

ACTIVITIES OF THE NATIONAL INSTITUTE OF PHARMACY

2004 -2007



CONTENTS

PREFACE

1. INTRODUCTION

1. 1. Main milestones of the Hungarian regulatory drug control
1. 2. Activities defined by the legislation
1. 3. Activities defined by the Foundation Deed
1. 4. Undertaking activities

2. ORGANIZATION AND HUMAN RESOURCES

2. 1. Organogram
2. 2. Data of human resources

3. MARKETING AUTHORISATION

3. 1. Marketing authorisation of human medicinal products
3. 2. Registration of paramedicines

4. OTHER AUTHORISATION ACTIVITIES

4. 1. Individual import licences
4. 2. Authorisation of clinical trials

5. POSTMARKETING SURVEILLANCE

5. 1. Quality objections
5. 2. Pharmacovigilance

6. INSPECTIONS

6. 1. Good Manufacturing Practice (GMP)
6. 2. Good Laboratory Practice (GLP)
6. 3. Good Clinical Practice (GCP)
6. 4. Good Distribution Practice (GDP)
6. 5. Pharmacovigilance inspection

7. REGULATORY (INDEPENDENT) DRUG INFORMATION

7. 1. Direct information service on drug affairs
7. 2. Drug Information Pharmacist' Network

8. REGULATORY CONTROL OF DRUG INFORMATION

8. 1. Registration of medical representatives of pharmaceutical firms

8. 2. Control of drug information and drug advertisement

9. METHODOLOGY

10. LIBRARY SERVICES

11. ACTIVITIES OF NIP SPECIALISTS IN INTERNATIONAL PROFESSIONAL ORGANIZATIONS

12. PARTICIPATION OF NIP SPECIALISTS IN THE EDUCATION PROVIDED BY UNIVERSITIES

13. PUBLICATIONS

PREFACE

Tempora mutantur, et nos mutamur in illis

I. Lothar

Without any doubt, the times and the circumstances are changing in the National Institute of Pharmacy as well. The question is whether We are capable of changing and if yes, whether to the right direction.

The writer of these lines has the privilege to work for the NIP since 1978 – i. e. for 29 years with a short pause between September 2001 and June 2002 - and since 1984 – for 23 years – as the Head of the Institute. Let us see what can we recall if we follow the lines above seeking among the slowly fading memories.

Tempora mutantur...

Some memories from the many...

In Hungary, until the mid-80's of the last century a "selective" marketing authorisation process was going on. This meant that there was only one kind of medicine available from one kind of active agent or combination and there were not too many alternatives from similar pharmacological groups either. This principle wasn't unique in Europe however the system of the selection in Hungary didn't have to much connection with the „necessity clause” which was applied for example in the Scandinavian countries, strictly based upon professional grounds. In Hungary a permission from the then Ministry of Health was necessary for the NIP to register a new medicine and the permission was given or refused almost alone on political and financial causes. Thus the domestic medicine could be registered (then the medicine had to be produced by the factory which was the property of the state in the annual quantity the Ministry required). The new medicines produced in the "rubel-accounted" countries were rarely refused. (The introduction of same or similar medicines were precluded by the consequence that the Council for Mutual Economic Aid (Comecon) divided up the production of the medicines among the Comecon countries). Medicines from „hard-currency” countries got „red light” with few exceptions and the NIP had to reject the applications with the reason that there was no need for the medicine in question in the Hungarian healthcare. The Head freshly appointed in 1984 however did not accept the refusal of the best and most modern medicines in such a ridiculous way and negotiated with the Ministry until finally in 1985 an agreement was reached: the NIP acquired the title to evaluate and register every professionally appropriate medicine, however still the Ministry issued the marketing authorisation. The latter was only given to the medicines which – according to the Ministry – „the budget could afford”. At the end of the 80's hardly more than half of the registered medicines had a marketing authorisation. This situation lasted until 1991 when the two separate categories of „registration and marketing authorisation” were abolished and the NIP authorised the medicines under one procedure solely on professional bases. The situation however was not solved

completely as the reform of the social insurance system was delayed. In the early 90's almost all medicines were subsidized even the OTC ones if they were prescribed. This tendency of financial support could not keep pace with the quickly growing number of medicines. The devotees of the former system preferred the NIP to refuse the authorisations than to admit the financial difficulties. Is it believable now, when as the member of the European Union, laws are saying that an application for marketing authorisation can only be refused on professional reasons, that in 1994 the press launched a campaign against the NIP because it authorises so many medicines *needlessly*? Is it believable now when the generic substitution enjoys the priority of governance that at end of the 80's high-ranking government official labelled the generics as "useless copies"?

It is interesting to point out how these reflect in numbers: In 1984, 36 new medicines were authorised by the NIP, in 1986 there were 73, in 1996 there were already 562. (In 2006 – as it is going to be demonstrated later on – 638 medicines received marketing authorisation.)

Naturally the former scarce medicine hoard (for example in 1984 there were 699 active agents from which there were 1586 preparations) was never sufficient for treating every patient. The law institute of „individual medicine import” was supposed to alleviate this deficit for which the permission was given at that time also by the Ministry of Health. The NIP acquired the title to assess and issue such applications in 1992 and in this year we have already received 17 745 similar applications. The effect of the authorisation of new medicines manifested slowly: the number of applications decreased to 15 739 in 1996 (in 2006 it was 11 291, see below). Why is there so many? As I wrote, 25 years ago the domestic industry thought twice before authorising a new medicine because later on it was obligatory to produce it in the required quantity and the medicines from the „western world” cannot enter the country. For this reason there were few medicines. Although the situation got better for now, the range of medicines is still not wide enough for the treatment of many patients. Why? Hungary is a „small market” for the private pharmaceutical companies, the authorisation of too many medicines is not a „good deal” (on the official website of the NIP, there is a separate section for the temporarily or permanently unobtainable medicinal products). Times are changing, the problem remains the same?

When the „green wave” reached Hungary in the mid-80's and the need for the natural healing products had grown, the new category of „paramedicines” (preparations containing substances of natural origin but not considered as medicines) - which is a transitional category between medicines and food-products – has been devised under the leadership of the NIP. It was introduced by a decree in 1987. About 20 years ago a quite similar transitional category has been worked out in Canada as well, but ours had to be abrogated because of our joining to the EU. While there are continuous discussions in the EU on the category „traditional herbal medicine” and there are hardly any preparations in this category, many herbal preparations have been marketed – doubtedly legally or obviously illegally – as food-supplements, or without any authorisation but with a medical indication, the distribution of our formerly authorised „paramedicines” have to be stopped until 2011. (This category flourishes in

Canada so much, that the Canadian Authority has a separate office for it.) All we have left is that we can be proud to have come out with it 20 years ago...

The NIP has always been in the forefront in the cooperation between drug regulatory authorities – but the relations were also changing as time went by. The NIP was the Coordination Centre for Pharmaceuticals in the Comecon till 1990, the dissolution of the Comecon. It has joined early in 1976 to the European Free Trade Association's (EFTA) first open (not only for EFTA states) Pharmaceutical Inspection Convention (PIC, which is the mutual agreement on GMP-inspections. Of course it was often criticized by the Soviets). This was followed by the membership in the EFTA's Pharmaceutical Evaluation Report Scheme in 1991, then in the OECD's (Organisation for Economic Co-operation and Development) GLP-Working Party (from 1992 as an observer, from 1993 as a full member) – the odd thing about this is that Hungary was not a member of the OECD that time, while the NIP has been a full member of the Working Party. Approaching the European Union the NIP launched the Collaboration Agreement between Drug Regulatory Authorities in the European Union Associated Countries (CADREAC) in 1997, the cooperation between the majority of the acceding countries, which established the Pan-European Regulatory Forum (PERF). Now we are the member of the European Union, and more than 40 colleagues of the NIP participate – more or less regularly – in the different meetings of the EU-working parties...

In 1991, after the dissolution of the Comecon, Hungary joined immediately the Convention on the Elaboration of a European Pharmacopoeia as an observer. 10 more years passed by, as the Government started to deal with the full membership as a priority...

...et nos mutamur in illis

The NIP was originally founded as an organizational-methodological and scientific institution and gradually got more and more public administrative (official) duties which became nowadays our major function. (Compared to the mid-80's the duties of the NIP tripled as an official authority.)

Naturally (?) the number of the staff could not increase in such a rapid way. In 1986 the number of the employees was 165, between 1996 and 1999 – due to the obligatory staff reduction among civil servants – it was 154. (In 2006 we were 217.)

What can we do for our renewal? On one hand, we founded new departments for the new tasks constantly, mainly by regrouping and rethinking the priorities. On the other hand: before every significant change we rearranged the structure of the Institute.

