SIP

Societal Impact of Pain

Implementation of Article 8.5 of the EU directive 2011/24/EU in the EU member states

The scientific framework of the "Societal Impact of Pain" (SIP) platform is under the responsibility of the European Pain Federation EFIC®. Cooperation partners for SIP 2016 are Pain Alliance Europe (PAE) and Active Citizenship Network (ACN). The pharmaceutical company Grünenthal GmbH is responsible for funding and non-financial support (e.g. logistical support). The scientific aims of the SIP symposia have been endorsed by a large number of international and national pain advocacy groups, scientific organisations and authorities.

The European Union is a confederation of 28 member countries in Europe, started in 1957 as the European Economic Community (EEC). It has created a common economic area with Europe-wide laws allowing people to move and trade in other EU countries almost the same as they do in their own.

Free movement
A person who is a citizen of a European Union country can live and work in any of the other 27 member countries without needing a work permit or visa. For example, a British person can move to Greece to work there, or just to live there, and he or she does not need permission from an authority in Greece.

In the same way, products made in one member country can be sold in any other member country without any special permissions or extra taxes. For this reason, the members agree rules on product safety - they want to know that a product made in another country will be as safe as it would be if it had been made in their own.

FIELDS FOR WHICH THE MEMBER STATES REMAIN RESPONSIBLE AND IN WHICH THE EU MAY PLAY A SUPPORTING OR COORDINATING ROLE:

- protection and improvement of human health
- industry
- culture
- tourism
- education, vocational training, youth and sport
- civil protection
- administrative cooperation

History on Directive 2011/24/EU

The appearance of several cases in the European Court of Justice dealing with the requests of European citizens claiming the reimbursement of cost for healthcare services received in other member states than their members state of affiliation, most famously the *Kohl and Decker* case in 1998 and the *Watts* case in 2006, created the need for a European legal framework on planned cross-border healthcare.

In these rulings, the Court made clear that **as healthcare is provided for remuneration, it must be regarded as a service within the meaning of the EU Treaty and thus relevant provisions on free movement of services apply.**

Thus, after a consultation on the issue, the European Commission adopted a proposal for a Directive on «the Application of Patients' Rights in Cross-border Healthcare» in 2008, which was voted in the European Parliament on 19th of January 2011 and published as Directive (2011/24/EU) in the Official Journal of the European Union on 4th of April 2011, with a transposition date for members state the 25th of October 2013.

http://www.moh.gov.cy/moh/cbh/cbh.nsf/page02_en/page02_en?OpenDocument
http://europa.eu/rapid/press-release_MEMO-08-473_en.htm?locale=en
http://ec.europa.eu/social/main.jsp?catId=572&langId=en
http://dspace.library.uu.nl/bitstream/handle/1874/241945/Pennings%20-%20Cross%20border%20-%202011.pdf?sequence=1

Aims and Provisions of the Directive 2011/24/EU

The Directive clarifies patients' rights to access safe and good quality treatment across EU borders, and be reimbursed for it. Its main aims are the following:

1. The provision of clear rules and reliable information to patients for exercising their rights to access and reimbursement for healthcare received in another EU Country.
2. The provision of information on safety and quality of cross-border healthcare to the patients, which will enable them to make informed choices before going abroad for healthcare.
3. The establishment and assurance of formal cooperation between health systems.
4. The strike of the right balance between maintenance the sustainability of health systems while protecting patients' right to seek treatment outside their home country.

The Directive includes provisions that will enable the application of patients' rights on a cross border perspective, the main of which are as follows:

1. Information to Patients
2. Reimbursement of cross-border healthcare
3. Prior authorization
4. Administrative procedures
5. Safety, quality and continuity of care
6. Patients with rare diseases
7. Cooperation between health systems

http://www.moh.gov.cy/moh/cbh/cbh.nsf/page02_en/page02_en?OpenDocument

Pain is explicitly mentioned in EU directive 2011/24/EU

DIRECTIVES

DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2011

on the application of patients' rights in cross-border healthcare

§8.5 Without prejudice to points (a) to (c) of paragraph 6, the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7, and when this healthcare cannot be provided on its territory within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, **the degree of the patient's pain** and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN

Per 25 October 2013 EU law in force enshrines citizens' right to go to another EU country for treatment and get reimbursed for it as all EU countries should have transposed the Directive on Patients' rights in Cross-border Healthcare, into their National law.

EUROPEAN COMMISSION

MEMO

Brussels, 25 October 2013

Statement by Health Commissioner, Tonio Borg, on the entry into force of the Directive on Patients' Rights in Cross-border Healthcare

"Today is an important day for patients across the European Union. As of today, EU law in force enshrines citizens' right to go to another EU country for treatment and get reimbursed for it. From today, all EU countries should have transposed the Directive on Patients' rights in Cross-border Healthcare, adopted 30 months ago, into their National law.

For patients, this Directive means empowerment: greater choice of healthcare, more information, easier recognition of prescriptions across-borders. The Directive is also good news for Europe's health systems, improving cooperation between Member States on interoperable eHealth tools, the use of health technology assessment, and the pooling of rare expertise.

For patients to benefit from the rights granted by EU law, the law needs to be properly transposed and enforced. The Commission has provided a great deal of support to Member States during the transposition period. Now I urge all Member States to deliver on their obligations and fully transpose this Directive. The Commission will carefully monitor transposition, provide assistance, and take appropriate action where necessary."

