

**Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique**



SELLING AND ADVERTISING OF MEDICINES ON THE INTERNET

Prepared by the Committee of Experts on Pharmaceutical Questions

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Preface

The Council of Europe

The Council of Europe is a political organisation which was founded on 5 May 1949 by ten European countries in order to promote greater unity between its members. It now numbers 44 member states¹.

The main aims of the Organisation are to reinforce democracy, human rights and the rule of law and to develop common responses to political, social, cultural and legal challenges in its member states. Since 1989 the Council of Europe has integrated most of the countries of central and eastern Europe into its structures and supported them in their efforts to implement and consolidate their political, legal and administrative reforms.

The Council of Europe has its permanent headquarters in Strasbourg (France). By Statute, it has two constituent organs: the Committee of Ministers, composed of the Ministers of Foreign Affairs of the 44 member states, and the Parliamentary Assembly, comprising delegations from the 44 national parliaments. The Congress of Local and Regional Authorities of Europe represents the entities of local and regional self-government within the member states.

The European Court of Human Rights is the judicial body competent to adjudicate complaints brought against a state by individuals, associations or other contracting states on grounds of violation of the European Convention on Human Rights.

Partial Agreement in the social and public health field

Where a lesser number of member states of the Council of Europe wish to engage in some action in which not all their European partners desire to join, they can conclude a 'Partial Agreement' which is binding on themselves alone.

The Partial Agreement in the social and public health field was concluded on this basis in 1959. At present, the Partial Agreement in the Public Health Field has 18 member states².

The principal areas of activity are:

- rehabilitation and integration of people with disabilities
- protection of public health and especially the health of the consumer. The aim of the Partial Agreement public health activities is to protect the consumer from potential risks connected with the present-day way of life. The committees of experts provide the scientific base for national and international regulations concerning products which have a direct or indirect impact on the human food chain (control of foodstuffs, nutrition, food safety, consumer health, food contact materials, flavouring substances), pharmaceuticals and cosmetics.

Pharmaceutical activities are supervised by the Committee of experts on pharmaceutical questions whose terms of reference, defined by the Public Health Committee, are the "harmonisation of provisions concerning several areas in the field of medicines, with a view to protecting public health".

¹ Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland.

² Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland.

The present publication was prepared by the Portuguese delegation¹ and approved for publication by the committee of experts in October 2002.

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Scope

The Internet's access has grown exponentially within the last few years. In fact, a little under one in two Europeans use the Internet, either at home, at work or in other circumstances (48% in total EU 15).⁰ There is also an increased demand for electronic access to all kinds of goods, and this will, in due course, exert its effects on the demand of medicinal products in countries where this type of commerce is not allowed. The convenience of the electronic method, which includes home delivery, wider choice of products or lower prices, more public information available or direct debit payments⁰, is unquestionable. But it is also known that most of the public demand goes to the "fashionable medicinal products" (i.e. prescription-only medicinal products that, through advertising or other means, have reached public opinion), which can endanger their health and consequently become a public health issue.

The global and cross-border nature of the Internet makes it an excellent medium to promote health but also to publicise all kinds of misleading information and treatments. So far, several organisations have intended to harmonise and standardise health information and e-commerce via the Internet, as well as alert the public to the risk that can be associated with this media. Examples of these organisations are World Health Organization (WHO), Pharmaceutical Group of the European Union (PGEU), Health on the Net Foundation (HON), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Official Medical College of Barcelona and National Association of Boards of Pharmacy.

Several studies^{0,0} have been made to evaluate and survey the sale of medicinal products on the Internet, generally reaching somewhat similar conclusions, but so far, few, if any, of the proposed measures have been undertaken. As an example, the following measures can be pointed out: the establishment of quality standards and self-control regulations; educational campaigns directed to the public; adoption of regulations taking into account the Internet's characteristics; empowerment of customs to prevent cross-border abuses of existing pharmaceutical regulations; regulatory barriers inhibiting cross-border on-line ordering of medicinal products, including product categorisation, pricing and reimbursement policy, advertising and areas where the principle of mutual recognition of national authorisations should be applied. Any measures undertaken must consider the positions of third-countries; therefore regulations or other measures undertaken would benefit if adopted at the worldwide level.

Nevertheless existing national regulation differences and cultural or social perspectives of public health protection might be preventing a global position, as jurisdictional issues will arise.

