Subsidiary Legislation made under s. 36 of the Medical and Health Act, 1997 and section 23(g)(i) of the Interpretation and General Clauses Act.

CROSS-BORDER HEALTHCARE REGULATIONS 2013

(LN. 2013/145)

Commencement **25.10.2013**

Transposing:
Directive 2011/24/EU
Directive 2012/52/EU

EU Legislation/International Agreements involved:

ARRANGEMENT OF REGULATIONS

Regulation

GIBRALTAR CROSS-BORDER HEALTHCARE CONTACT POINT

SCHEDULE 4
CROSS-BORDER PRESCRIPTIONS

Subsidiary 2013/145

CROSS-BORDER HEALTHCARE REGULATIONS 2013

This version is out of date

In exercise of the powers conferred upon him by section 36 of the Medical and Health Act, 1997 and section 23(g)(i) of the Interpretation and General Clauses Act, and for the purpose of transposing into the law of Gibraltar 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 and Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State, the Minister has made the following Regulations–

PART 1
PRELIMINARY

Title and commencement.

1. These Regulations may be cited as the Cross-border Healthcare Regulations 2013 and come into operation on 25 October 2013.

Scope.

2.(1) These Regulations–

(a) provide the framework for facilitating the access to cross-border healthcare; and

(b) clarifies the relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004,

with a view to application of patients' rights.

(2) These Regulations apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

(3) These Regulations do not apply to–

(a) services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;

(b) allocation of and access to organs for the purpose of organ transplants;

(c) save as may be otherwise provided for in these Regulations, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the

population of Gibraltar and which are subject to specific planning and implementation measures.

(4) These Regulations shall not affect any enactment relating to the organisation and financing of healthcare in situations not related to cross-border healthcare, in particular, nothing in these Regulations shall allow a person to seek the reimbursement of costs of healthcare provided by healthcare providers established in Gibraltar, if those providers are not part of the social security system or public health system of Gibraltar.

Relationship with other European Union provisions.

3. These Regulations apply without prejudice to the European Union measures set out in Schedule 1, to the extent that these apply to Gibraltar.

Interpretation.

4. In these Regulations–

"cross-border healthcare" means healthcare provided or prescribed in a Member State other than the Member State of affiliation;

"Directive" means 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 cases, as the same may be amended from time to time;

"Gibraltar Cross-border Healthcare Contact Point" or "GCHCP" means that body established under regulation 10;

"healthcare" means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;

"health professional" means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person who by virtue of an enactment is considered to be a health professional and regulated as such;

"healthcare provider" means any natural or legal person or any other entity legally providing healthcare in Gibraltar, or where the context so requires, elsewhere the European Union;

"health technology" means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare;

"insured person" means–

(a) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No

883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and

(b) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;

"medical device" means a medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;

"medicinal product" means a medicinal product as defined by Directive 2001/83/EC;

"medical records" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process;

"Member State of affiliation" means–

(a) for persons referred to in paragraph (a) in the definition of "insured person", the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;

(b) for persons referred to paragraph (b) in the definition of "insured person", the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, but if no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State,

and where the context so requires shall mean Gibraltar;

"Member State of treatment" means the Member State on whose territory healthcare is actually provided to the patient, and in the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established, and where the context so requires shall mean Gibraltar;

"national contact point" means the body designated pursuant to Article 6 of the Directive, and in the case of Gibraltar means the Gibraltar Cross-border Healthcare Contact Point;

"patient" means any natural person who seeks to receive or receives healthcare in a Member State;

"prescription" means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued.

PART 2
RESPONSIBILITIES WITH REGARD TO CROSS-BORDER HEALTHCARE

Responsibilities where treatment is given in Gibraltar.

5.(1) Where treatment is given in Gibraltar, such treatment shall be provided in accordance with–

(a) any applicable laws;

(b) any applicable standards and guidelines on quality and safety; and

(c) any applicable European Union legislation on safety standards,

and taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare

(2) Where treatment is to be or has been given in Gibraltar, the Minister shall ensure that the matters set out in Schedule 2 are complied with.