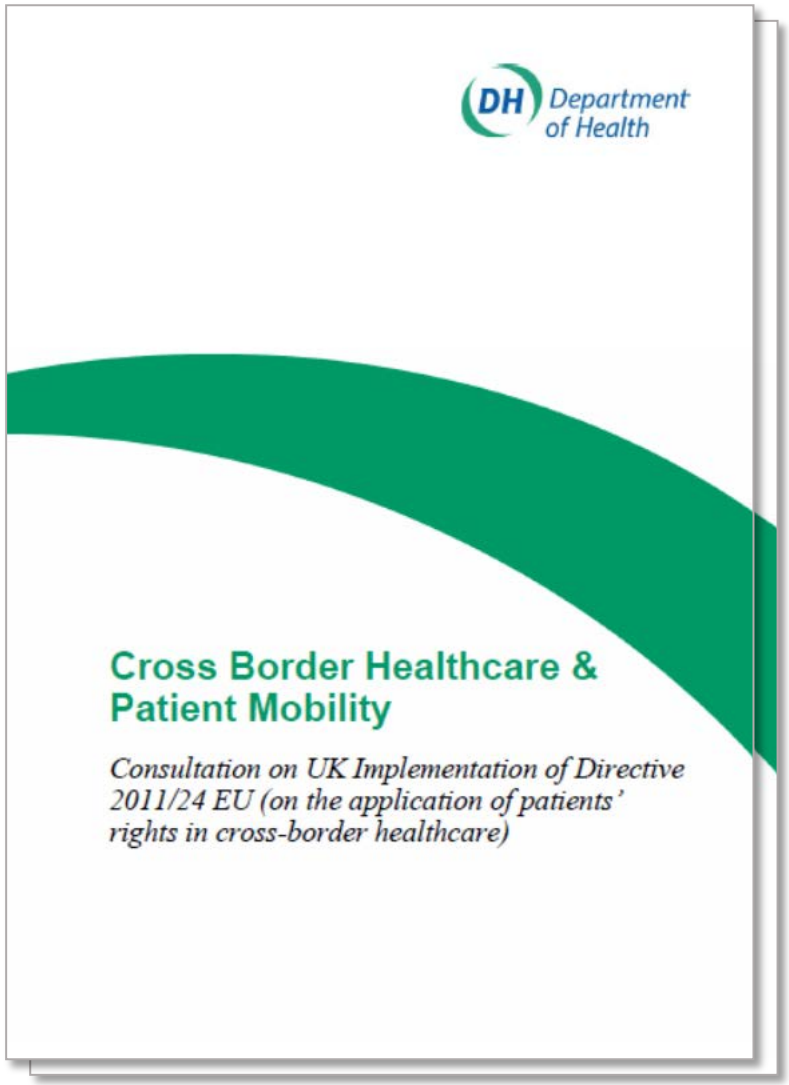
For more information on patients' rights in cross-border healthcare: MEMO/13/918

http://europa.eu/rapid/press-release_MEMO-13-932_en.htm

For patients to benefit from the rights granted by EU law, the law needs to be properly transposed and enforced. The Commission has provided a great deal of support to Member States during the transposition period. Now I urge all Member States to deliver on their obligations and fully transpose this Directive.

https://www.youtube.com/watch?v=XYCccUrn0rk

Anticipating the assessment by the commission in 2015 on the implementation of the directive some member states prepared their own assessment.

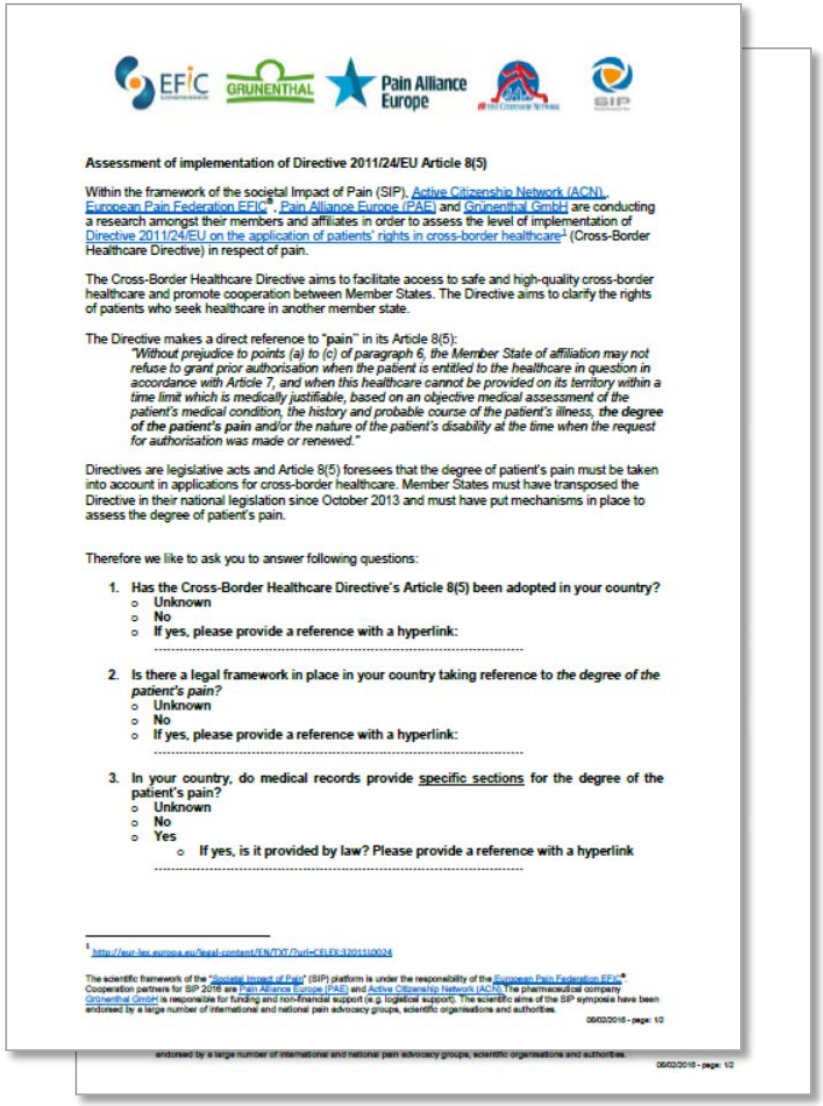


6.117. …… the NHS would also need to set out for each patient it wished to refuse, exactly what would from a medical standpoint represent "undue delay" in their individual case. This would be in order to avoid patients being refused authorisation but being forced to wait longer than medically necessary for treatment at home. The list of services subject to prior authorisation and the restrictions that apply would need to be developed and agreed, with the same safeguards applied as with option [i]. In providing evidence of the proportionality of refusal, the NHS would need to do the following:

