

Table of contents

Frame of the cards: identical structure for each country

THEME	Biological identity	
Identification of technology	Central repository of electronic prescriptions	
Technology used/tool (For each teams, a card pro tool)	Database	
Country/ use area	Czech republic/ Prague	
Frame of use	Repository was established for the collection and processing of electronically prescribed medicinal products ¹ but is being used also for control of distribution and use of the medicinal products, "OTC medicinal products subject to sales restriction» - which contain some active substances which can be misused narcotic at illegal drug market, ² and for processing of information on prescription of pharmaceuticals to individuals	
Population concerned: target and age	Patients using electronic prescription, patients using certain drugs for flu or pain killers, generally all individuals using pharmaceuticals	
% of users/of young users	Not revealed	
Trends (measured / supposed)	Central repository was established by the end of 2008, ³ data started to be collected by May 2009, amount of data processed and stored rapidly grow since than, in July 2009 data on medication of the	

¹ Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, Section 81, see

http://www.sukl.cz/uploads/Legislativa/Zakon_o_levicich_EN_corr_clean2.pdf

² State Institute for Drug Control: INFORMATION FOR MARKETING AUTHORISATION HOLDERS, http://www.sukl.cz/uploads/Registrace/OTC_s_omezim/OTC_o_omez_drzitele_EN.pdf

³ Jaromír Weber : SUKL rekapituloval, in Medical Tribune, 2009/01/06, p 7

	200 000 patients were daily submitted to the database ⁴	
Known or potentials dangers /Risks	Repository was created by the law to collect and process data on electronic prescription of the drugs, however in 2009 State Institute for Drug Control (SÚKL) started to request pharmacies to ask in the repository whether specific patient have received medical products subjected to sales restrictions, Pharmacies are also requested to submit to the central repository data on distributed pharmaceuticals to individual patients, this is being done without detail legislation by law just on the basis of Direction LEK 13 ⁵ issued by the State Institute for Drug Control. Patients are not asked for their consent with procession of their sensitive nor properly informed on the extend of the processing of their data. ⁶ SÚKL has already announced a plan to establish till the end of 2009 online application that would enable patients to enter through using of specific code information on the medication they were subscribed by the physicians and sold by pharmacutists and history of their drug taking. ⁷ Some of the media also raised concerns over the fact that software solutions, procession and coding of the data is subcontracted to the private companies. Some of the has the links on commercial health insurance companies. ⁸	
Others	Complains by the Czech association of pharmacutists are currently being investigated by Czech DPA ⁹	
Generated data bases		

⁴ Veronika Rodriguez: Office collects sensitive data that can be easily misused (Úřad sbírá citlivá data, která se dají lehce zneužít), in Aktualne.cz, 2009/06/06, <http://aktualne.centrum.cz/domaci/zivot-v-cesku/clanek.phtml?id=639077>

⁵ <http://www.sukl.cz/lek-13-verze-1?red=1>

⁶ Commentary of the Czech association of pharmacutists to the system of the electronic prescription, obligation to pass information on distributed medical substances and accounting of the distributed medical substances with pseudoefedrin of the 4. 5. 2009, <http://www.lekarnici.cz/download/pro-neprihlasene/sukl/Komentar%20CDu.pdf>

⁷ Václav Pergl : Patients will have their own record on pharmaceuticals (Pacient bude mít vlastní lékový záznam), in Právo, 2009/06/03, p. 19

⁸ Veronika Rodriguez: Office collects sensitive data that can be easily misused (Úřad sbírá citlivá data, která se dají lehce zneužít), in Aktualne.cz, 2009/06/06, <http://aktualne.centrum.cz/domaci/zivot-v-cesku/clanek.phtml?id=639077>

⁹ Commentary of the Czech association of pharmacutists to the system of the electronic prescription, obligation to pass information on distributed medical substances and accounting of the distributed medical substances with pseudoefedrin of the 4. 5. 2009, <http://www.lekarnici.cz/download/pro-neprihlasene/sukl/Komentar%20CDu.pdf>