This study aims to provide an overview on the state of e-commerce and electronic advertising of medicinal products in the member states of the Partial Agreement. Due to the complexity of the subject and the short number of questions chosen, these results do not reflect the state-of-the-art of this theme. Future activities on this subject should clarify the:

Existence of codes of conduct, mandatory parameters, or other means of control, to website holders, whether from Marketing Authorisation holders, wholesalers, pharmacies, etc.

Existence of Guides/Brochures advising the public in general about e-commerce.

Existence of "pressure groups" for or against e-commerce of medicinal products (e.g. consumers associations, pharmacies)

Dimension of the e-commerce phenomena within the EU countries, i.e., number of customs' seizures, number of infractions detected and other concrete data.

Legal instruments available and effectively in use: measures taken against infractions within and outside national borders, existence and methods of "web inspection", etc.

Capability of handling the e-commerce and the Internet advertising phenomena

Electronic transactions between manufacturers, wholesalers and retail settings – existence, etc.

Proposals on how to deal with e-commerce and "notification network" – information exchange networks
Transposed EU directives regarding distance selling and e-commerce and specific legislation regarding e-commerce of medicinal products.

These lines of action are consonant with paragraph 9 of the Council of Europe Committee of Ministers' *Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security*⁰, which, concerning practices related to the Internet, states the following:

“A specific set of pharmaceutical good practices for the Internet (GIP) must be drawn up. These should, in particular, be implemented by those governments contemplating the sale of medicines by Internet. If necessary, they should guarantee real (as opposed to virtual) contact between the patient and a health professional.

International legislation should be drawn up, or in its absence the legislation of the country of final sale should prevail over that of the country of origin.

With regard to information and advertising, it is necessary to introduce an accreditation system and a quality mark.

Consumers must be made aware of the issues, both individually and through mass information campaigns.

Public health authorities should use the Internet to direct the public to reliable information.”

In the light of the results of the questionnaire and the main points of paragraph 9 of the above resolution, the Committee of Experts on Pharmaceutical Questions considers it necessary to further work in the field of medicines and the Internet. It can therefore be seen as an example, in exploring possible routes and developing one concrete activity from amongst the multitude of activities that are not being pursued.

II. Results

The survey was answered by 11 delegates representing: Austria (AT), Belgium (BE), Finland (FI), Germany (DE), the Netherlands (NL), Norway (NO), Portugal (PT), Spain (ES), Sweden (SE), Switzerland (CH) and United Kingdom (UK)

1. Pharmacy is for most countries (SE, PT, ES, SE, FI) the only place where it is allowed to sell medicinal products. In CH dispensing doctors are also authorised. Depending on the type of product (OTC, general sales medicines, herbals or medical devices) selling may also be allowed outside pharmacies (such as drugstores and supermarkets).
2. Traditional delivery of medicinal products (with no e-mail or mail order) that can only be sold in a pharmacy remains the only process available in AT, DE¹, PT, FI and ES. In BE mail or home delivery is allowed but only after pharmacy order directly by the patient or his or her representative. NL, SE and UK accept mail or e-mail orders and mail or home delivery, as long as requirements applied to traditional distribution are guaranteed. In no any order method is accepted and mail or delivery may be allowed providing it stays within customers' restriction circle. CH allows mail or fax order to "mail order pharmacy"².
3. NL, SE and UK allow selling of medicinal products, including prescription only medicines, on the Internet (e-mail orders or electronic transferred prescription followed by mail or home delivery) providing general rules are maintained and supply is made by a registered pharmacy, the MA holder, wholesalers or the same facility as in traditional distribution. In other countries selling on the Internet is only allowed for some products or in certain restricted conditions.
4. All countries (except CH) stated that they are adopting measures to monitor buying of medicinal products from another country but they count on Customs control to prevent medicines illegal import or to notify enforcement authorities. UK is seeking to clarify this area.
5. Almost all countries accept MA holders and pharmacies having web sites (except BE where pharmacies' web sites are not allowed) providing general rules on advertising are followed. Control or intervention by regulatory authorities is undertaken on a "same as other mean" basis except for NL and UK where special concern is dedicated to the Internet.
6. Using the Internet for advertising or promotion purposes is generally accepted according to EU regulation (OTC to general public and prescription only medicines to health professionals) and the Internet is considered the same as any other means. BE is preparing specific legislation that will prohibit advertising to general public by electronic media.

¹ For medicines obtainable outside pharmacies phone, e-mail, or fax order is allowed.

² Delivery methods not specified in the answers to the questionnaire.