As the system of the "selective" marketing authorisation process came to an end, it was predictable that the number of applications concerning new medicines may increase. Therefore we set up the Application Screening Department, which has to examine the applications and indicate the

insufficiencies immediately. The necessity of the department was not appreciated by many people, they „felt sorry” for the professionals taken out of the „professional assessment”, nevertheless, nowadays such activity is a requirement in the European Union. This year we rearranged the Registration and Pharmaceutical Departments – which were quite similar in many ways – founding the Quality Review of Product Information Department on the basis of the latter for the supervision of the Summary of Product Characteristics (SPC) and Patient Information Leaflets (PIL).

In 2002, before we acceded to the EU we founded a separate group as a „matrix-organization” for the renewal of the documentation. We also made our discussions public for the representatives of the companies affected.

„On the eve” of our accession to the European Union we established the Coordination Department. Its main task is to keep the standards and requirements of the European proceedings and to organize the work of the different units of the Institute concerned.

Our technical conditions have improved as well. While in the 80's only one, „the” liquid-cromatograph was operating, our further „high-tech” apparatus was a gas-cromatograph and a spectrophotometer. For today, we also have appliances like HPLC-MS (and EC-MS). I remember having the first word processor – at the beginning of the 80's – which arouse a large interest. We obtained it as a result of the cooperation with the WHO (it was placed in the Director-General's vestibule and everyone was looking for the appropriate Hungarian expression for „word processor”). Today, 25 years later all the administrators – including every assistants – have their own computers connecting to the Institute's own system.

To achieve all this results we also needed a certain financial independence. Until the mid-80's deed stamps had to be put on the authorisation-applications of new medicines. After convincing the competents of the Ministry of Health of that time (it was a hard nut to crack!), from the late-80's an administration fee had to be paid and a (small) part of it was left in the Institute. (Many people did not understand that it was not the applicants, that is to say the pharmaceutical industry, who financed the Institute, since the administration fee had to be paid regardless of the outcome of the procedure – thus in case of the refusal of the application as well.) This proportion had been increasing progressively, and since 2000 we practically do not get any money from the state itself, the NIP became self-supporting, moreover it earns money for the state by transferring the received sum over its financial plan. (There are not many health institutes in Hungary which may be able to do the same!) This is an important question because in case of a temporary increase in the quantity of work we can manage the situation more flexible due to this (excess) amount – for example by employing more contributors. Times are changing and so are we – hopefully in the future as well.

Dr. Tamás Paál
Director-General, regius professor

1. INTRODUCTION

1.1 Main milestones of the Hungarian regulatory drug control

The National Institute of Pharmacy was formed from the Technical Development Section of The Ministry of Health in 1962. In 1968 NIP merged with the Chemical Section of the National Institute of Public Health in order to produce a unified drug control agency with general responsibility for marketing authorization and supervision of manufacturing, wholesale and retail trade of the medicinal products.

In 1998 the Ministry of Welfare issued the new deed of foundation of NIP. That defines the NIP as a controlling authority of GMP, GDP and as a licensing authority for the marketing authorization of the most medicinal products. NIP is also responsible for licensing the individual medicine import, authorisation of duty-free donations of medicines in and out of Hungary.

1.2 Activities defined by the legislation

- Evaluation and marketing authorization of human medicinal products
- Registration of paramedicines
- Authorization of clinical trials
- Issuing GCP licenses, inspections
- Issuing GLP licenses, inspections
- Issuing GMP licenses, inspections
- Issuing GDP licenses, inspections
- Licensing parallel medicine import
- Licensing individual medicine import
- Authorisation of duty-free donations of medicines
- Supervision of medicine supply
- Control of drug information and drug advertisement
- Editing and amending of Hungarian Pharmacopoeia
- Editing and amending of Formulea Normales
- Qualifying of the electronic information-system on medicinal products used by non-pharmacies

1.3 Activities defined by the Foundation Deed

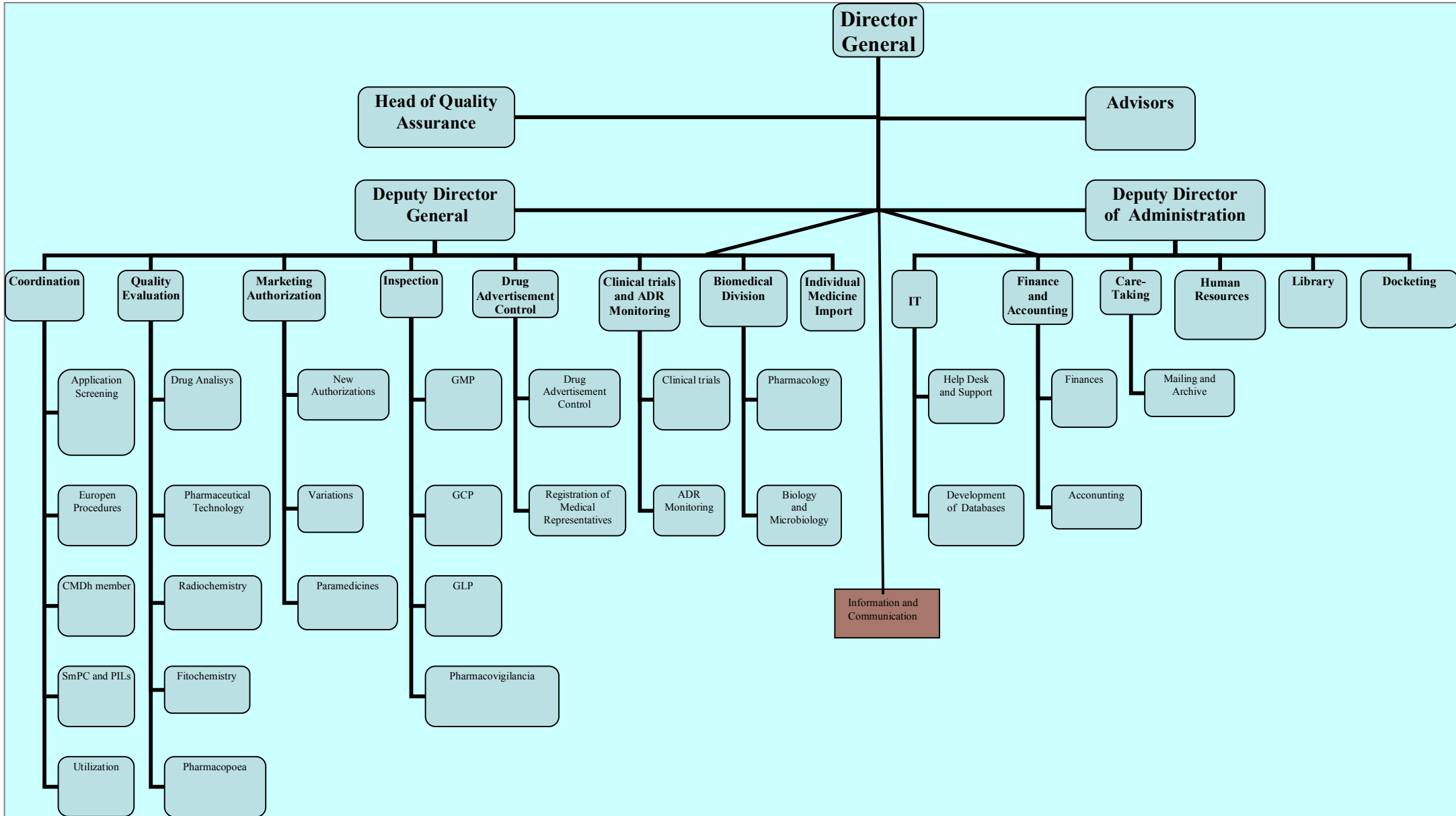
- Preparatory and advisory contribution for request in the legislation of human medicines
- Contribution for request in the harmonization of EU legislation
- Developing and providing the public information systems regarding the data in its competency
- Establishing and maintaining international relations regarding its competency
- Contribution with WHO
- Pharmaceutical organizational-methodological, training and research institute of the Ministry of Health, in co-operation with the National Health Service and the professional colleges
- Analyzing the data of utilization, developing the pharmaceutical science, methodology, encourage the practical use of new scientific achievements
- Issuing pharmaceutical methodological letters
- Maintaining an independent network of Medicine Reviewers
- Maintaining a direct information service on drug affairs
- Contribution with universities in the training of pharmacists

1.4 Undertaking activities

- Teaching activities
- Organizing scientific, specialists trainings
- Publishing pharmaceutical publications
- Scientific expert report for request

2. ORGANIZATION AND HUMAN RESOURCES

2.1 ORGANOGRAM



2.2 DATA OF HUMAN RESOURCES

Total number of employees : 211

The rate of graduates/non.graduates versus total number

Year	Total number of empl.	Graduates	Graduates %	Non-graduates
1996	153	71	46,4	82
1997	164	77	47,0	87
1998	168	79	47,0	89
1999	173	80	46,2	93
2000	173	77	44,5	96
2001	172	77	44,8	95
2002	172	73	42,4	99
2003	172	81	47,1	91
2004	194	95	49,0	99
2005	206	95	46,1	111
2006	217	106	48,8	111
2007	211	96	45,5	86

