according to local data protection laws will be disclosed? • Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?	• Legal basis for disclosure is a must to comply with legal obligation. • Published data remain publicly accessible for 3 years. • No possibility for HCOs or HCPs to influence the amount of data disclosed.	• Legal basis for disclosure is data subject's consent. • Published data must be publicly accessible for at least 3 years from the day first published unless (i) the data protection laws set a shorter period; or (ii) the data subject has revoked consent to disclose personal data. • The national code does not set a list of data to be disclosed; however, the information must be disclosed by filing a report sample (annex 2 to the code; note: not yet publicly available). • No explicit possibility for FCOs/HCPs to influence the amount of disclosed data established; however, the right arises from their right to consent to personal data disclosure.
8. Procedure • Person / Authority responsible for monitoring • Who decides about penalties and the amount (Arbitration board)?	• State Medicines Control Agency. • State Medicines Control Agency may impose a penalty for infringing Art. 51 para. 9 of the Law on Pharmacy. Its decisions may	• The Ethics Committee for Pharmaceutical Marketing. • The Ethics Committee for Pharmaceutical Marketing decides upon penalties for infringement of the disclosure code. Its decisions may be appealed to a court. • Anonymous applications are not examined.

EFPIA disclosure code

• If there is a kind of arbitration procedure – who is allowed to complain?	be appealed to a court. • Any person may apply to the State Medicines Control Agency regarding a potential infringement. Anonymous applications are also possible. However, in the latter case the State Medicines Control Agency has discretion to decide whether to initiate an investigation. The court may only be approached by subjects entitled to appeal the decision of the State Medicines Control Agency.	Investigation may also be started upon initiative by the ethics committee.
9. Sanctions and penalties • Types of penalty set in the code / other national legal acts	• A fine from EUR 1 448 to EUR 2 896 may be imposed upon the directors of legal persons.	• Sanctions for infringements of disclosure obligations are set in the Code of Ethics for Pharmaceutical Marketing; • The ethics committee may impose the following sanction(s) for breach of the disclosure code: – written warning; – notification to central head office of the company; – notification to IFPA, VGA and their members; – notification to EU associations on the infringement; – proposal to IFPA or VGA to remove the infringing pharmaco from the association; – to transfer the material to state authorities for further investigation.

Poland

EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation		• The EFPIA Disclosure Code was implemented by an association called INFARMA (Związek Pracodawców Innowacyjnych Firm Farmaceutycznych "Association of Employers from the Innovative Pharma Company Sector") by adopting the INFARMA Transparency Code (the INFARMA code) to EFPIA rules. • It came into force before 1 January 2014. • Deviations: There are no substantial deviations within Polish implementation but only structural deviations. Some aspects are more clarified. For instance, references to Polish legislation, to the INFARMA Statutes and to the Code of Good Practice, which is also a self-regulatory code adopted by INFARMA members, are included.
2. How does publication of data take place?		• Information should be published on the website of the responsible company being a signatory of the INFARMA code for at least 3 years as of first publication (unless the recipient withdraws consent earlier). • For the time being no central platform is planned.
3. IF on a central platform • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?		• n/a.
4. Regulations regarding foreign recipients		• Relevant data must be published on the website of an affiliated or subsidiary company in the country

EFPIA disclosure code

- Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?

where the recipient has its physical address, in accordance with the relevant transparency code of the EFPIA member association in that country.
- If there are no affiliated or subsidiary companies, then the pharmaco must publish the data under the INFARMA code.
- There are no regulations in the INFARMA code as to a case where the recipient has its physical address in a country that is not a member of the EFPIA. It may, however, be construed that ultimately the member-company should apply the INFARMA Code and publish data on its own website.

→ **5. Does the national disclosure code cover all pharmaceutical companies?**

- The INFARMA code applies primarily to member companies (signatories of the INFARMA code). Subsidiary and affiliated companies are indirectly bound by virtue of regulated trans-border benefits. The member company should take into account in its aggregate report benefits transferred by companies from its capital group (subsidiaries and affiliates).
- Currently 31 member companies are listed on the INFARMA website.
- Non-member companies are also welcome to implement the INFARMA code and abide by its provisions. They adopt it as a collection of norms, compliance with which ensures high ethical standards of business.
- Member companies are bound to ensure that their capital group companies providing benefits to Polish resident recipients also supply data on such benefits. This should enable members to include those data in their annual report. Nonetheless companies from the same capital group as member companies are not automatically bound by the INFARMA code.