Replies received:

Austria	Portugal
Belgium	Spain
Finland	Sweden
Germany	Switzerland
The Netherlands	United Kingdom
Norway	

SELLING OF MEDICINAL PRODUCTS ON THE INTERNET

1. Where may medicinal products be sold in your country?

Pharmacy only

Others (please specify)

Belgium	Portugal	Spain	Sweden
Pharmacy only	Pharmacy only	Pharmacy only	Pharmacy only

Austria	Finland	Germany	The Netherlands	Norway	Switzerland	United Kingdom
b) Some herbal medicinal products in drugstores	b) Some herbal remedies may be sold outside pharmacies (defined case by case in marketing authorisation)	In general in pharmacy only, except those medicinal products which may be sold outside pharmacies.	Pharmacy only – Prescription-only medicines Others – Pharmacy and druggist for OTC pharmaceuticals	b) In the meaning selling to ordinary patients. In practice almost all medicines are sold only in Pharmacies. But the ministry can allow other than pharmacies to sell OTC and this is now proposed. Hospitals can buy medicinal products from wholesalers	b) Dispensing doctors; Chemist's (OTC)	Medicines on the General Sales List can be sold from premises that can be closed to exclude the public, such as shops and supermarkets.

2. Can medicinal products be sold by any other means than direct-to-consumer sale (e.g. mail order)?

If yes, please specify.

Austria	Finland	Portugal	Spain
No	No	No	No

Belgium	Germany	The Netherlands	Norway	Sweden	Switzerland	United Kingdom
No, it's not possible to deliver medicinal products outside the pharmacy. All medicinal products have to be delivered directly to the patient or his or her representative. But medicinal products may be sent home (by mail or delivery) after pharmacy order.	No, except for the products mentioned above.	Yes, as long as the person responsible for the selling is a druggist or a pharmacist working in a registered drugstore or pharmacy.	Medicinal products can be sent by post or delivery when it is necessary for the patient (long distance to pharmacy), but the pharmacies are not allowed to send outside their local circle of customers and this prohibits ordinary "mail-order". There is no restriction on how pharmacies can obtain their orders.	All Swedish pharmacies are run by a state owned company "Apoteket AB" and no one else is allowed to sell medicinal products to the lay public. The sale can be done via pharmacies or via remote orders including the Internet, as long as set requirements on safety and information to the customer are fulfilled.	Mail order pharmacy: Prescription is needed.	Yes, by on-line pharmacy and non-pharmacy services, mail order and home delivery.

3. Is the selling (e-commerce) via the Internet allowed?

Yes

No

If yes, please indicate the legislative provisions

Austria	Finland	Portugal	Switzerland
No	No	No	No. But can not be controlled by offers from outside of the country.

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Belgium	Germany	The Netherlands	Norway	Spain	Sweden	United Kingdom
No, for the public in general Yes, among professionals	See items 1 and 2.	Yes. See item 2. The same requirements are applicable as in direct-to-consumer situation.	In general: Yes Medicinal products: In practice: No. (It's allowed to advertise on the Internet and also to take orders via Internet, but the opportunity to send medicinal products is strongly regulated. In practice selling by post-order and e-commerce is prohibited in the normal sense of these terms.)	No, for medicinal products Yes, for others.	Yes, see item 2.	For prescription only and pharmacy medicines, the supply must be made from a registered pharmacy premise. The Royal Pharmaceutical Society of Great Britain, which registers pharmacy premises, has set out a service specification for on-line pharmacy services. Medicines on the General Sale List must be pre-packed and sold from lockable premises.

4. If yes, what kind of products can be sold on the Internet?

Medicinal products

Others (please specify)
 (E.g. medical devices, herbals, cosmetics)

Belgium	Finland	Germany	The Netherlands	Norway	Spain	Sweden	United Kingdom
		See answer 2.	Medicinal products (OTC and non-OTC) and others (medical devices, herbals and cosmetics).	Almost all products. The exceptions are harmful products like inflammable products.	Others: Medical devices non reimbursed; Herbals without mention to therapeutical uses (art 42 medicines law 1990) Cosmetics	For the time being only OTC products and cosmetic and hygiene products are sold via Internet. Apoteket AB will also start selling POM via Internet, mainly from electronically transferred prescriptions from the doctor or another pharmacy, this autumn.	Medicinal products (OTC and non-OTC) and others (medical devices, herbals and cosmetics).

5. Who is allowed to sell via Internet?

Pharmacy only

Marketing authorisation holder

Others (please specify)

Belgium	Germany	The Netherlands	Norway	Sweden	United Kingdom
Pharmacy: No Marketing Authorisation Holders: Yes, but only to others MA holders, wholesalers and pharmacies.	MA holders, wholesalers, pharmacies and others (but only those medicines obtainable outside pharmacies).	Pharmacy and druggist.	To ordinary customers: Pharmacy only To hospitals: not regulated – anyone who has permission to wholesale (and pharmacies)	Pharmacy only. See item 2.	Pharmacy and on-line retail service providers

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6. How can the order be done?

