PUBLIC ADMINISTRATION AND PUBLIC FINANCE QUESTIONS IN THE ADMINISTRATION OF MEDICINES, ESPECIALLY THE EUROPEAN UNION'S RESPONSIBILITY ON IT

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ABSTRACT: *This study describes the concept of health management refers to management activities by state and local government agencies to protect the health of a community, and how taking administrative measures for the protection against diseases. The authors examine what is the general Hungarian legislation on it, and the role of the European Union in the health administrations, financing, especially the administration of medicines and pharmacies. In this study the authors want to highlight the problems of the legislation, generally.*

KEYWORD: *public administration, health care, public financing,*
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1. INTRODUCTION

In organic sense - The European Union Administration is the sum of the union and national ("regional and local") institutions, that prepare EU decisions and ensure their implementation and effectiveness. So it is clearly seen, that the organizational sense "notion not only the European government administrative departments of the Community, namely self-management and administration of the Community include, but embraces the Community and Member States' administrations as well.[1]

The relationship between the only *centrally operating* and EU institutions, and as well as the *"regional and local" operating* authorities at national institutions (parliaments, governments, courts and governments) can be characterized with the *principle of supplementary*. The EU institutions envisage the objectives of the Union, collect information, plan, decide, and coordinate and control. Implementation of it's decision are primarily the responsibility of Member States, in the Member States including all state bodies, not just the administration.

In this organizational and operational model, the EU institutions and the Member States form together a whole state apparatus.

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[1] Prof.Dr. András Torma: EU-Public Administration, 2013. University of Miskolc, University Press

The presence of the legislation, the state - and the administration - in the health sector is essential to the community as a whole, as well as the state is responsible for the protection of smaller groups and to regulate matters related to health.

2. THE CONCEPT OF HEALTH MANAGEMENT AND FINANCING

The concept of health management refers to management activities by state and local government agencies to protect the health of a community, and taking administrative measures and by taking measures for the protection against diseases associated with.

Indeed, it is fruitful to see how the law, which is it an art (ars iuris), captures the imitation of nature by various techniques regulated by law. However, this research quickly reveals its limitations insofar as the purpose of the law (recreated kind) is so multifaceted that it becomes elusive point of view of normative coherence. Health, ethical concerns have grown in the movement to defend human rights after the Second World War.[2]

Tasks related to the organization and management of health care for, exercise and fulfilling obligations liability related rights, rests and the responsibility is pressing the National Assembly, the Government, the Secretary for Health, local governments, health care providers other maintainers, health insurance organizations, and Regional Health Councils.

Carrying out the responsibilities of health care, in addition, also has taken part the Hungarian Army and Police Forces, medical services, medical transport organizations and the National Public Health and Medical Officer Service[3], Food and Drug Administration, health professional associations[4], professional colleges[5].

The medicine management is a special field of the health management and administration. In this area, the National Public Health Service and the OGYI has special entitlement's and rights, because the state administration has gave official powers for this institution, assigned by law, to carry out administrative tasks.

The above-mentioned bodies have both legislative and discretionary privileges arising enforcement powers. For example, within the broad discretion enjoyed by the Commission of the European Union belong to the arrangements for the medicinal products, particularly gaze trials performed in patients with scientific uncertainties.[6]

However, to determine what level to ensure the protection of public health, and the manner in which it is implemented already, it is the scope for Member States. It shall take decisions regarding the pharmacy.[7]

The European Union, - with the primary and secondary instruments - attempt to achieve coherence, harmonization in some areas[8], which is reflected in health administration and within the field of pharmacy administration well. The Pharmaceutical Code provides a comprehensive regulatory framework, which includes the marketing,

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[2] Dragoş Chilea „LE Régime Juridique De L`Identité Génétique De La Personne En Droit Européen", pg 53-68, Curentul Juridic 2010.

[3] 323/2010. (XII. 27.) Governmental Directive ont he State Health-care and health-officer service

[4] 2006. évi XCVII. Act on the Chambers in the field of Health-care

[5] 52/2008. (XII. 31.) Health-care Ministerial Directive on professional colleges

[6] The judgement of the EU Court in the T-429/05. case.

[7] The judgement of the EU Court int he C-531/06. and C-171/07. and C-172/07. cases.