- Consider the patient's medical history;
- Consider the **extent of any pain**, disability, discomfort or suffering that is attributable to the medical condition to which the service relates to;
- Whether **any such pain**, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks;
- The extent to which the provision of the service would be likely to alleviate, or enable the **alleviation of pain**, disability, discomfort or suffering; and
- Set out what is the medically necessary time limit within which the treatment that the patient needs should be carried out (NB – this is **not to be confused with waiting time limits** or averages within the system which may not be appropriate in the context of the individual circumstances of the patient.)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181168/Cross_Border_Healthcare_and__Patient_Mobility.pdf

In order to validate the implementation of article 8.5 3 questions where send Feb 2016 to:



Assessment of implementation of Directive 2011/24/EU Article 8(5)

Within the framework of the societal Impact of Pain (SIP), Active Citizenship Network (ACN), European Pain Federation EFIC®, Pain Alliance Europe (PAE) and Grünenthal GmbH are conducting a research amongst their members and affiliates in order to assess the level of implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[1] (Cross-Border Healthcare Directive) in respect of pain.

The Cross-Border Healthcare Directive aims to facilitate access to safe and high-quality cross-border healthcare and promote cooperation between Member States. The Directive aims to clarify the rights of patients who seek healthcare in another member state.

The Directive makes a direct reference to "pain" in its Article 8(5):

*"Without prejudice to points (a) to (c) of paragraph 6, the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7, and when this healthcare cannot be provided on its territory within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, **the degree of the patient's pain** and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed."*

Directives are legislative acts and Article 8(5) foresees that the degree of patient's pain must be taken into account in applications for cross-border healthcare. Member States must have transposed the Directive in their national legislation since October 2013 and must have put mechanisms in place to assess the degree of patient's pain.

Therefore we like to ask you to answer following questions:

1. **Has the Cross-Border Healthcare Directive's Article 8(5) been adopted in your country?**
   - **Unknown**
   - **No**
   - **If yes, please provide a reference with a hyperlink:**
2. **Is there a legal framework in place in your country taking reference to *the degree of the patient's pain*?**
   - **Unknown**
   - **No**
   - **If yes, please provide a reference with a hyperlink:**
3. **In your country, do medical records provide specific sections for the degree of the patient's pain?**
   - **Unknown**
   - **No**
   - **Yes**
     - **If yes, is it provided by law? Please provide a reference with a hyperlink**

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024

The scientific framework of the "Societal Impact of Pain" (SIP) platform is under the responsibility of the European Pain Federation EFIC®. Cooperation partners for SIP 2016 are Pain Alliance Europe (PAE) and Active Citizenship Network (ACN). The pharmaceutical company Grünenthal GmbH is responsible for funding and non-financial support (e.g. logistical support). The scientific aims of the SIP symposia have been endorsed by a large number of international and national pain advocacy groups, scientific organisations and authorities.

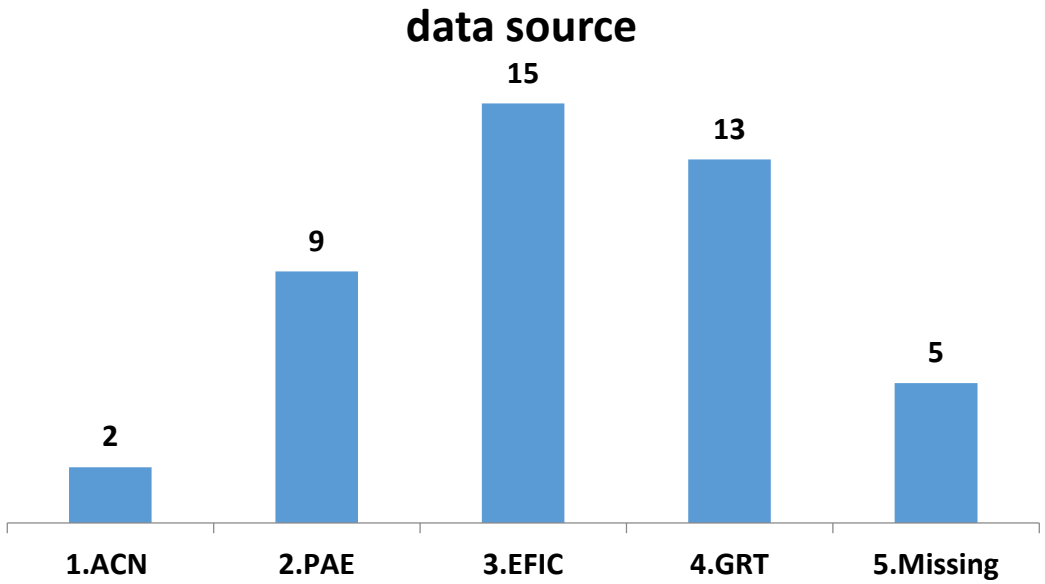
06/02/2016 - page: 1/2

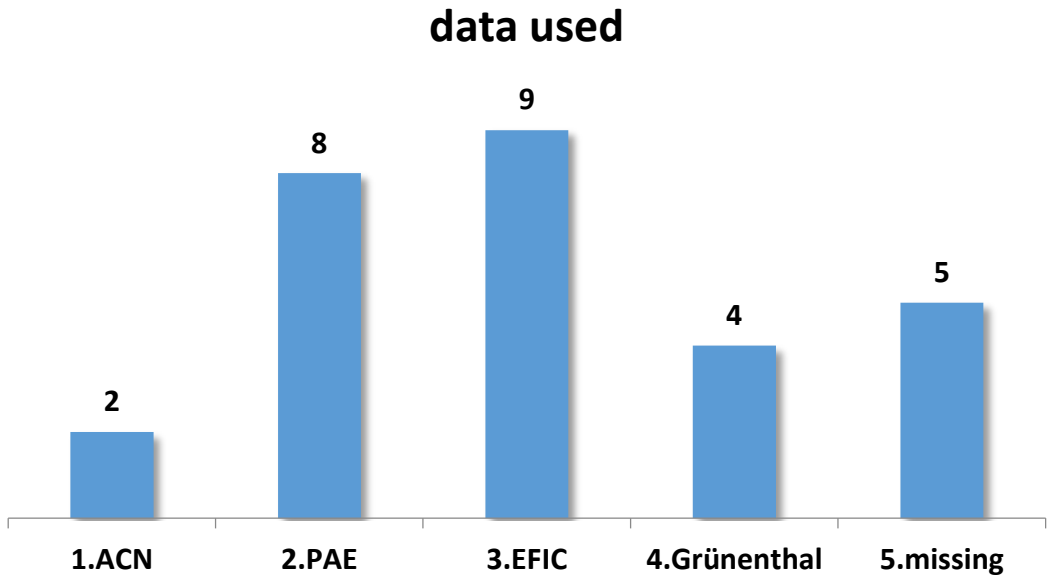
- Partners of Active Citizenship Network (ACN)
- Members of Pain Alliance Europe (PAE)
- Chapters of European Pain Federation EFIC®
- Affiliates of Grünenthal