Fluctuation

	2002	2003	2004	2005	2006	2007
joined employees	29	25	28	34	29	34
left employees	18	13	18	22	16	48

Amount of part-time employees

year	total number	full-time		part-time	
		professional	non-professional	professional	non-professional
1996	153	60	67	11	15
1997	164	61	74	16	13
1998	168	61	72	18	17
1999	173	62	75	18	18
2000	173	61	79	16	17
2001	172	62	78	15	17
2002	172	63	87	10	12
2003	172	71	75	10	16
2004	194	81	85	14	14
2005	206	81	92	14	19
2006	217	92	96	14	15
2007	211	96	86	14	15

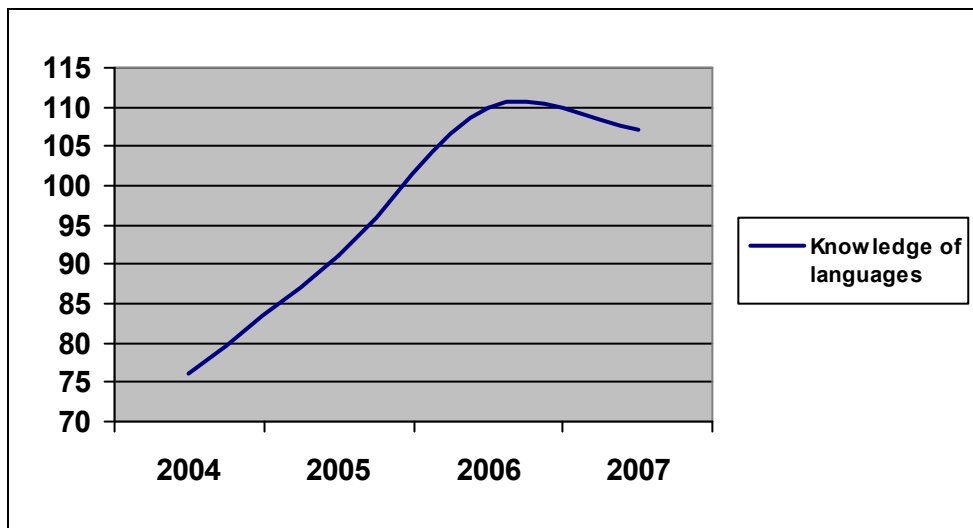
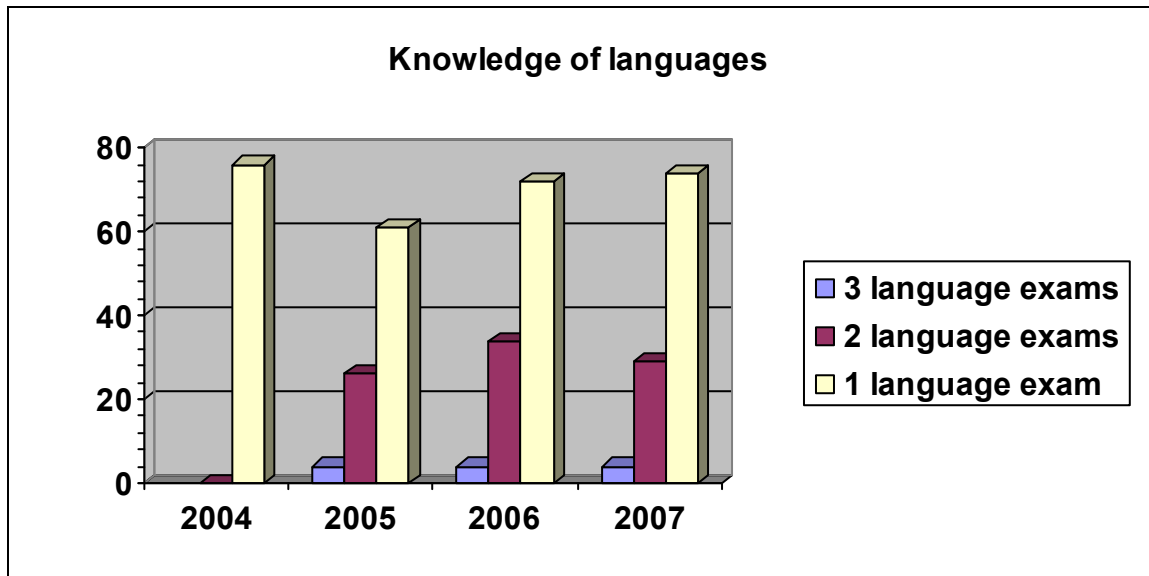
Knowledge of languages

2004: 76 persons

2005: 91 persons (26 persons have 2 language exams, 4 persons have 3 language exams)

2006: 106 persons (34 persons have 2 language exams, 4 persons have 3 language exams)

2007: 107 persons (29 persons have 2 language exams, 4 persons have 3 language exams)



Other statistics (2007))

Total number: 211	
Women	88%
Disabled	1%
Above 40 year	66,3%

PhDs, Univ. Drs	14
Pharmacists	61
Pharmaceutical Specialist	47
<i>Postgraduates:</i>	
Certified legal pharmacists	2
Certified economical pharmacists	2
Pharmacist specialized in International business affaires	1
Chemists	8
Biologists	2
Medical Specialists	9
EEG assistant	1
Others	12

3. MARKETING AUTHORISATION

3. 1. MARKETING AUTHORISATION OF HUMAN MEDICINAL PRODUCT

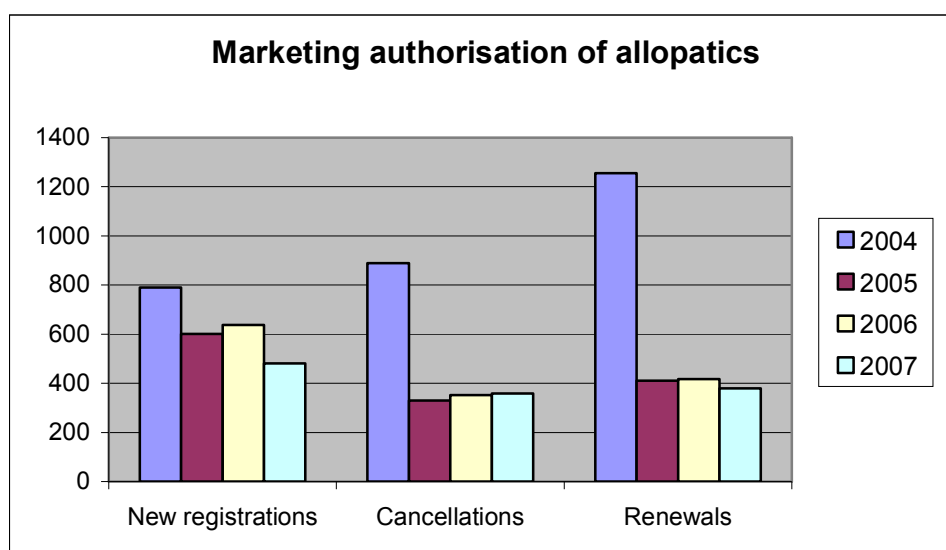
The Decree No. 52 of 18, November, 2005 Minister of Health assigns the marketing authorisation of human medicinal products to the competence NIP. There are four types of procedures to issue the marketing authorisation in Hungary – as it is common in the EEA (European Economic Area) as well:

- **centralized procedure:** the documentation of the new product is assessed by the EMEA-CHMP, the authorisation is issued by the European Commission.
- **decentralized procedure (DCP):** the new product has not been authorised in any European countries in the time of the submission of the application; the National Institute of Pharmacy is entitled to assess the documentation and to issue the marketing authorisation.
- **mutual recognition procedure (MRP):** the new product has been authorised at least in one European country in the time of submission of the application; the National Institute of Pharmacy is entitled to assess the documentation and to issue the marketing authorisation.
- **national procedure:** assessment is carried out by the National Institute of Pharmacy; the marketing authorisation is valid only in Hungary.