→ **6. How about those companies that are not covered by implementation?**

- n/a.
- Withdrawing from the INFARMA code is possible by terminating membership (on 30 days' notice).
- This procedure is not to be expected. Being under the INFARMA code increases public confidence in each of the member companies. All members are published on the website of INFARMA.
- No special benefits accrue from membership, besides good PR, public awareness and confidence.

→ **7. Data protection – problems and solutions**
- Legal basis for disclosure
- Period of disclosure

- The legal basis for disclosure is the consent of the individual. The INFARMA code itself is not recognized as a legal basis justifying any legitimate interest in processing and disclosing personal data.
- Relevant data must remain on the website for 3

EFPIA disclosure code

- What kind of data according to local data protection laws will be disclosed?
- Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?

years unless a recipient withdraws consent earlier (in the case of specific data).
- According to the INFARMA code and its Annex 1, at least the following must be published: full name of the recipient and business address. The professional number / doctor's number is optional. In the end, identification of the recipient should be possible. A member company must do its best to obtain the necessary consent for disclosure, in line with the Polish Data Protection Law.
- As in all EU member state legislatures, one of the leading principles of the Polish Data Protection Law of 1997 (PDPL) is the principle of data minimization.
- The principle of data minimization allows collection of only as much personalized data as is sufficient to achieve the aim of the given data controller and of the data processing done. For collaboration between HSPs / HCOs and pharmaceutical companies it is necessary to identify collaboration partners. The data mentioned above are especially necessary to identify the collaborating HCP.
- HCPs as individuals may either not grant consent or revoke previously granted consent.
- HCOs are not protected by PDPL, which means they cannot directly interfere with publication of data. On the other hand, confidentiality rules governing the legal relations between pharma companies and HCOs have to be taken into account.
- Last but not least, both HCPs and HCOs are subject to codes of ethics and rules of transparency preventing corruption and money-laundering, which leads to the conclusion that transparency is the given principle over confidentiality. Nevertheless, while transferring benefits it is advisable to clearly inform the company about the intended disclosure.

→ **8. Procedure**

- Person / Authority responsible for monitoring
- Who decides about penalties and the amount (Arbitration board)?
- If there is a kind of arbitration procedure – who is allowed to complain?

- The penalty procedure is governed by Chapter III of the INFARMA code as well as by Chapter VIII of the INFARMA Code of Good Practices and by the Rules of the INFARMA Arbitration Court.
- No single person / authority is responsible for monitoring.
- Breach of the INFARMA code leads to arbitration. This has one resort only. The Arbitration Court decides on the penalty.
- A complaint may be filed by any signatory of the INFARMA code, an INFARMA member or by any other entity (in the last case via the INFARMA Management Board).

→ **9. Sanctions and penalties**

- The INFARMA code does not regulate penalties and sanctions or their amount. These regulations

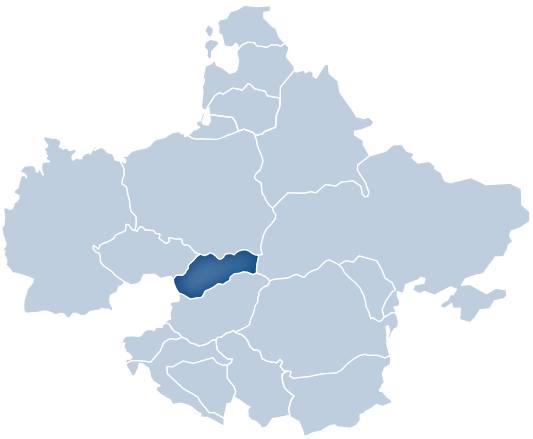
EFPIA disclosure code

- Types of penalty set in the code / other national legal acts

can only be found in the INFARMA Code of Good Practice.
- There are no monetary fines.
- Sanctions are as follows:
  - order to cease and desist conduct questioned (complained about), in particular an order to immediately recall questioned advertising;
  - admonition or reprimand;
  - order to make an appropriate statement in the mass media;
  - notification of the Main Pharmaceutical Inspectorate (a governmental authority) about the arbitration award;
  - notification of EFPIA or IFPMA about the arbitration award;
  - notification of mother company from capital group
  - obligation to publish the arbitration award;
- Sanctions may be adjudicated jointly.