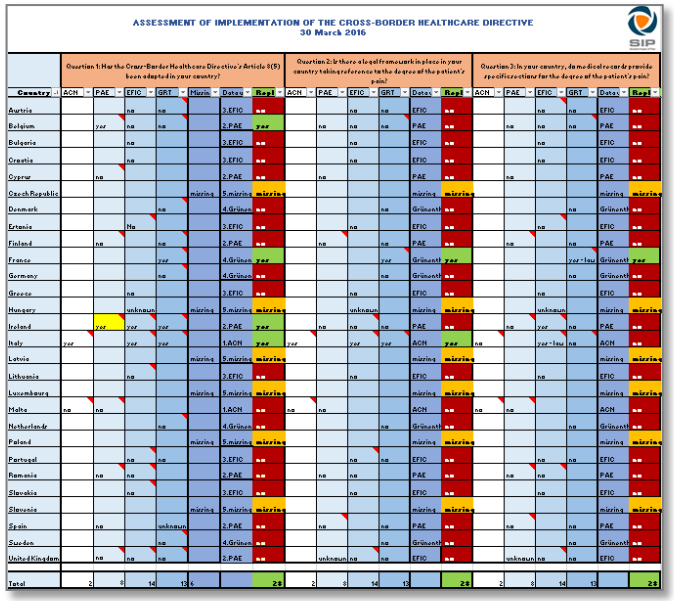
Information was collected by Burson Marsteller and analysed by Burson Marsteller & Grünenthal in order to create this presentation

Main obstacle was the lack of familiarity of the respondents with the EU directive and it´s implementation.
This made follow up with clarifying questions necessary in order to understand the context of the answers given.

39 responses representing 23 countries






ASSESSMENT OF IMPLEMENTATION OF THE CROSS-BORDER HEALTHCARE DIRECTIVE
30 March 2016

Information was allocated according to following ranking

Citizens 1 ACN - *when unavailable then*

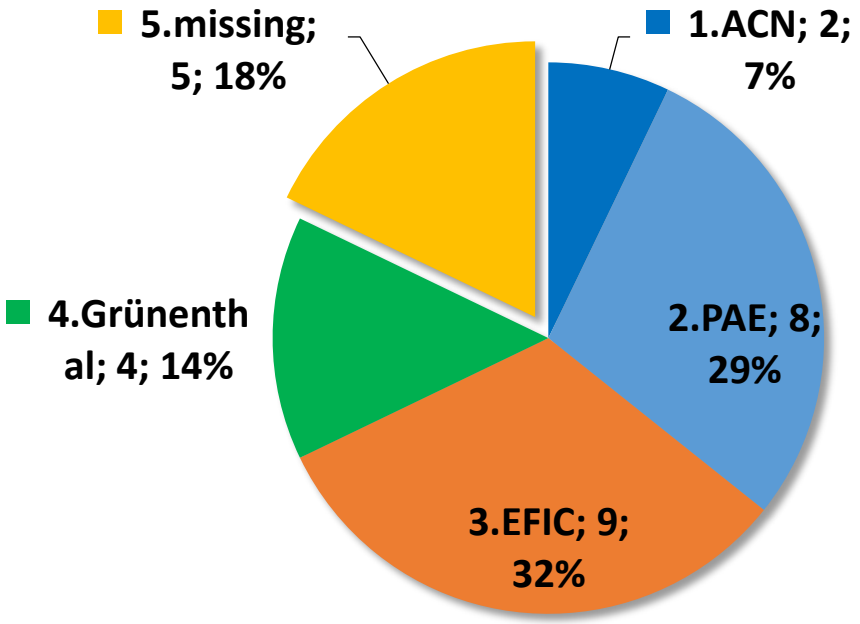
Patients 2 PAE - *when unavailable then*