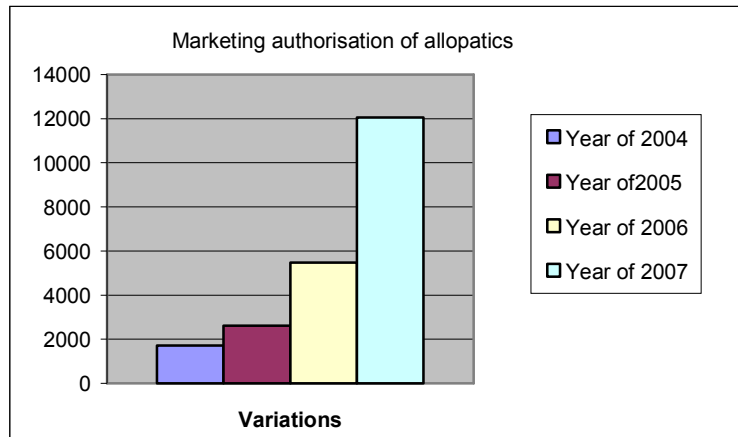
Marketing authorisation of allopatrics

Year	2004	2005	2006	2007
New registrations	790	601	638	481
Cancellations	889	330	352	358
Renewals	1255	411	417	379

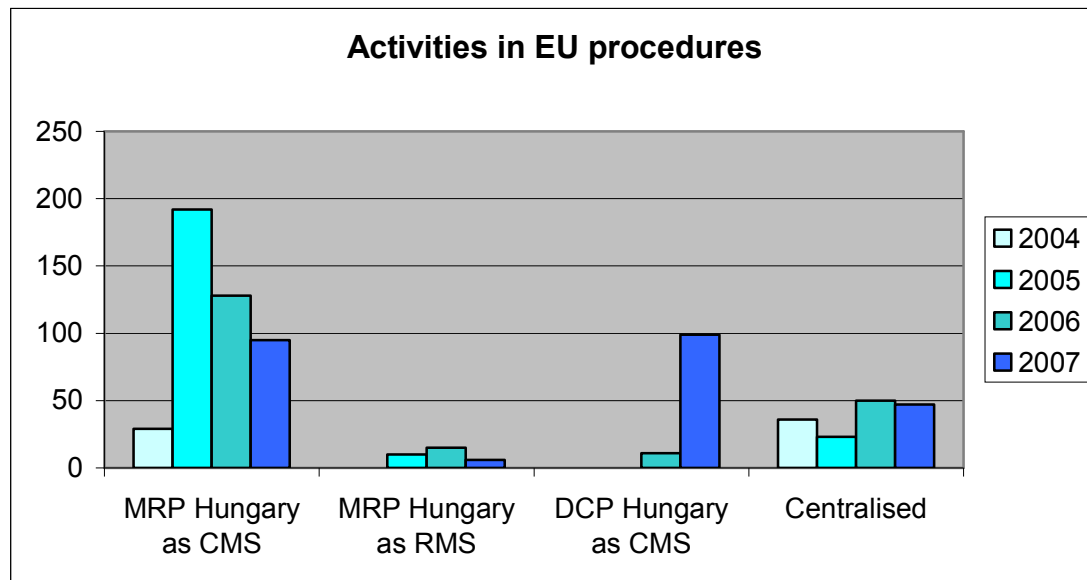
*New active substance, or new combination of well known substances or new potential, but new batches are taken account in one permission



Year	2004	2005	2006	2007
Variations	1718	2618	5472	12 050

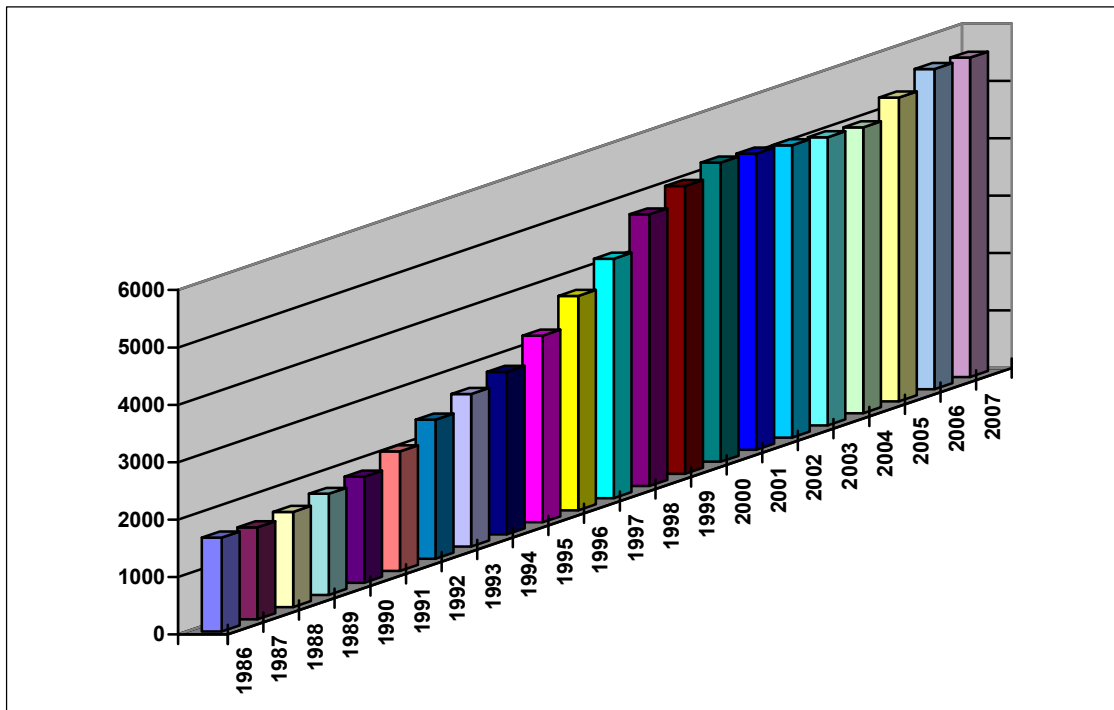


	2004	2005	2006	2007
MRP				
RMS	0	10	15	6
CMS	29	192	128	95
DCP				
RMS	0	0	0	0
CMS	0	0	11	99
Centralised				
(Co-Rapporteur)	36	23(3)	50(7)	47(5)



The total number of registered allopatrics between 1986-2007

Year	Number
1986	1636
1987	1599
1988	1660
1989	1763
1990	1849
1991	2080
1992	2422
1993	2657
1994	2832
1995	3250
1996	3735
1997	4171
1998	4733
1999	5015
2000	5210
2001	5156
2002	5090
2003	5019
2004	4981
2005	5290
2006	5576
2007	5564



Marketing authorisation of homeopatics

	2004		2005		2006		2007	
	mono comp.	complex	mono comp.	complex	mono comp.	complex	mono comp.	complex
Registered homeopatics	867	85	699	89	658	82	658	78
New registrations	22	2	0	6	0	0	0	1
Cancellation	3	8	168	2	37	9	0	3
Variations	68	2	419	2	0	9	0	6
Renewals							25+15 Coll*.	7+13 Coll.*

**Coll.= collective renewal*

3. 2. REGISTRATION OF PARAMEDICINES

In Hungary, since 1987 there is a category for those natural based medicines (herbal, animal, mineral, vitamine origins), which have: guaranteed quality, recognized efficacy, acceptable safety, impact on the protection of public health, and can be used without the supervision of a health care professional. At the end of 2005 the Decree No. 53 of 18 November, 2005 Minister of Health entered into force, and from that time no new application can be submitted in this category, but those ones which have already granted can be in the market till 2011.

	2004	2005	2006	2007
New registration	8	21	56	20
Issued MA licences	220	62	62	118+16
Cancellations	1	19	10	15
Renewal of registration	273	84		137
Variations	105	71	70	170
Total number of registered paramedicines	482	287	349	372

4. OTHER AUTHORIZATION ACTIVITIES

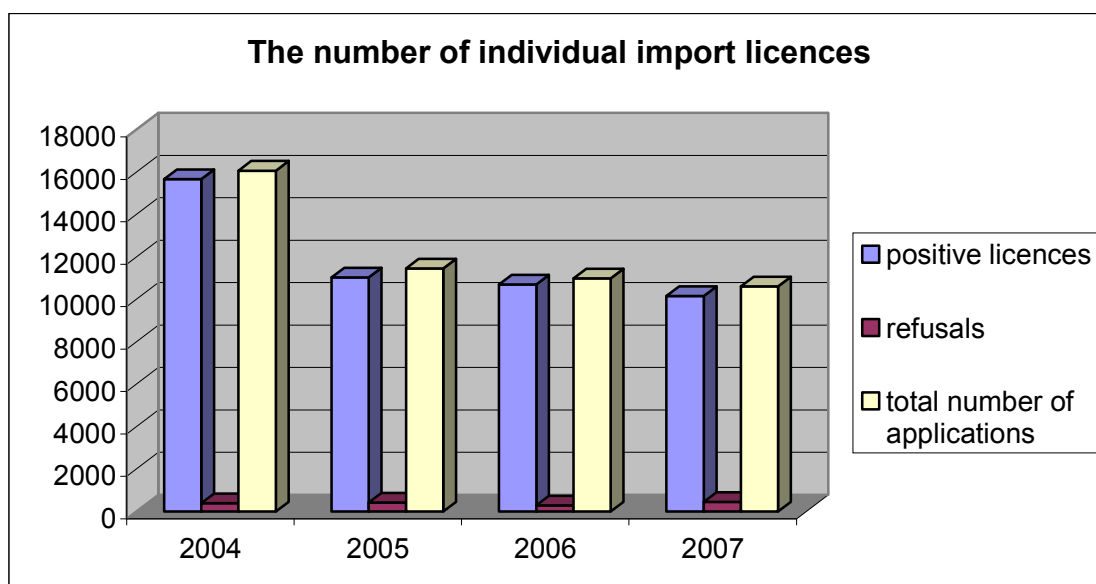
4. 1. INDIVIDUAL IMPORT LICENCES

Concerning to the Decree No.44 of 28 April, 2004 Minister of Health, Family and Social Affairs a medicinal products which have no marketing authorization in Hungary (but in the EEA or outside the EEA) may be imported within the frame of outpatient and bedpatient service.