Non-discrimination.

6.(1) In the application of the provisions of these Regulations, the principle of non-discrimination with regard to nationality shall be applied to patients from other Member States.

(2) Subregulation (1) shall be without prejudice to the possibility, where this is justified by overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, to adopt measures regarding access to treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within Gibraltar.

(3) The measures referred to in subregulation (2) shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination and shall be made publicly available in advance.

Prohibition of certain charges.

7.(1) Healthcare providers must apply the same scale of fees for healthcare for patients from other Member States, as for Gibraltar resident patients in a

comparable medical situation, unless the price is calculated according to objective, non-discriminatory criteria where there is no comparable price for Gibraltar resident patients.

(2) Subregulation (1) shall not operate to restrict the ability of healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

Information may be provided in different languages.

8. Information provided pursuant to these Regulations must be provided in English, and at the discretion of the provider of the information, in addition to English, in any other language.

Responsibilities when a Gibraltar patient receives treatment in a Member State.

9. Where Gibraltar is to be regarded as the Member State of affiliation under the Directive, the Minister shall ensure that-

(a) the cost of cross-border healthcare is reimbursed in accordance with Part 4;

(b) there are mechanisms in place to provide patients, on request, with information on their rights and entitlements in Gibraltar relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with regulation 12(5) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with regulation 15, in information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;

(c) where a patient has received cross-border healthcare and where medical follow-up proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided in Gibraltar;

(d) patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records, in conformity with, and subject to, national measures implementing European Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

PART 3
CONTACT POINT

Contact point for cross-border healthcare.

10.(1) There is hereby established the Gibraltar Cross-border Healthcare Contact Point ("GCHCP").

(2) The Minister shall ensure that its name and contact details are at all times publicly available and ensure that the European Commission is notified.

(3) The GCHCP shall, with such resources, including human resources as are made available to it by the Government, undertake the responsibilities set out in Schedule 3, and such other responsibilities as the Minister, in writing, may direct.

(4) In order to enable patients to make use of their rights in relation to cross-border healthcare, where treatment is to be provided in Gibraltar, the GCHCP shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice, information referred to in paragraph 1 of Schedule 3, as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to Gibraltar law, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

(5) Where Gibraltar is to be regarded as the Member State of affiliation the GCHCP shall provide patients and health professionals with the information referred to in regulation 9(b).

(6) The information referred to in this regulation shall be easily accessible and shall be made available by electronic means and in formats accessible to people with disabilities, as appropriate.

GCHCP may request information.

11.(1) The GCHCP may request any information from a healthcare provider established in or providing healthcare services in Gibraltar if such information is required for the purposes of compliance with these regulations or the Directive.

(2) A request under subregulation (1) may be made orally or in writing (which for the purposes of this regulation shall include by electronic means

of communication) and if made in writing it may provide a time limit for the addressee to reply.

(3) A person who, without reasonable excuse fails to provide the information requested within a stipulated time shall be liable to an administrative penalty under regulation 21.

PART 4
REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTH CARE

General principles for reimbursement of costs.

12.(1) Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of regulations 14 and 15, the costs incurred by an insured person who receives cross-border healthcare shall be reimbursed by the Government, if the healthcare in question is among the benefits to which the insured person is entitled in Gibraltar.

(2) Subregulation (1) shall not apply, and the Government shall assume the cost of healthcare to a person if the healthcare provided in accordance with these Regulations–

(a) is not subject to prior authorisation;

(b) is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004; and

(c) according to that Regulation and Regulation (EC) No 987/2009 Gibraltar is, in the end, responsible for reimbursement of the costs,

the assumption of the costs of the healthcare shall be in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that are established, provided that these are compatible with European Union law.

(3) Where Gibraltar is to be treated as the Member State of affiliation, nothing in these Regulations shall limit the Government's discretion to determine the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.

(4) The costs of cross-border healthcare shall be reimbursed or paid directly by the Government up to the level of costs that would have been assumed by the Government, had this healthcare been provided in Gibraltar without exceeding the actual costs of healthcare received.