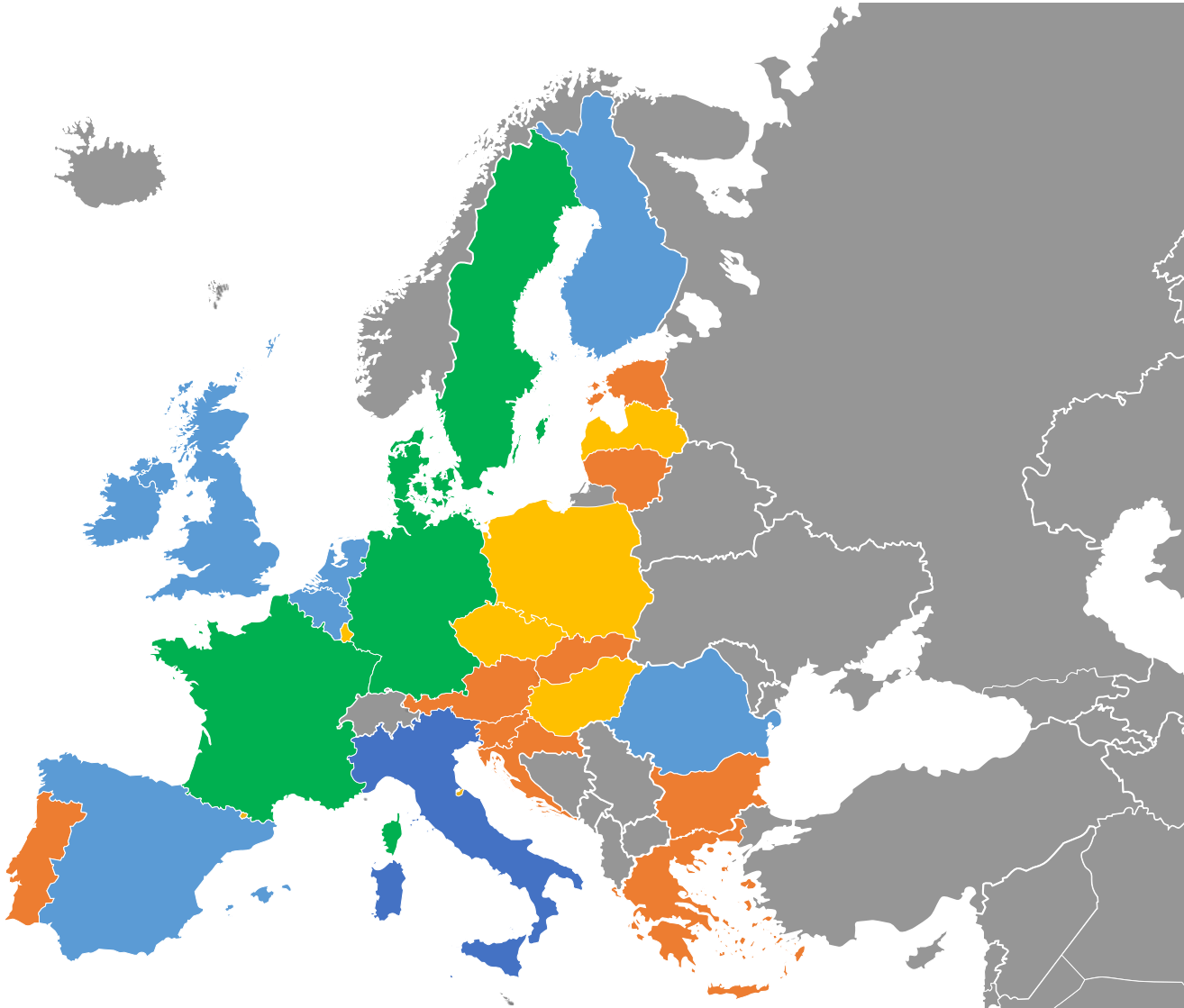
Professionals 3 EFIC - *when unavailable then*