Slovakia

EFPIA disclosure code



Question	Implementation by law	Implementation by statutes of associations
1. How does implementation take place? • Status of the implementation • Implementation by law or by statutes of an association • Deviations from the EFPIA Disclosure Code in national implementation	• No direct implementation, but similar obligations were implemented in Slovak Act No. 362/2011 on medical products and medical devices in section 15 (1)u, 18 (1)r, 60(1)u, which came into force on 1 December 2011. • Producers, MA holders and wholesalers must annually (before 31st January) submit to the Ministry of Health a report on the amount of costs provided directly or indirectly to health care providers in the previous year for advertising, marketing and non-financial performance; the Ministry of Health will publish the report on its website without undue delay. • Producers, MA holders and wholesalers must provide the National Health Information Centre without undue delay with a list of all medical employees (first name and surname, name and address of medical facility where the medical employee works as a medical professional), who attended expert meetings financed by Producers, MA	• The EFPIA-Disclosure-Code was implemented by an association called AIFP (“Asociácia Inovatívneho Farmaceutického Priemyslu” / “Innovative pharmaceutical Industry Association”). • It came into force on 1 January 2014. • Deviations: There are no substantial deviations within Slovak implementation, only structural deviations. Some aspects are more clarified. For instance personalized data that are meant to be published (see below).

EFPIA disclosure code

		holders or wholesalers or financed by a third party under an agreement; the National Health Information Centre will publish the list on its website without undue delay after submission. • In order to increase transparency and ex post control, provision of monetary or in kind compensation to any HCP and its medical employee or medical worker from producers, MA holders and wholesalers (in general all pharma companies) or on their behalf is subject to withholding tax (as of 1 January 2015).
→	**2. How does publication of data take place?**	• The Ministry of Health will publish the cost report on its website without undue delay and the National Health Information Centre will publish a list of medical employees on its website without undue delay after submission.	• Publication takes place once a year through a publication form for transfers of value on the website of each member or on a central platform e.g. administrative service, regulation service or authority of an association.
→	**3. IF on a central platform** • Responsibility of the central platform operator • Is it enough for the pharmaco to send the data to the central platform operator in time to avoid negative consequences?	• Data must be sent electronically to the Ministry of Health and the National Health Information Centre, respectively.	• If publication takes place through publication on a central platform the provider is responsible for publishing data on a standardized template (in Slovak) – www.aifp.sk • The provider must report data annually. Detailed instructions on the process of sending data are not yet elaborated.
→	**4. Regulations regarding foreign recipients** • Which code is applicable to foreign recipients: code of the country where the recipient has its physical address / code of the country where the pharmaco is located?	• Obligations under the Act on medical products and medical devices concern only Slovak recipients.	• Relevant data must be published on a website of an affiliated or subsidiary company in the country where the recipient practises. • The code of the country where the recipient practises applies. • If there are no affiliated or subsidiary companies, then the Slovak company must publish the data. • In both cases publication should take place in accordance with the code of the country where the recipient practises. • In the case of publication on a central platform the applicable law is the same as mentioned above. • There are no regulations, either in the EFPIA Disclosure Code or in the AIFP Transparency Code,

EFPIA disclosure code

		for a recipient practising in a country that is not a member of the EFPIA.
5. Does the national disclosure code cover all pharmaceutical companies?	• Yes, all producers, MA holders and wholesalers.	• It covers all member companies. • National disclosure code applies to member companies, subsidiary companies, affiliated companies that have their physical address in Slovakia and are members of the EFPIA.
6. How about those companies that are not covered by implementation?	• See question 5.	• Pharmaceutical companies not being members of the AIFP are invited to observe and accept the AIFP Transparency Code. • Withdrawing from the AIFP Transparency Code is possible by terminating membership. In this case companies are only subject to Slovak Act No. 362/2011 on medical products and medical devices. • This procedure is not to be expected. Being under the AIFP Transparency Code increases public confidence in each of the member companies. All members and those who agreed on the rules of AIFP Transparency Code are published on the website of AIFP. • No special benefits accrue from membership, besides public confidence.
7. Data protection – problems and solutions • Legal basis for disclosure • Period of disclosure • What kind of data according to local data protection laws will be disclosed? • Do HCOs / HCPs have any possibilities to influence the amount of data disclosure?	• As it is an obligation under the Act, data protection is not an issue and the following are publishable: first name and surname, name and address of medical facility where the medical employee works as a medical professional.	• The legal basis for disclosure is the AIFP Transparency Code itself. • Relevant data should remain on the website for 3 years, unless a shorter period is set by law. • According to the FSA Transparency Code at least the following are to be published (only with agreement): full name of the recipient, business address and professional number / doctor's number. In the end identification of the recipient should be possible. • The amount of data corresponds with the requirements of Slovak Act No. 362/2011 on medical products and medical devices, Act No. 122/2013 on Protection of Personal Data.
8. Procedure • Person / Authority responsible for monitoring • Who decides about penalties and the amount (Arbitration board)? • If there is a kind of arbitration procedure – who is allowed to complain?	• The Ministry of Health can impose penalties.	• The authority responsible for monitoring is the AIFP Ethical Commission.