(5) For the purposes of subregulation (4) the Minister shall ensure that there is a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person, based on objective, non-discriminatory criteria known in advance.

(6) The mechanisms referred to in subregulation (5) may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of tele-medicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, as it would impose if this healthcare were provided in Gibraltar, including an assessment by a health professional or healthcare administrator if this is necessary for determining the individual patient's entitlement to healthcare, but no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this subregulation may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in Gibraltar or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

(7) Reimbursement of costs of cross-border healthcare shall not be subject to prior authorisation except in the cases set out in regulation 14.

(8) The Minister may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in Gibraltar or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

(9) The decision to limit the application of the rules on reimbursement pursuant to subregulation (8) shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services, and the Minister shall ensure that the European Commission is notified of any decisions to limit reimbursement on the grounds stated in subregulation (8).

(10) Notwithstanding subregulation (8), the Minister shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed in accordance with the authorisation.

Application for reimbursement.

13.(1) A person who, under these Regulations, is entitled to reimbursement shall apply to the GCHCP.

(2) In considering an application for reimbursement, the GCHCP shall ensure that the applicant is entitled to claim all or part of the sums claimed, and where admissible, it shall pay such sums to the applicant.

(3) For the purposes of this regulation, the GCHCP may require applications to be made in such form and shall provide such supporting evidence (whether in the form of receipts or otherwise) as it may require for the purposes of these Regulations and compliance with the Directive.

PART 5
PRIOR AUTHORISATION

Healthcare that may be subject to prior authorisation.

14.(1) Cross-border healthcare to which these Regulations apply shall be the subject of prior authorisation procedures as provided for in this regulation and regulation 15.

(2) The GCHCP, in applying the prior authorisation requirement, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

(3) Healthcare that may be subject to prior authorisation is limited to healthcare which–

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in Gibraltar or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and–

(i) involves overnight hospital accommodation of the patient in question for at least one night, or

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(b) involves treatments presenting a particular risk for the patient or the population; or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to European Union legislation ensuring a minimum level of safety and quality throughout the European Union.

(4) The Minister shall ensure that the European Commission is notified of the categories of healthcare referred to in subregulation (3)(a).

(5) Where an insured person, with a view to receiving cross-border healthcare, makes a request for prior authorisation, the GCHCP shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met, and where those conditions are met, prior authorisation shall be granted pursuant to that Regulation, unless the patient requests otherwise.

(6) When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, the GCHCP, may require a clinical evaluation be carried out by experts in that field and if no experts can be found in Gibraltar or if the expert's opinion is inconclusive, the GCHCP, with the prior consent of the Minister, may request scientific advice.

(7) Without prejudice to subregulation (8)(a) to (c), the GCHCP may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with regulation 12, and when this healthcare cannot be provided in Gibraltar 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 or the nature of the patient's disability at the time when the request for authorisation was made or renewed, or both.

(8) The GCHCP may refuse to grant prior authorisation if–

(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross- border healthcare;

(b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;

(c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and

patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;

(d) this healthcare can be provided in Gibraltar within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned.

(9) The GCHCP shall ensure that information is made publicly available on which healthcare is subject to prior authorisation for the purposes of these Regulations, as well as all relevant information on the system of prior authorisation.

Administrative procedures regarding cross-border healthcare.

15.(1) The Minister shall ensure that, where Gibraltar is to be treated as the Member State of affiliation, that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved.

(2) Any administrative procedure of the kind referred to in subregulation (1) shall be–

(a) easily accessible;

(b) made publicly available at the appropriate level; and

(c) capable of ensuring that requests are dealt with objectively and impartially.

(3) The Minister shall determine on the basis of what is reasonable and thereafter inform the GCHCP and make publicly available the period of time within which requests for cross-border healthcare must be dealt with.

(4) In considering a request for cross-border healthcare the following factors may be taken into account–

(a) the specific medical condition;

(b) the urgency and individual circumstances.

(5) A person who is the subject of a decision regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in

another Member State shall be provided with a properly reasoned decision and shall be informed as to the right to have that decision reviewed.