Pharma 4 Grünenthal - *when unavailable then*

5 Missing (unknown was counted as missing)

82% of the EU member states are covered with the information received

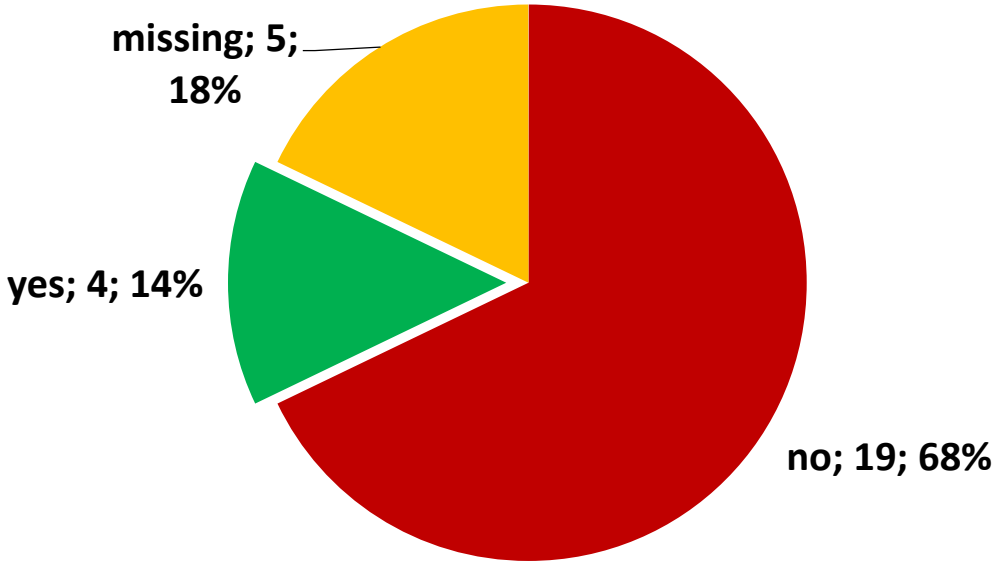


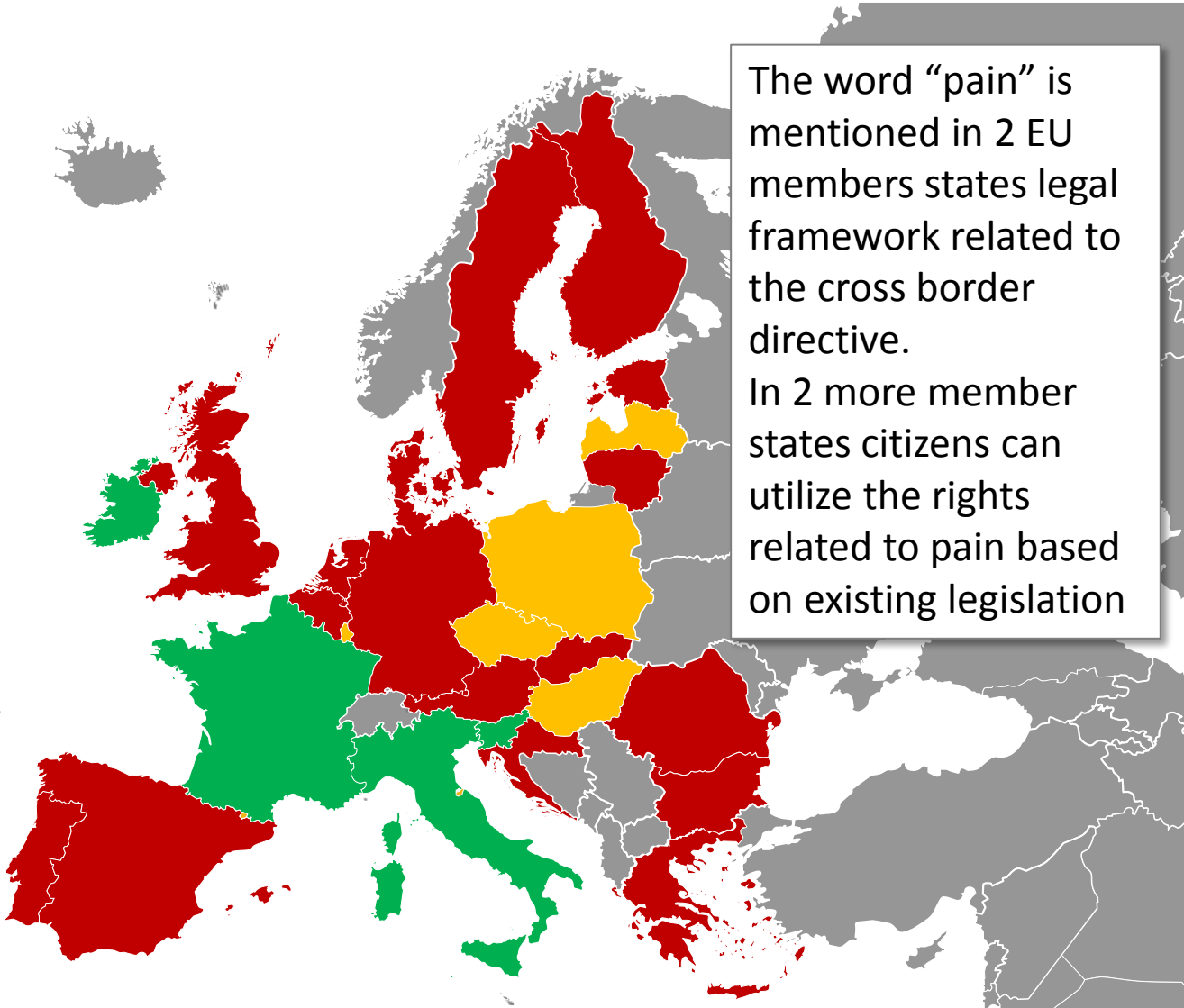


Information missing from:

1. Czech Republic
2. Hungary (reported as unknown)
3. Latvia
4. Luxembourg
5. Poland

Q1: Has the Cross-Border Healthcare Directive's Article 8(5) been adopted in your country?
Follow up question: is the word "pain" mentioned"?





The word "pain" is mentioned in 2 EU members states legal framework related to the cross border directive.
In 2 more member states citizens can utilize the rights related to pain based on existing legislation

In Italy and France legislation was in place prior to the EU directive referring to pain

- **Italy**: Decreto legislativo, 04/03/2014 n° 38, (G.U. 21/03/2014). The art.9.5 of this Italian law translates art. 8.5 of the Directive "the degree of the patient's pain" talking about "intensità del dolore"; http://www.sossanita.it/doc/2014_03_TRANSFR_ass_Dlgs_38.pdf

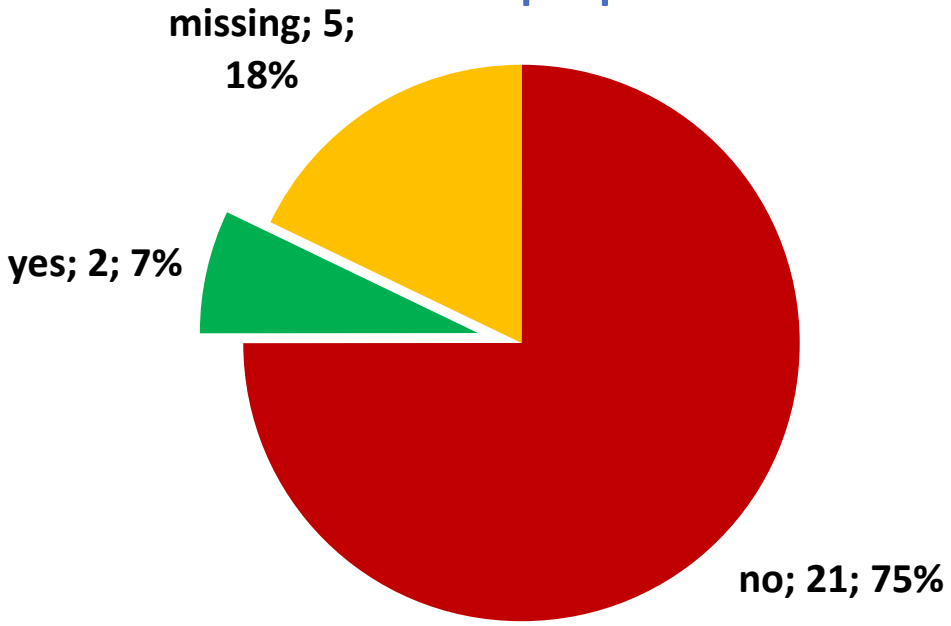
- **France**: Loi n°2002-303 du 4 mars 2002 - art. 3 JORF 5 mars 2002; https://www.legifrance.gouv.fr/affichTexteArticle.do;jsessionid=61E25ADD0A152AD090738FC423572BC5.tpdila16v_2?cidTexte=JORFTEXT000000227015&idArticle=LEGIARTI000006697386&dateTexte=20050422&categorieLien=id#LEGIARTI000006697386