By phone

By e-mail

Other (please specify)

Belgium	Germany	The Netherlands	Norway	Sweden	United Kingdom
By phone or e-mail among professionals.	By phone, e-mail and fax.	By e-mail. There are some specific requirements for electronic prescriptions.	Not regulated.	By phone, e-mail, letter, fax etc.	By phone or e-mail

7. Is a medical prescription always required?

Yes, for any medicinal product

Yes, for prescription only medicines

No

If yes, please indicate how does the prescription order reach the seller.

Norway	Germany	The Netherlands	Sweden	Switzerland	United Kingdom
Yes, for prescription-only medicines. The prescription is obtained by post, phone, electronic (not open systems) or delivered at the pharmacy (i.e. like any other prescription, but phone / telefax or by post are the most probable ways)	No	Yes, for prescription-only medicines. By electronic transmission or mail if the prescription is a paper document.	No. See item 4.	Yes for any medicinal product. By letter or fax.	Yes, for prescription-only medicines. By post. The electronic transfer of prescriptions is also currently on trial.

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8. What is the role of the pharmacist?

Switzerland	Germany	The Netherlands	Norway	Sweden	United Kingdom
A mail order pharmacy has the same legal obligations as a public pharmacy.	No special role (see answers 1 and 2).	To dispense medicines: The Inspectorate holds him responsible for the delivering to the home address of the patient. In terms of information: the same requirements as in the 'traditional' pharmacy.	In this connection: The same as for any other delivery of medicinal products: make sure the patients get the right medicine, dosage, information and so on.	The same as in other dispensing i.e. make the pharmaceutical assessment of the prescription.	All legal and professional requirements must be met by the pharmacist as for other medicines supply routes.

9. May pharmacies and marketing authorisation holders have websites?

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
Yes	Yes – MA holders No – Pharmacies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Pharmacies and MA holders must not infringe advertising controls for medicines

10. If yes, what kind of websites:
Specific websites
Included in general websites

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Switzerland	Sweden	United Kingdom
Both		Included in general websites	Both	Specific websites	Not regulated	Both	Both	Both	Both	Both

11.If yes, is there any form of control/intervention by the regulatory authority?

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Switzerland	Sweden	United Kingdom
The normal rules concerning advertising apply.	Yes	No systematic form of control	Yes	Yes, especially in terms of controlling if the selling and dispensing is done from a licensed pharmacy or a licensed druggist (for OTC products). If not, the Inspectorate enforces closing down the web site! For web sites abroad: no competence of Dutch Inspectorate.	Not very intensive control, but we follow the development with great attention.	No	No	No	There is no specific control of those web sites so far.	The Royal Pharmaceutical Society of Great Britain, which registers pharmacy premises, has set a service specification for on-line pharmacy services. The Medicines Control Agency has recently taken part in an Internet sweep, co-ordinated by the Office of Fair Trading (OFT), where sites containing misleading advertising about health care products and services were identified. The Agency and OFT are taking joint action to curtail illegal activity and give advice where appropriate.

12. In case a citizen from your country orders/buys a medicinal products via Internet from a country where it is allowed, are there any measures applied to control its entry in your country?
If yes, please describe the procedure.

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
In Austria selling of medicines via Internet is not allowed (see question 3). If a citizen orders medicines via Internet from abroad the entry into Austria is stopped by the customs.	When entering the country, merchandise is controlled by Customs. When medicinal products are involved, the Customs service contact "Inspection de la Pharmacie" that determines whether the product may be imported or not.	According to the administration regulation "importing medicines for private use" 6/2001 the medicine (imported) must be legally supplied. According to that regulation medicines may not be ordered via Internet. The customs suppress the import.	Yes, by the customs, by chance.	The customs control the borders from the EU and control at random or specific packages. If they find a package with medicinal products, they confiscate it.	The citizens are allowed to buy limited amounts of (non-narcotic) pharmaceuticals from EEA. From other countries the customer must apply for permission, and in most cases permission is not given. Citizens are referred to import via wholesaler and pharmacies. All packets are controlled for declaration. The Customs take random tests of packets entering Norway.	If a citizen orders medicines via Internet from abroad the entry into Portugal is stopped by the customs.	If they are products with a marketing authorisation in Spain, there is a custom control to apply the legislation (resolution 23-12-1983, DGFPS); If the product does not have a marketing authorisation in Spain, it can not be imported, only if specifically authorised by the General Directorate of Pharmacy (art 37 medicines law 1990).	There are regulations for the import of medicinal products for personal use. It follows EU-directives.	No	We are currently seeking to clarify the law in this area.