PART 6
COOPERATION IN HEALTHCARE

Mutual assistance and cooperation.

16. The GCHCP shall provide the assistance set out in Part 2 of Schedule 2.

PART 7
PRIVATE HEALTHCARE

Professional indemnity insurance, guarantee etc.

17.(1) Healthcare providers shall at all times maintain professional liability insurance at a level of cover which is appropriate to the nature and extent of the risk, having regard to the nature and range of healthcare provided.

(2) A healthcare provider who, satisfies the Minister, that it has in place a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and extent of the risk, shall not be required to comply with subregulation (1).

Complaints procedure.

18. Healthcare providers must provide patients with a system for addressing complaints that is transparent and fair.

Access to medical records.

19.(1) A person who is receiving or has received treatment must, on request, be provided with written or electronic medical records regarding that treatment.

(2) A healthcare provider may be entitled to charge an administration fee for the production of such records but such fee shall not be greater than the costs involved in the provision of the requested information.

(3) A healthcare provider may withhold information until it receives the administration fee.

Part 8
Enforcement

Minister may issue directions.

20.(1) The Minister may issue a direction–

(a) for the purpose of ensuring compliance with any of the matters set out in Schedule 2;

(b) for the purpose of complying or seeking the compliance by another with any other duty arising from these Regulations or from the Directive;

(c) in any other case where the Minister considers it appropriate to do so.

(2) A direction issued pursuant to subregulation (2) shall be in writing and–

(a) shall be addressed to the person or persons who must comply with the Direction;

(b) shall state the matter which the addressee must comply with; and

(c) may include a time for compliance with the Direction.

Administrative penalty.

21.(1) A person who, without reasonable excuse–

(a) fails to comply with a Direction under regulation 20; or

(b) fails to provide information when required to do so pursuant to regulation 11,

shall be liable to an administrative penalty which shall not exceed £5,000.

(2) An administrative penalty shall be issued in writing by the Ministry for Health and any monies received by it under subregulation (1) shall be paid into the consolidated fund.

(3) Any sum due under subregulation (1) shall be a debt due to the Government and may be recovered as a civil debt.

Appeals.

22.(1) A person against whom an administrative penalty has been imposed may appeal to the Magistrates' Court within 21 days of receipt of the administrative penalty.

(2) Upon hearing an appeal in accordance with subregulation (1) the court may confirm, vary or quash the administrative penalty.

PART 9
RECOGNITION OF CROSS-BORDER PRESCRIPTIONS

Recognition of prescriptions issued in a Member State.

23.(1) If a medicinal product is authorised to be marketed in Gibraltar, prescriptions issued for such a product in a Member State for a named patient can be dispensed in Gibraltar as though that prescription had been issued in Gibraltar, and any enactment providing otherwise shall not apply to a prescription falling under this regulation.

(2) The Minister shall ensure that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are limited to what is necessary and proportionate to safeguard human health, and non-discriminatory.

(3) A person who is authorised to dispense medicinal products may refuse to recognise a prescription issued in a Member State only if such refusal is based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

(4) The recognition of such prescriptions shall not affect any rules governing prescribing and dispensing including generic or other substitution.

(5) The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products.

(6) Reimbursement of costs of medicinal products is covered by Parts 4 and 5.

(7) The requirement for recognition of prescriptions shall not affect a pharmacist's right to refuse, for ethical reasons, to dispense a product that was prescribed in a Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in Gibraltar.

(8) In addition to the recognition of the prescription, the Minster shall take all necessary measures in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in Gibraltar and where dispensing is sought in Gibraltar.

(9) This regulation shall also apply to medical devices that are legally placed on the market in Gibraltar.

(10) This regulation shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

Form of cross-border prescription.

24. Where a person informs a healthcare professional that a prescription is to be dispensed in a Member State, the prescription shall, as a minimum, contain the information set out in Schedule 4.

(2) A prescription which has been issued in a Member State and which contains at least the information set out in Schedule 4 may be dispensed in Gibraltar.

(3) Nothing in this regulation shall require a healthcare professional to issue a prescription which that person would not otherwise have issued it.