All applications are examined thoroughly within 8 days - if necessary in cooperation with a medical expert advisory panel – and a declaration or a decision is issued by the National Institute of Pharmacy dependently whether the medicine is being imported from the EEA or outside the EEA:

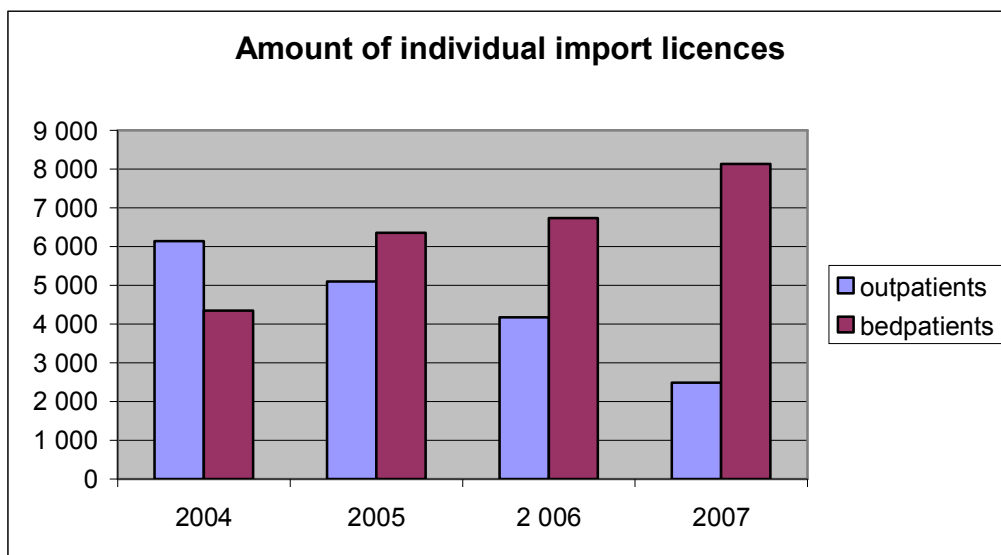
- if the product would be imported from the EEA the National Institute of Pharmacy will issue a declaration whether the request is reasonable;
- if the product would be imported from outside the EEA the National Institute of Pharmacy will issue an authorisation after the examination of the necessity of the medicine

Year	2004	2005	2006	2007
Licences and positive expert reports	15 674	11 031	10 997	10 156
Refusals and negative expert reports	396	424	294	460
Total number of applications	16 070	11 455	10 997	10 616



Amount of individual import licences

Year	Outpatients	Bedpatients
2004	6 141	4 348
2005	5 103	6 352
2006	4 176	6 736
2007	2 484	8 132

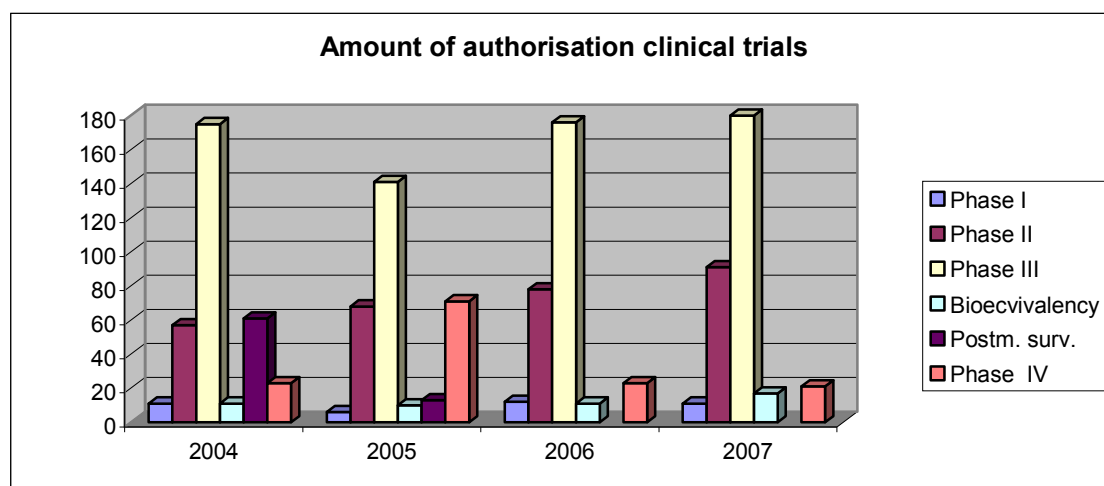


4. 2. AUTHORISATION OF CLINICAL TRIALS

In Hungary, the human phase I-III clinical trials and bioequivalence studies must be authorised before started, independently from their purpose (registration or clinical research). Authorisation, after careful assessment and approval of the Ethics Committee belonging to the Scientific Health Council, is granted by NIP.

Amount of authorisation clinical trials

	2004	2005	2006	2007
Type of trials				
Phase I	11	6	12	11
Phase II	57	68	78	91
Phase III	175	141	176	180
Bioequivalency	11	10	11	17
Postmarketing surveill.	61	13	-	-
Phase IV	23	71	23	21



5. POSTMARKETING SURVEILLANCE

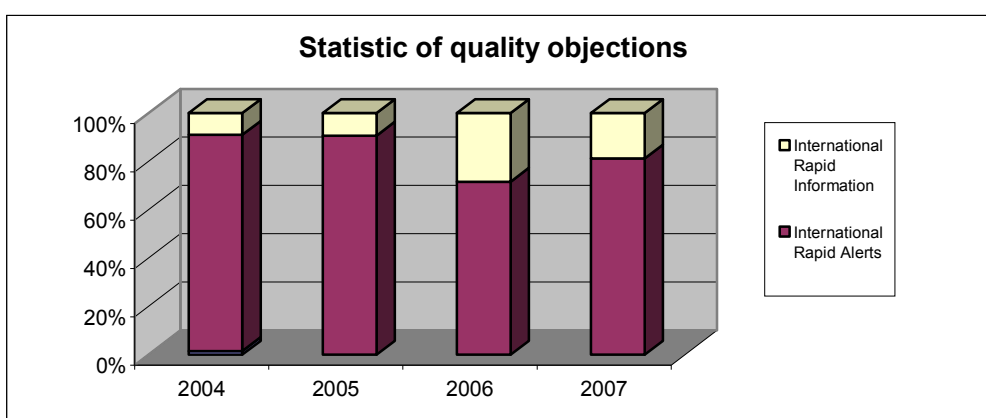
5. 1. QUALITY OBJECTIONS

The professional supervision of the wholesaler trade of medicines and the official control concerning the responsible medicine supply fall within the competence of the National Institute of Pharmacy according to the XCV Medicines Act of 2005. According to the Decree No. 53 of 2 June, 2004 of the Minister of Health as amended the wholesaler takes the responsibility for the maintenance of the quality of the marketed product concerning the product range determined in the wholesaler authorisation, and for the re-collection of the manufactured batches if due to their defect a withdrawal is ordered.

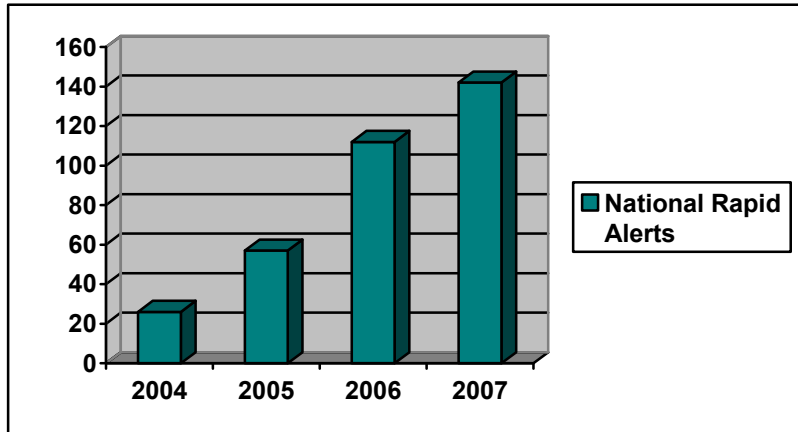
In favour of protection of the public health it may be necessary to act without no delay and withdraw a batch of medicinal products from the market. All manufacturing places owning a manufacturing authorisation for medicinal products are obliged to work out a system for withdrawing activities and have it function effectively. The Marketing Authorisation Holder is obliged to notify the competent authority about all defects or other factors which may result in the withdrawal of a medicine from the market.