<p>Associated data base/ creation (a line pro database)</p>	<p><i>Central repository of electronic prescriptions</i></p>	
<p>What justifies the inscription in the file /Risks?</p>	<p>Electronic prescription of pharmaceuticals, state health policy/ Disclosure of sensitive data of the patients, misuse of the data by commercial health insurance companies, discrimination in access to the medical treatment</p>	
<p>Purposes /contents, main data included / Risks?</p>	<p>Section 81 Central repository of electronic prescriptions The central repository of electronic prescriptions shall be established by the Institute as its organisational part to ensure the fulfilment of the following tasks: a) to accept and collect electronic prescriptions sent by prescribing doctors; b) to notify the doctor immediately after the receipt of the electronic prescription of the identification code for the prescription on the basis of which the prescribed medicinal products will be dispensed in the pharmacy; c) to provide free-of-charge access to the electronic prescription on the basis of which the medicinal products is to be dispensed to the pharmacist dispensing medicinal products in the concerned pharmacy immediately after the receipt of his or her request; d) to ensure a continuous, free-of-charge access to the database of electronic prescriptions for prescribing doctors and pharmacists dispensing prescribed medicinal products in pharmacies; e) to ensure that electronic prescriptions in the database of stored electronic prescriptions are safe and protected from damage, abuse or loss pursuant to a special legal regulation³⁶); f) to ensure the protection and handover of data in the case of terminating operation; g) to immediately label the electronic prescription made available pursuant to letter (c) and issued pursuant to Section 82.¹⁰/ Main data include : number of health insurance (birth number or date of birth name), code of medication, amount of medication, price by manufacturer, payment by health insurance company, batch of medication, ID of physician</p>	

¹⁰ Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts

	subscribing medication, ID of pharmacy. ¹¹ / For risks see above	
File masters? Risks?	Státní Ústav pro kontrolu léčiv (SÚKL) State Institute for Drug Control / part of the data processing is being subcontracted – outsourced to private companies with links to health insurance companies	
Who accesses the files/ Sharing of the data base? Access limits? /Risks	Detail information on right to the access to the files are not available, data are accessed by personnel of SÚKL and pharmacologists.	
Data retention delays/ risks Right to be forgotten	Not revealed	
Rights to know or to modify data?	Unclear	
Covert purposes/ Risks/uncontrolled future evolution	See Known or potentials dangers /Risks	
Others (interconnections...)		
Legislation in application		
Law /rules / others (?) (implemented for this data base or this technology)	Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts ¹² , Direction LEK 13 ¹³ issued by the State Institute for Drug Control.	
Risks for freedoms despite the law	See Known or potentials dangers/Risks	
If revision of the regulation: reasons? Result: improvement or aggravation (compared to the protection of the DP)	Not foreseen	
Conformity with the European right (Charter of fundamental rights, directives...)	Might contravene : Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe, CETS No. 108), The Czech Republic ratified the Convention CETS No. 108 on 9 July 2001 and it entered into force in the Czech Republic on 1 November 2001, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Applies also: Position No. 3/2004 Personal Data Processing in the Context of Clinical Testing of Drugs and Other Medical Substances ¹⁴	

¹¹ Veronika Rodriguez: Office collects sensitive data that can be easily misused (Úřad sbírá citlivá data, která se dají lehce zneužít), in Aktualne.cz, 2009/06/06

¹² see http://www.sukl.cz/uploads/Legislativa/Zakon_o_licivech_EN_corr_clean2.pdf

¹³ see <http://www.sukl.cz/lek-13-verze-1?red=1>

¹⁴ <http://www.uouu.cz/index.php?l=en&m=left&mid=02:109&u1=&u2=&t=>

Implementation (or not) of the legislation? / Risks		
Others		
This tools and young public or young adults		
How far are young people concerned?	Number of youngsters among subjects of a data not revealed by the Institute.	
Awareness of issues or of risks	None research made so far, probably very low	
Indifference or reaction	None	
Awareness campaigns/ results	None	
Good practises	None	
Campaign to be led. On which themes?	Awareness campaign on extend of data currently processed, importance of free consent with data protection and legislation change	
Others		
Conclusions		
Recommendations	Clarification of a concept of the central repository. Inclusion of free consent of the patient with the procession of the data. Defining of the data retention periods. Legislation change. Campaign raising awareness with risks related with procession of sensitive information for health specialists as well as for broader public	



Ministerstvo práce a sociálních věcí

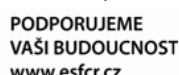
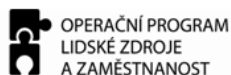
Podpořili nás:



Trust for Civil Society in Central & Eastern Europe



Open Society Fund Praha



Podpořeno grantem z Islandu, Lichtenštejnska a Norska v rámci

Finančního mechanismu EHP a Norského finančního mechanismu

prostřednictvím Nadace rozvoje občanské společnosti.