(4) Nothing in this regulation shall restrict the operation of regulation 23 and in particular the circumstances under which a cross-border prescription need not be recognised.

SCHEDULE 1

Regulation 3

European Union measures listed in Article 2 of the Directive

(a) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems;

(b) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices;

(c) Directive 95/46/EC and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector;

(d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services;

(e) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;

(f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin;

(g) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

(h) 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;

(i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components;

(j) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

(k) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications;

(l) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation;

(m) Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality;

(n) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

(o) Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems;

(p) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC);

(q) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work;

(r) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non- contractual obligations (Rome II) and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law;

(s) Regulation (EU) No 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality.

SCHEDULE 2

Regulations 5, 16, 20

Part 1

1. The matters that must be complied with are–

(a) healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. (Where healthcare providers already provide patients resident in Gibraltar with relevant information on these subjects, these Regulations do not oblige healthcare providers to provide more extensive information to patients from other Member States);

(b) there are transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the laws of Gibraltar if they suffer harm arising from the healthcare they receive;

(c) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided in Gibraltar;

(d) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with the Data Protection Act 2006 and in particular Directives 95/46/EC and 2002/58/EC;

(e) in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to the Data Protection Act 2006 and in particular Directives 95/46/EC and 2002/58/EC.

PART 2
ASSISTANCE

2. The GCHCP shall render such mutual assistance as is necessary for the implementation of the Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information including on provisions on supervision and mutual assistance to clarify the content of invoices.

3. Where a person is treated in Gibraltar, the GCHCP shall ensure that information on the right to practise of health professionals listed in the Gibraltar register pursuant to the Medical and Health Act is, upon request, made available to the authorities in other Member States, for the purpose of cross-border healthcare, in accordance with–

(a) Chapters II and III of the Directive; and

(b) the Data Protection Act 2004 and the Communications (Personal Data and Privacy) Regulations 2006.

4. The exchange of information shall take place via the Internal Market Information system established pursuant to Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data.

SCHEDULE 3

Regulation 10

GIBRALTAR CROSS-BORDER HEALTHCARE CONTACT POINT

1. Upon request, the Gibraltar Cross-border Healthcare Contact Point shall provide a patient relevant information–

(a) on the standards and guidelines referred to in regulation 5(1)(b), including provisions on supervision and assessment of healthcare providers;

(b) information on which healthcare providers are subject to these standards and guidelines; and

(c) information on the accessibility of hospitals for persons with disabilities;

2. The GCHCP shall provide patients, on request, with contact details of national contact points in other Member States.

3. The GCHCP shall facilitate the exchange of information referred to in regulation 10(4) and shall cooperate closely with national contact points in other Member States and with the European Commission.

4. The GCHCP shall inform patients about the elements to be included, pursuant to these Regulations, in prescriptions issued outside Gibraltar for use in Gibraltar, and vice versa.

5. The contact point shall, in the discharge of its duties under these Regulations, consult with patient organisations, healthcare providers and healthcare insurers.

SCHEDULE 4

Regulation 24

CROSS-BORDER PRESCRIPTIONS

Non-exhaustive list of elements to be included in medical prescriptions

(Headings appearing in bold in this Schedule are not required to feature in prescriptions).

Identification of the patient

Surname(s).

First name(s) (written out in full, i.e. no initials).

Date of Birth.

Authentication of the prescription.

Issue date.

Identification of the prescribing health professional

Surname(s).

First name(s) (written out in full, i.e. no initials).

Professional qualification.

Details for direct contact (email and telephone or fax, the latter both with international prefix).

Work address (including the name of the relevant Member State).

Signature (written or digital, depending on the medium chosen for issuing the prescription).

Identification of the prescribed product, where applicable

'Common name' as defined by Article 1 of 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.

The brand name if-

(a) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1.(b) of Annex I (Part I) to Directive 2001/83; or

(b) the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name.

Pharmaceutical formulation (tablet, solution, etc.)

Quantity.

Strength, as defined in Article 1 of Directive 2001/83/EC.

Dosage regimen.