Statistic of quality objections

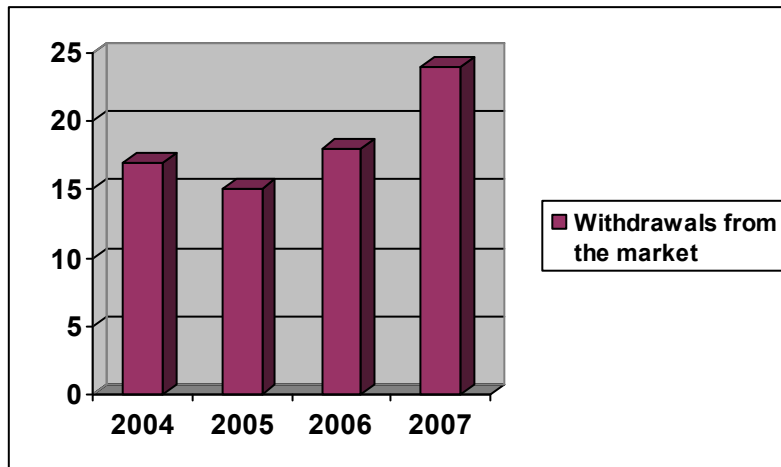
	2004	2005	2006	2007
International Rapid Alerts	60	68	58	65
International Rapid Information	6	7	23	15



	2004	2005	2006	2007
National Rapid Alerts	26	57	112	142



	2004	2005	2006	2007
Withdrawals from the market	17	15	18	24



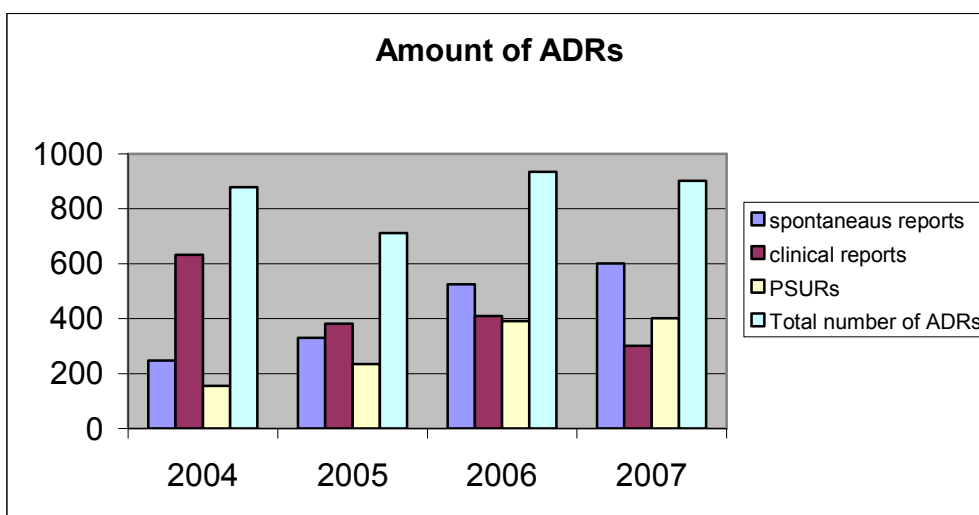
5. 2. PHARMACOVIGILANCE

During the evaluation of side-effect reports they are classified (mentioned or not in the data Sheet/SPC, its severity, etc.) the possibility of quality defect as the source of adverse reaction is excluded by laboratory control and the real ADRs are registered. In case of necessity, the Data Sheet may be modified or even the medicine deleted from the register. Since 1989, the NIP has been participating in the WHO ADR Monitoring Service. Thus, side-effects registered in Hungary are reported to the Uppsala WHO Centre twice a year while the NIP has access to the Data Bank of the Uppsala Centre.

We select the more serious adverse effects from the ADRs. If one adverse effect became more often we examine its presency and frequency among the ADRs from the Annual AD Register issued by the Uppsala Centre. Considering any difference between our findings and of the WHO reports, we consult about it with the Centre and with other registration authorities.

Amount of ADRs

Year	2004	2005	2006	2007
Type of ADRs				
Spontaneous reports	247	330	525	601
PSUR	155	234	391	401
Total ADRs %	62	71	74	67
Clinical report	632	382	410	301
Total number of ADRs	879	712	935	902



6. INSPECTIONS

6. 1. GOOD MANUFACTURING PRACTICE (GMP)

Good manufacturing practice is part of the quality assurance system in the pharmaceutical industry which ensures the medicinal product to be manufactured and controlled according to the requirements prescribed, the facts stated in the Manufacturing Authorisation and to be appropriate for the purpose they have been granted.

Any manufacturing process of medicinal products in Hungary (this includes manufacturing and packaging of active substances, manufacturing, batch release and quality control of medicinal products) has to be carried out only in possession of a valid manufacturing licence for medicinal products issued by the National Institute of Pharmacy.

The National Institute of Pharmacy – as the responsible authority for the supervision of manufacturing medicinal products – makes certain through their colleagues working as GMP inspectors that manufacturing of medicinal products meets the requirements stated in the Marketing Authorisation and is proceeded according to GMP directives.

The manufacturing site owning manufacturing authorisation for medicinal products is being inspected regularly by the competent authority to follow the activity of manufacturing of medicinal products with attention continuously. According to the EU requirements frequency of these GMP inspections is in case of a medicinal product once in two or three years' time and occasional in case of an active substance.

The National Institute of Pharmacy has the right to make an exceptional GMP inspection if a fault with the quality or with the manufacture of the medicinal product or if any changes in the circumstances concerning the manufacturing process or quality of the medicinal product (e.g essential change in the places or equipment) occurs.

During the process of granting a Marketing Authorisation for a medicinal product it may become necessary to make a GMP inspection at a manufacturing site in a so called „third country” beyond inspecting the Hungarian manufacturers – the inspectors of the National Institute of Pharmacy will carry these inspections as well out.

Number of manufacturing licences	2005	2006	2007
total	76	88	82
new licences	15	33	21
withdrawals	10	21	17
Number of GMP inspections foreign	157 8	180 8	154 10

6. 2. GOOD DISTRIBUTION PRACTICE (GDP)

GDP is part of the pharmaceutical quality assurance which enables the medicinal products having been released by the manufacturer before putting on the market to be handled by detailed certification (to be controlled, transported and stored). The medicinal products should also keep their original quality until the date of expiry and hereby meet the requirements included in the Marketing Authorisation and be appropriate for use.

All wholesale trade activities of medicines for human use in Hungary (including the wholesale trade of the active substances and the medicinal products) are to be carried out only in case of having a valid wholesaling authorisation for medicines issued by the National Institute of Pharmacy; or in case of owning a valid manufacturing authorisation for medicinal products as a legally entitled wholesale dealer of medicines.

Number of wholesalers licences	2005	2006	2007
total	81	95	93
new licences	27	16	23
withdrawals	-	2	19

6. 3. GOOD LABORATORY PRACTICE (GLP)

GLP is the system of quality issues which deals with organizing and making non-clinical and environmental assurance investigations; it includes planning, execution, control, certification, archives and issuing final report.

To control the appropriate work of the research places whether they follow the GLP requirements, to determine the GLP levels of particular investigations, and to keep the requirements met are duties of the National Institute of Pharmacy –as the competent and responsible authority.

A local inspection is carried out by the GLP inspectors of the NIP at the research place in the course of which the level of meeting the GLP requirements is supervised and controlled on the basis of the investigation reports and all the available data. The research place and the GLP level of a particular investigation is then assessed according to the results of the supervision.

The research places owning GLP assessment are controlled at least once in every two years by the GLP inspectors.

	2005	2006	2007
Number of GLP inspections	19	23	28

6. 4. GOOD CLINICAL PRACTICE (GCP)

GCP is the system of internationally accepted ethical and scientific requirements which have to be taken into consideration during planning, executing, certifying and reporting any human clinical trial – it includes bioavailability and bioequivalence investigations as well. The human rights, safety and protection of state of health of the participants are provided by meeting the requirements of GCP. It also ensures that the trials are well-established and valid.

The National Institute of Pharmacy makes certain by their inspectors at the local inspections whether the research place meets the requirements prescribed by laws and directives. All inspections are carried out at the research places- these include all places where any activities relating to the investigations are proceeded. Accordingly the research place may include the seat of the investigator, sponsor/CRO, the research laboratory or the manufacturing place of the investigated products.

The GCP inspections may be carried out due to a schedule, however an exceptional inspection may also be necessary occasionally (e.g. if divergences from laws and regulations make new questions arise). The inspection of the research place may be carried out in any phase of the investigation: consequently during preparing for the investigation, in the course of the investigation, and after closing the investigation as well.