[8] ÉVA ERDŐS : The European Tax-harmonization, as the tool of prohibiting the harm-tax competition. Publicationes Universitatis Miskolcinensis Sectio Juridica et Politica, Tomus XXX/1. (2012) pp. 255–270.

production and import of medicines regulation, labeling and package leaflet to determine the content and supervision of medicinal products.[9]

The underlying principles recorded in high level in the health care legislation. In addition, the basic rights and duties have been laid down by the Basic Law for the Health Act regulations. In the basic law rights and obligations of public health, we can find fundamental regulation on the health care system, health services, professional requirements and the rights and obligations of health professionals, government agencies responsibilities, the man performed medical research in the psychiatric patient medication administration, the organ and the patient.

The Health Act regulates the obligations of health care personally in accordance with the patients' rights. Occupies a prominent place among the patient's right to information law whose doctor is obliged to inform the patient about inter alia, health status (including its medical evaluation), the proposed studies, carrying out interventions or lack of potential benefits and risks, his right to decide the proposed studies and interventions with regard to the possible alternative procedures and methods, medicines and other benefits, as well as the recommended lifestyle.

However information giving on medicines and alternative procedures are not only the obligation of physicians or doctor. Legal rules can be found to the effect that the pharmacist is required to provide information to patients on medicinal products. It's not just the risk of medication, side effects of cover, but also in respect of the costs should be explained. Doctors and pharmacists are also required to inform patients, including about the available potentially cheaper generics. This obligation is also import to monitor the functioning of the National Health Insurance as well.

It is no coincidence, that the regulation is very strict on generic drugs as preference is given for the goods, as the biggest advantage of being cheaper than originator medicines. This price difference systems from the fact, that generic copy of an approved and authorized and outstanding original (factory original, patented) drugs, which after the expiry of patents on the original molecular anyone prepare and marketing may apply, but a different name, different outfits, other formulation, other packaging, but with chemically identical active ingredient.[10]

Their advantage comes from not only the goods, they owe more to their popularity, that is the approval process, which is much simpler than with the original products as well as comprehensive regulation of the insurance process is greatly facilitated.[11]

Although we can see, that the benefits of generic drugs are existing, but it also have a number of disadvantages. It appears from the generic concept, that the only match of the drug with respect to the reference medicine, but also includes differences in several respects. Even the active substances cannot be sure of the matched, because of the drug manufacturing process variations may arise as to who, where, how, starting raw materials, what machines, what quality control system is prepared. However it’s need to mention here, that in addition to drug codes have been mentioned in other EU Directives, that

[9] DR. CSABA KONTOR (National Resources Ministry, Pharmacy and Doctor-technology Main-department):The institutional system of the EU and the EU’s Pharmacy regulation
[10] 2004/27/ EU Directive: EU Parliament and Commission, - pharmacies for human’s
[11] 2006. year, XCVIII. Act on a safety and economical pharmacy and medical-devices.

formulate rules for good manufacturing practice for medicinal products.[12] Thus, the production of raw materials and related hazards, eliminate differences in principle.

However, the law exception is, that the inactive ingredients (carriers, solvents, preserving, protecting, colouring, flavouring), pharmaceutical dosage forms (tablets / capsules texture, consistency, quality) as well as in vivo, when they are in a template form.

The largest and perhaps the most dangerous deviation, - also authorize the act - the bioequivalence differences, which may vary by up to + -20% in compared to the reference medicine. This means, that bioequivalence, means the generic drug is absorbed in the same way up and the same blood levels can be achieved as the original. So this means, that one of the generic, say 20 percent, which exceeds originally a half times "stronger", than the same in said generic, which differs from a bioequivalence study, 20% down.

These differences, however, do not appear on the drug's label, package insert for information, but we see the same potency.[13] However, the pharmacist can get information on the medicine at the National Institute of Pharmacy.

In addition to the wide limits, which are imposed also a present threat to healthy humans, carried out in bioequivalence studies. However, to eliminate this danger, we can find the EU guidelines as investing strict rules for clinical trials from the European Union.[14]

In most European countries, agent-based prescribing is optional, that is not mandatory, but it is not forbidden. So if the doctors are only protesters, the active ingredient in the recipe gives by the pharmacist with the use of generics. In Greece and Austria, for example, this practice is not allowed, by contrast, in Britain, it is the major practice.

The regulations – on Hungarian compulsory health insurance and care about prescription and expenditure for human use - do not allow decision to pharmacists as to the basis of the price of choosing the required medicines issued or generics. After all, according to the special provisions, when the drug is replaced, and this doctor prescription has been ruled out, the pharmacist must inform the patients, that they are more affordable agents at the given moment, and with the agreement of this add up to him, so it should always be cheapest in stock offer.[15]

However, we cannot find any rules that define in what way have the pharmacies determine their supplies. Use only "necessary to ensure the supply of retail drug kit" concept of individual regulations, but its content is not defined[16]. In this case, the enforcement of a forced pharmacists discretion to find themselves, due to legislative shortcomings when they can determine their actions for themselves, to decide on the basis, which will be fitted.