EFPIA disclosure code

9. Sanctions and penalties • Types of penalty set in the code / other national legal acts	• Fines of up to EUR 25, 000.	• Fines of up to EUR 20 000. • Cancellation of membership. • Public rebuke.	

Notes

Notes

bnt attorneys-at-law contact details

Overall responsibility for the Survey and single contact point for all bnt | attorneys-at-law offices:

bnt Heemann Klauberg Krauklis APB
Embassy House
Kalinausko 24, 4th floor
LT-03107 Vilnius
Phone: +370 5 212 16 27
Fax: +370 5 212 16 30

contact person: Yvonne Goldammer
yvonne.goldammer@bnt.eu

Bulgaria
bnt Neupert Ivanova & kolegi, adv.dr.
Gladstone 48
BG-1000 Sofia
Phone: +359 2 980 11 17
Fax: +359 2 980 06 43
info.bg@bnt.eu

contact person: Stela Ivanova
stela.ivanova@bnt.eu

Czech Republic
bnt attorneys-at-law s.r.o.
Slovanský dům (budova B/C)
Na příkopě 859/22, CZ-110 00 Prague 1
Phone: +420 222 929 301
Fax: +420 222 929 309
info.cz@bnt.eu

contact person: Lukáš Havel
lukas.havel@bnt.eu

Estonia
bnt attorneys-at-law Advokaadibüroo OÜ
Tatari 6,
EE-10116 Tallinn
Phone: +372 667 62 40
Fax: +372 667 62 41
info.ee@bnt.eu

contact person: Thomas Hoffmann
thomas.hoffmann@bnt.eu

bnt attorneys-at-law contact details

Hungary
bnt ügyvédi iroda
Stefánia út 101- 103
H-1143 Budapest
Phone: +36 1 413 3400
Fax: +36 1 413 3413
info.hu@bnt.eu

contact person: Csaba Hajdu
csaba.hajdu@bnt.eu

Latvia
bnt Klauberg Krauklis ZAB
Alberta iela 13
LV-1010 Riga
Phone: +371 6777 05 04
Fax: +371 6777 05 27
info.lv@bnt.eu

contact person: Renars Gasuns
renars.gasuns@bnt.eu

Lithuania
bnt Heemann Klauberg Krauklis APB
Embassy House
Kalinausko 24, 4th floor
LT-03107 Vilnius
Phone: +370 5 212 16 27
Fax: +370 5 212 16 30
info.lt@bnt.eu

contact person: Monika Rudyte
monika.rudyte@bnt.eu

Poland
bnt Neupert Zamorska & Partnerzy sp.j.
ul. Chłodna 51,
PL-00-867 Warsaw
Phone: +48 22 373 6550
Fax: +48 22 373 6555
info.pl@bnt.eu

contact person: Kamil Kucharski
kamil.kucharski@bnt.eu

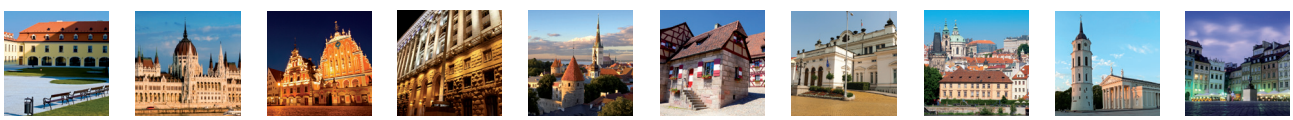
Slovakia
bnt attorneys-at-law, s.r.o.
Cintorínska 7
SK-811 08 Bratislava 1
Phone: +421 2 57 88 00 88
Fax: +421 2 57 88 00 89
info.sk@bnt.eu

contact person: Vladimír Kordoš
vladimir.kordos@bnt.eu

bnt

Attorneys-at-law in Central and Eastern Europe

www.bnt.eu



BRATISLAVA BUDAPEST MINSK NÜRNBERG PRAHA RIGA SOFIA TALLINN VILNIUS WARSZAWA