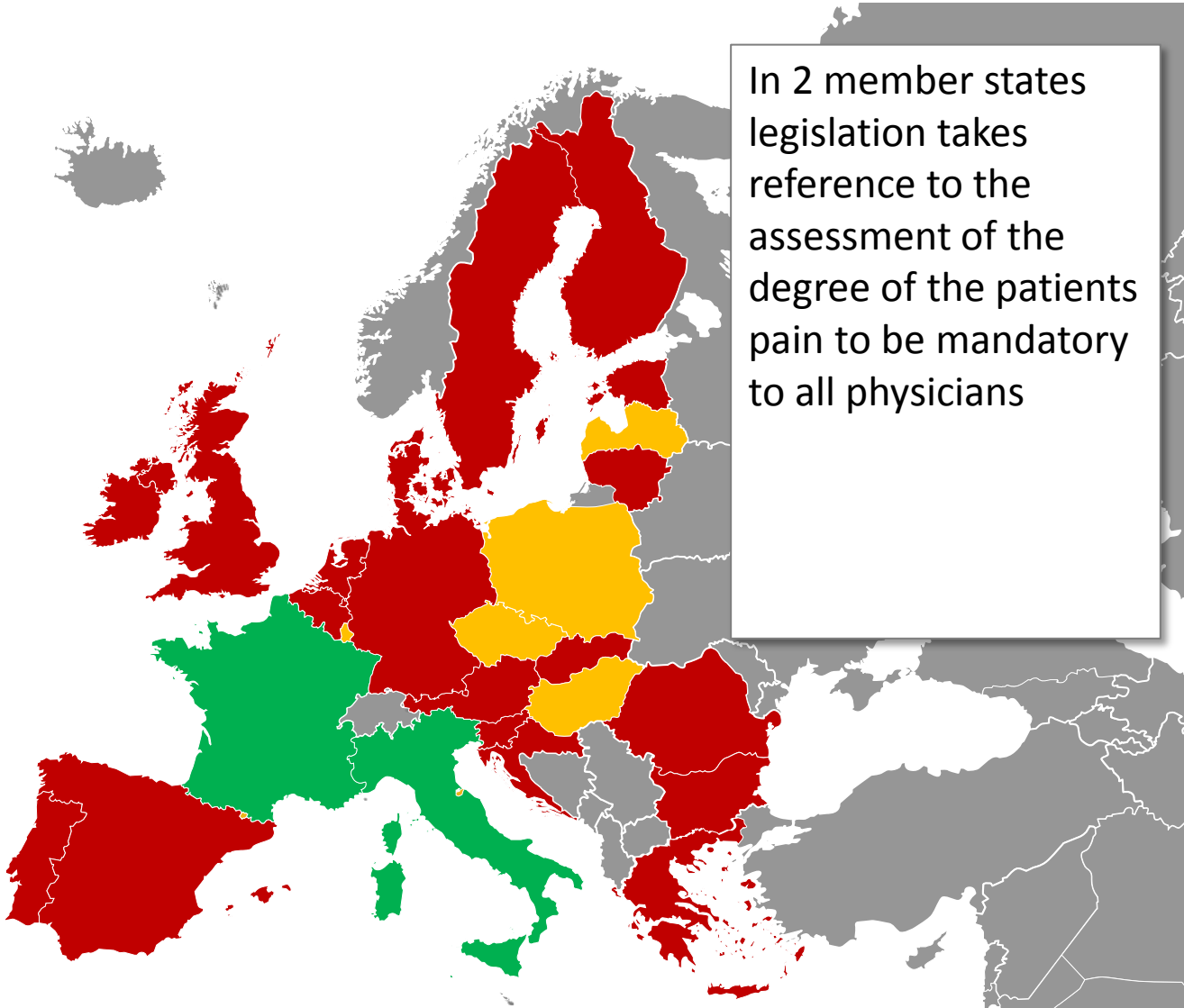
In Ireland and Slovenija the law was adapted mentioning pain

- **Ireland:** the 2014 implemented legislation on the CBHD explicitly refers to pain (§5.6); https://www.hse.ie/eng/services/list/1/schemes/cbd/Stutory_Instrument.pdf

- **Slovenia:** 455. Patients Rights Act (PACPA) Page 1045th ; Art. 17, refers to Pain: **https://www.uradni-list.si/1/content?id=84936**

Q2: Is there a legal framework in place in your country taking reference to the degree of the patient's pain?
Follow up question: mandatory for all physicians incl. GP´s?