So the pharmacy stocks are planning by the pharmacist in accordance with the requirements and according to the drug wholesalers. The current accounting system

[12] 2003/94 EU Commission Decision

[13]30/2005. (VIII. 2.) Health-care Ministerial Directive on the label's of human pharmacies and about the patient-information

[14] 2001/20/EU Directive on the clinical researches on the human pharmacies, and proper practice on them.

[15] Regulated by the transparency directive on the prices of pharmacies: Council Directive 89/105/

[16] 41/2007. (IX. 19.) Health-care Ministerial Directive on the working regulations on Public, Local, Institutional and „Handy'' Pharmacies

advanced by the pharmacist stocks, the patient will pay the compensation amount to be reimbursed only after the settlement of the insurance payment amount of drugs.

It should not be neglected that pharmacists, like doctors, must always act in the interests of patients. However, what is the best for patient, it is due to the indefinite law-concept, pharmacists have make the correct and complete content for themselves. Thus, taking into account the health interests of the patient in addition to economic interests. It is not always possible, however, to replace the original version of generic medications. For example, certain generic versions are not established, that shown to be bioequivalent to the original, because the comparison is based on guidelines, that have not yet been laid down. A very accurate dosing requiring generic drugs are less likely to be replaced product, because the real and harmful, or even ineffective dose range between (the so-called therapeutic with) is very small.

3. CONSEQUENCES

In fact, it should be very practical, that the pharmacist would have obligation to look up, what was previously referred to the patient as medicines, based on the bioequivalence[17]. These occur after comparing the prices, but the preferred biological medicine and the subsequent should also be equal under consideration.[18] It would be very useful to inform the patients about the results and possible side effects of value for money in comparison and then take place to select a common reference, the best interests of the patient's medication.

As we can see in this study it is a very important to highlight the tax's and public finance's side of the medicines and pharmacists, because these factors will be calculated during the determination process of the prices. It can takes pressure to the doctors or pharmacists or the patients, too.

In conclusion we can state, that the legal background and regulation of medicine's and pharmacies are situated in a very highlighted position in the EU,- for example the several EU Directives – so there is a classical 2-side system also in this field. First of all, the EU and the framework of it, is responsible for the mayor legislation, and secondly the public administration system of each member state, which are the executive board/ part in the process. Certainly there are also national regulations, but these always have to be coherent, and EU-Law abiding. As we could see in this short essay, the Hungarian public administrative authorities (e.g.: Health-care Ministry…etc.) are also taken a big part in this health-care field, to fulfill the common goals with EU:

„ Make and develop a better and healthier world for everybody.''

REFERENCES

Dr. András Torma: EU-Public Administration, 2013. University of Miskolc, University Press

ÉVA ERDŐS : The European Tax-harmonization, as the tool of prohibiting the harm-tax competition. Publicationes Universitatis Miskolcinensis Sectio Juridica et Politica, Tomus XXX/1. (2012) pp. 255–270.

[17] Transparency list of medicines: http://www.ogyi.hu/listak/

[18] Year of 2006. XCVIII. Act on the safety and economical medicine and medical devices

DR. CSABA KONTOR (National Resources Ministry, Pharmacy and Doctor-technology Main-department):The institutional system of the EU and the EU's Pharmacy regulation

SOURCES OF LAW AND PRECEDENTS:

323/2010. (XII. 27.) Governmental Directive on the State Health-care and Health-officer service
2006. évi XCVII. Act on the Chambers in the field of Health-care
52/2008. (XII. 31.) Health-care Ministerial Directive on professional colleges
The judgement of the EU Court in the T-429/05. case.
The judgement of the EU Court in the C-531/06. and C-171/07. and C-172/07. cases.
2004/27/ EU Directive: EU Parliament and Commission, - pharmacies for human's
2006. year, XCVIII. Act on a safety and economical pharmacy and medical-devices.
2003/94 EU Commission Decision
30/2005. (VIII. 2.) Health-care Ministerial Directive on the label's of human pharmacies and about the patient-information
2001/20/EU Directive on the clinical researches on the human pharmacies, and proper practice on them.
Council Directive 89/105/
41/2007. (IX. 19.) Health-care Ministerial Directive on the working regulations on Public, Local, Institutional and ,,Handy'' Pharmacies
Transparency list of medicines: http://www.ogyi.hu/listak/
Year of 2006. XCVIII. Act on the safety and economical medicine and medical devices