Number of inspections	2005	2006	2007
GCP	42	42	41
foreign	3	14	1

6. 5. PHARMACOVIGILANCE INSPECTION

Pharmacovigilance is the group of activities with the aim of the safe use of medicines. These include recognizing and reporting the side effects of a medicine, collecting and analysing them and preventing them with different arrangements. Doctors, pharmacists and other health professionals, furthermore manufacturers of medicinal products and distributors also take part in these activities.

The National Institute of Pharmacy supervises whether the Marketing Authorisation Holder satisfies the requirements prescribed by laws and directives concerning following the safety of authorised medicinal products with attention.

Pharmacovigilance inspections have been started at the end of 2006. By the end of 2007, 24 inspections were done.

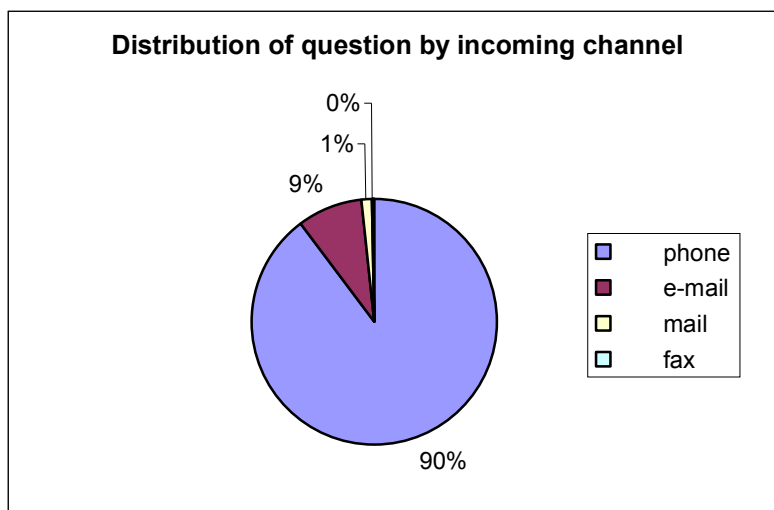
7. REGULATORY (INDEPENDENT) DRUG INFORMATION

7. 1. DIRECT INFORMATION SERVICE ON DRUG AFFAIRS

The direct information service on drug affairs of NIP is providing information about indications, side-effects and their managements, registration status, availability, about drug s are not registered in Hungary, those for rare diseases etc.

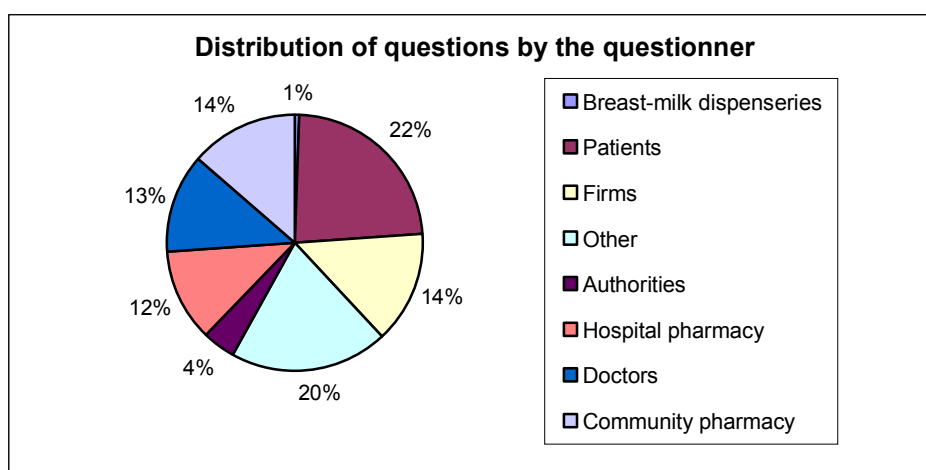
1. Distribution of questions by incoming channel

	2004	2005	2006	2007
phone	2189	2268	2192	2202
e-mail	211	325	444	509
mail	33	26	22	19
fax	9	29	3	0
Total number of questions	2442	2648	2661	2730



2. Distribution of questions by the questionner

	2004	2005	2006	2007
Patients	568	661	638	858
Firms	347	471	600	506
Community pharmacy	331	371	334	227
Doctors	306	294	217	206
Hospital pharmacy	285	237	205	159
Authorities	97	109	62	62
Breast-milk dispensaries	13	8	4	2
Other	485	486	593	303



3. Distribution by the object of questions

	2005	2006	2007
Specialities	1472	1499	1433
Veterinary medicines	2	5	0
Diagnostics	4	2	6
Products prepared by the National Formulary	7	6	6
Galenics	1	0	1
Medical devices	17	17	20
Material of medicines	8	3	3
Traditional medicines	24	46	43
Homeopatics	4	10	9
Food supplements	-	21	33
Nutritional products	4	10	7
Cosmetics	2	4	11
Medicines prepared by indiv. prescribing	8	8	4
Unknown sort of products	53	67	50
Other	12	12	13

4. Distribution of questions by registrational status of medicine

	2005	2006	2007
Registered in Hungary	835	982	900
Not registered in Hungary	121	144	127
Cancelled	163	136	172
Foreign	353	297	246
EU centralized	156	122	148

5. Distribution of questions by ATC classification

		2005	2006	2007
A	Gastrointestinal tract and metabolism	170	171	187
B	Blood	76	76	79
C	Cardiovascular system	233	226	227
D	Dermatology	49	48	44
G	Urogenital tract	84	96	70
H	Systemic hormonal products, excl. sexual hormones	73	35	38
J	Systemic antiinfectious drugs	199	171	174
L	Antineoplasms and immunomodulant agents	139	150	111
M	Musculoskeletal system	87	98	99
N	Central Nervous System	217	229	207
P	Antiparasitics, anthelmintics and repellents	21	22	17
R	Respiratory tract	65	61	64
S	Sensorials	24	18	25
V	Others	25	32	42

6. Distribution of questions by subject

	2005	2006	2007
Active ingredient	296	226	128
Supplements	9	14	19
Indication	99	93	59
Interaction	11	14	15
Side-effects	29	44	55
Gravidity/Breastfeeding	24	12	13
Dosis	24	25	11
Lactose intolerance	32	23	13
Glutene intolerance	11	14	10
ATC-code	5	9	6
Drug supply	176	150	170
Price of drugs	44	44	24
Identification of drugs	7	9	6
Substitution of drugs	35	51	43
Registrational status	608	554	705
SPC, PIL	115	390	295
Manufacturer/ MAH	152	90	25
Other	712	724	679

7. 2. DRUG INFORMATION PHARMACIST' NETWORK

Since 1957 the National Institute of Pharmacy has had a network of 35 Medicine Reviewers which is unique in Europe. Tasks of the representatives are: providing information for physicians and pharmacists on medicinal products independently from any pharmaceutical company's interest - this activity is carried out on medical conferences and other forums in light of the local margins -; coordination of programmes of pharmaceutical companies; personal consultation, etc.

The medical representatives of the National Institute of Pharmacy work as contractors, partly in commission, for a nominal payment. The members of the network are well-equipped professional pharmacological pharmacists with profound knowledge the work of whom are helped with regular further trainings: they take part in the Conference of Medicine Reviewers quarterly, they are also provided with a publication edited for them and for the participants of the conference (the edition is now suspended for technical reasons). The subject of the publication, which is issued in every second month, is in connection with the Conference of Medicine Reviewers. We publish the answers for the tests being related to the courses performed at the conferences – these are necessary for obtaining credits – and extracts of the lectures, gleanings from the publication of the National Center for Epidemiology and from foreign publications.

8. CONTROL OF DRUG INFORMATION

The Division of Supervision of Drug Advertising and Registration of Medical Representatives acts by right of the Act LVIII of 1997 and the Ministerial Decree 64/2003 about the advertising of medicines and paramedicines.

8. 1. REGISTRATION OF MEDICAL REPRESENTATIVES *

The above mentioned decree declares, that all the activities increasing the sales or the utilization (prescription and marketing) of medicines are part of promotion and have to be controlled by the National Institute of Pharmacy. The 6.§ of this decree all the medical representatives of pharmaceutical MAH-s have to be registered in the NIP.