13. Additionally we would be interested in knowing if it is allowed to have websites where medical diagnostic is performed.

Austria	Belgium	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
No	No	No	Yes	It not regulated, but health authorities regard such a website as inconsistent with good medicine practice.		Yes	?	No	

14. In countries where there exists pharmacies on line:

Do you have any data about the use of medicines bought through Internet? Correct use, kind of medicines, type of user, pharmacist control, etc. (Question proposed by SPAIN)

Austria	Belgium	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
			No			No commerce yet.		

ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

15. Is it allowed?

Yes

No

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
Yes	Yes, but only non-prescription medicinal products, and regarding the existing regulation concerning advertising of medicinal products.	Yes	Yes, but only for non-prescription drugs.	Yes	Yes	Yes	Yes	Yes	Yes	Yes

16. What kind of products can be advertised?

Medicinal products (non-OTC)

OTCs

Others (please specify)

(E.g. medical devices, herbals, cosmetics)

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
OTCs, as far as advertising to the general public is concerned.	Prescription only medicinal products – No. OTCs – Yes.	Medicinal Products (non-OTC) – for physicians and pharmacists OTCs – for public	Only non-prescription drugs	OTCs and others. The Netherlands has some specific requirements for the dispensing of high risk IVD's: they must be dispensed by a pharmacist. Advertising for prescription only medicines is forbidden. The inspectorate enforces.	All pharmaceuticals with a marketing authorisation can be advertised, but pharmaceuticals obtained only by prescription may only be advertised to health professionals who can prescribe these pharmaceuticals (and pharmacists). Other products than pharmaceuticals are not allowed to advertise medical effects.	Any of them, regarding existing legislation (prescription drugs only to health professional)	Any of them, regarding existing legislation (prescription drugs only to health professional, OTC with previous control)	OTCs Medical devices Herbals Cosmetics.	OTCs, some conditions as "normal" PR.	Yes, for OTC and others (e.g. medical devices, herbals, cosmetics)

19. Is there any form of control/intervention by the regulatory authority?

Yes

No

Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
Yes, by the competent authorities (Bezirksverwaltungsbehörden).	Yes	No (not systematic)	Yes	Yes	The Norwegian Medicines Control Authority shall monitor advertising of medicinal products.	Yes	Yes	Yes	No, in preparation.	Yes

20.If yes, please describe procedures available

Austria	Belgium	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	United Kingdom
Any person who undertakes advertising not complying with the provision of the Medicines Act, unless the act is sanctioned by criminal penalty, is guilty of an administrative offence punishable with a fine by the Bezirksverwaltungsbehörden that are competent authorities. If infringements of the advertising provisions come to the knowledge of the Health Ministry the Bezirksverwaltungsbehörden are informed accordingly	There isn't a specific procedure. The files are evaluated case by case.	If the contents do not follow the MAA.	The Inspectorate has a unit (4 persons) which enforces advertising for pharmaceutical products. They react on signals and enforce the law.	In the event of contravention of the provisions relating to advertising, the Norwegian Medicines Control Authority may require that the advertisement in question be stopped or withdrawn and may order the company responsible for the advertising to issue a corrective statement to all recipients of the illegal advertising. In the event of repeated contravention of the provisions, the Norwegian Medicines Control Authority may prohibit all advertising for the product in question for a specified period or permanently. Grounds shall be given for the decision of the Norwegian Medicines Control Authority and the decision shall be made public. The above provisions do not preclude the establishment of a self-	Punctual control when an irregularity is seen. It is communicated to the Inspectorate of pharmacy who initiates procedure.	Punctual control when an irregularity is seen. It is communicated to the Inspectorate of pharmacy who initiates procedure	The MPA may intervene if rules are not followed.	Yes, see question 12 above.

Austria	Belgium	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	United Kingdom
				regulatory body for medicinal product advertising. Such a body may deal with any contravention of the Regulations. Reference is also made to the penal provision set out in section 3 of the Act concerning Medicinal Products.				

21. Are there websites accredited by the regulatory authority?

Yes

No

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Austria	Belgium	Finland	Germany	The Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
No	No, in preparation.	No (not systematicly)	No	Not yet. A health portal is being developed.	No	No	No	No	No	No

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