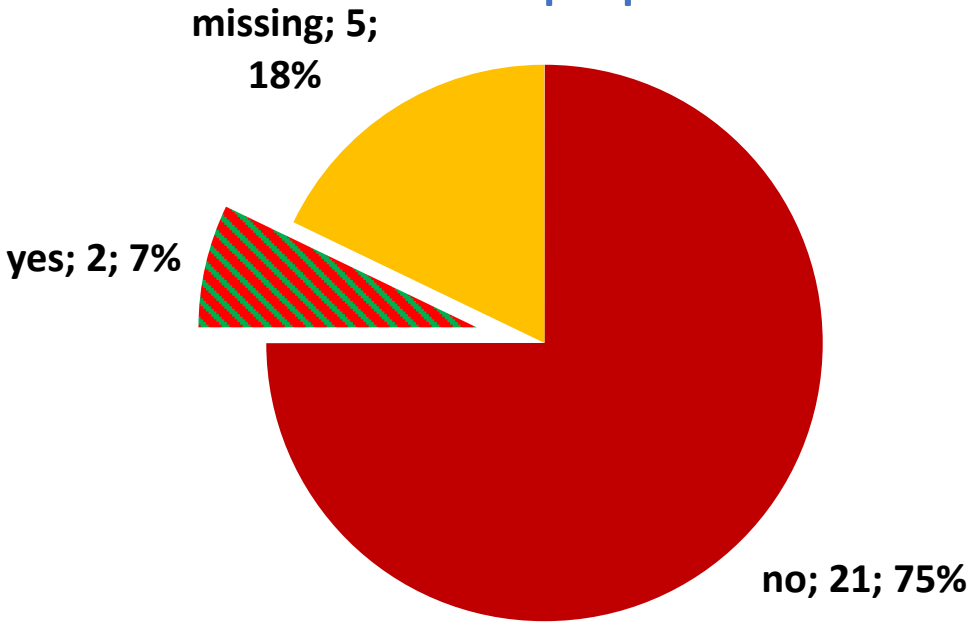


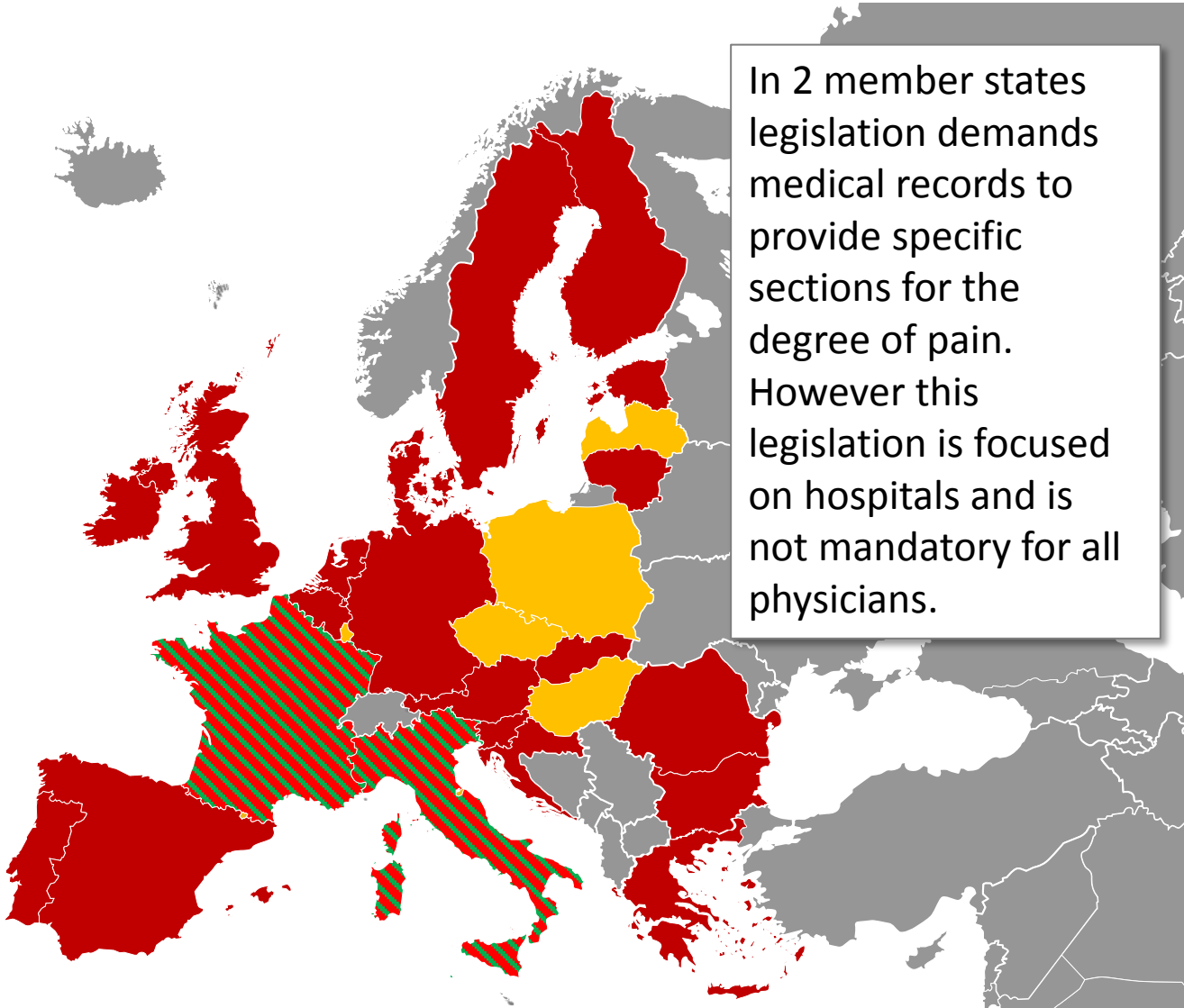


- **Italy**: the art. 7 of the Italian Law 15/03/2010 n° 38, (G.U. 19/03/2010 n.65) "Disposizioni per garantire l'accesso alle cure palliative e alla terapia del dolore" establishes that is mandatory to report the pain tracking in the medical record. The law doesn't mention "the degree of the patient's pain" ("intensità del dolore"), even if it talks about "valutazione e rilevazione del dolore" (evaluation/assessment of pain and pain tracking). http://www.sossanita.it/doc/2014_03_TRANSFR_ass_Dlgs_38.pdf

- **France**: Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé; http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000227015

Q3: In your country, do medical records provide specific sections for the degree of the patient's pain?
Follow up question: mandatory for all physicians incl. GP´s?





In 2 member states legislation demands medical records to provide specific sections for the degree of pain. However this legislation is focused on hospitals and is not mandatory for all physicians.

- **Italy**: Indeed, according civic assessment "In-dolore" (ACN -2014) in 46 Italian hospitals, there is a specific space on pain management in medical record in 8 of 10 cases. However no mandatory legal framework is in place for all physicians use documentation on the degree of the patient's pain

- **France**: This certification, conducted by the National Health Authority (HAS) is to evaluate the quality and safety of care and all services delivered from many criteria, some called "Owed Priority Practices" criteria in which a level of requirement is reinforced. The Management of Pain Practice is a callable Priority. More in detail, there are three indicators to follow the evaluation and management of pain for the hospital's certification by High Authority of Health.
  http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000227015

Conclusions on the implementation of DIRECTIVE 2011/24/EU §8.5

- 5 years after the DIRECTIVE 2011/24/EU on the application of patients' rights in cross-border healthcare was decided upon member states still struggle with its implementation.
- For most European citizens and pain patients the benefits of article 8.5 are not within reach as the degree of the patient's pain is not specified in national regulations.
- In only few member states a legal framework is in place taking reference to the degree of the patient's pain
- In no member state medical records provides specific sections for the degree of the patient's pain mandatory to be used by all physicians treating pain patients.

Discussion

For citizens to benefit from DIRECTIVE 2011/24/EU documentation for each patient should be available on:

- **the extent of pain**, disability, discomfort or suffering that is attributable to the medical condition to which the service relates to;
- **the extent of pain**, disability, discomfort or suffering making it impossible or extremely difficult for the patient to carry out ordinary daily tasks;
- The extent to which the provision of the service would be likely to alleviate, or enable the **alleviation of pain**, disability, discomfort or suffering