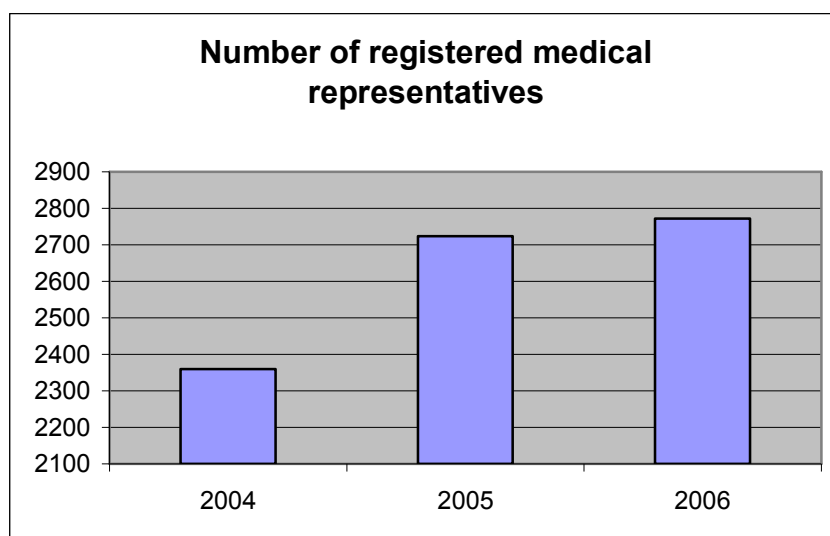
The employees of different drug manufacturers receive personally his own issue (official decision of the NIP) and identity cards (badge). The NIP sends an issue to the MAH too. The registration of the medical representatives is up-to-date because all the changes are registered immediately.

Most of the medical representatives, who are cancelled from our registration, request new registration at another pharmaceutical firm, and receive a new identity card.

The table below shows the number of the registered medical representatives in each year.

Year	2004	2005	2006
Number of registered medical representatives	2360	2724	2772

** At the beginning of 2007 the registration of medical representatives moved to the Health Insurance Supervisory Authority*



8. 2. CONTROL OF DRUG INFORMATION AND DRUG ADVERTISMENT

The role of the National Institute of Pharmacy according to the 98th Act of 2006 is:

- Independently acting authority on the cases described by §18 of the 98th Act 2006.
- Cooperation as a professional authority: in the activities of the General Inspection of Consumer Protection and the Health Insurance Supervisory Authority (HISA) concerning advertisement control.
- In other cases: giving expert advice
 - upon the request of other authorities e.g. Competition Council, the court, National Public Health and Medical Officer Service, other professional organizations, committees on the ethics, self-regulating corporations;
 - request by an advertising agency for a preliminary opinion concerning prospectus of a medicinal product for health professionals or advertisements for the public: brochures, booklets in pharmacies, newspaper advertisements, commercials, websites etc. – it is not compulsory to give any professional advice but the National Institute of Pharmacy may be requested – on payment of the fees - to give expert opinion before the publication of a particular advertisement.

Control of drug information and drug advertisement

	2005	2006	2007
Sanctions initiated by NIP	-	Total 14 Before court 3	Total 32 Appealed to HISA 1
Complaints to other authorities	22	Total 6	Total 16 Appealed to HISA: 4 (3 expert advice, 1 appeal)
Professional advice upon the request of other authorities	69	Total 81	Total: 153 Appealed to HISA : 3

Year	2004.	2005.	2006.	2007
FVF (Consumer Protection Supervisory Agency)	40	61	62	130
ORTT	2	-	-	-
Szabadalmi Hivatal (Patent Office)	-	1	-	-
Reklámszövetség (Hungarian Advertising Association)	1	3	4	3
Association of Innovative Pharmaceutical Manufacturers	-	5	6	4
Advertising Regulatory Board	1	3	3	3
ÁNTSZ (National Health and Medical Officers' Service)	6	6	12	4
OÉTI (National Institute for Food Safety and Nutrition)	2	11	3	3
MOK (Chamber of Hungarian Physicians)	-	-	-	2
MGYK (Chamber of Hungarian Pharmacists)	-	2	3	1
GVH (Competition Authority)	12	8	10	8
Ministry of Health	9	20	12	10
OEP (National Health Insurance Fund)	-	5	-	2
MAGYOSZ (Hungarian Pharmaceutical Manufacturers Association)	-	4	1	-
Association of Generic Pharmaceutical Manufacturers	-	1	-	-
Universities	9	13	-	-
Coordinfo Kft. (Ltd. For Advertising)	23	2	2	2
Pharmaceutical Firms	48	100	103	105
Pénzjegynyomda Rt. (Banknote Printing Corporation)	-	15	18	2
Other	85	74	123	62
Total	238	334	362	352

9. METHODOLOGY

In the wording of the Deed of Foundation of the National Institute of Pharmacy (published in the Official Gazette of Social Welfare, Ed. 11., 26 June 1998, p. 1633) basic activities of the Institute include „the improvement of pharmaceutical sciences, pharmaceutical methodology and promotion of scientific achievements to be brought into practice” as public tasks to be performed.

According to the above mentioned statements the Pharmaceutical Methodology Department takes part in collecting and issuing practical instructions, methodological letters and guidelines with regard to both public and clinical pharmacies.

Professional boards also participate in preparing methodological letters: in case of public pharmacies the Professional Board of Medicine Supply, concerning the clinical pharmacies the Professional Board of Hospital and Clinical Pharmaceutics. Methodological letters may be initiated either by a professional board in the form of a draft version or by the National Institute of Pharmacy.

The topics of the methodological letters issued by the National Institute of Pharmacy are based on the fields specified in decrees or may also derive from the questions emerging during the pharmaceutical practice.

The regulation of some fields may realize on a higher legal level – in these cases the topic of the methodological letter is covered in a particular decree or in the annex of a decree.

There have been important changes in the method of magistral preparation of pharmaceuticals since the new edition of *Formulae Normales* (*Formulae Normales VII*) and *Pharmacopoeia Hungarica VIII* have come into force.

Guidelines, methodological letters in force

Handling of pharmaceuticals prepared in clinical pharmacies but not applied in the same health institute (OGYI-P-62-1998)

Guideline on the application of hard gelatine capsules in public pharmacies

Preparation of mixed infusions (OGYI-P-63-2004)

Preparation of cytostatic mixed infusions (OGYI-P-64-2004)

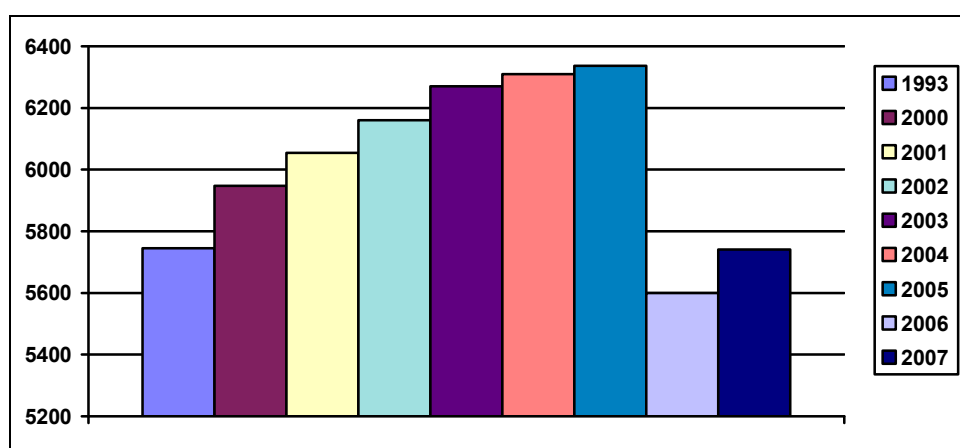
The methodological letter of the National Institute of Pharmacy on the doses of certain starting materials for magistral preparation of pharmaceuticals according to the *Formulae Normales VII* (OGYI-P-65-2004)

The qualification standards of the electronic systems promoting the distribution of pharmaceuticals outside the pharmacy (OGYI-T-66-2007)

10. LIBRARY SERVICES

The library of NIP is opened for the public also.

Year	The growth of the volume
2000	129
2001	107
2002	106
2003	110
2004	40
2005	27
2006	81
2007	141



*In 2006 large-scale of weed out

The total number of journals in recent years

year	2000	2001	2002	2003	2004	2005	2006	2007
volume number	8041	8077	8153	8250	8309	8437	8527	8619

11. ACTIVITIES OF REPRESENTATIVES OF NIP IN INTERNATIONAL AND NATIONAL PROFESSIONAL ORGANIZATIONS

Dr.Zsuzsanna Aubel-Hajdú

- *EDQM Galenical and Pharmaceutical Technology Expert Group member*

Prof. Dr. János Borvendég

- *laureate member of „Brutium” Academy, Rome*

Andrea Cseh-Pálos

- *EDQM Certification Team, assessor*

Dr. Gabriella Détári

- *PIC/S Committee of Officials member*

Dr. Lenke Ernyei-Laczkó

- *PIC/S Expert Circle on GDP member*

Judit Fehér:

- *PIC/S Expert Circle on Quality Risk Management member*

Dr. Ágnes Gyurasics

- *ESDP: European Society for Developmental Perinatal and Pediatric Pharmacology member; a Társaság folyóiratának rendszeres bírálója (Pediatric and Perinatal Drug Therapy)*
- *International Union of Pharmacology member*
- *European Society of Toxicology member*

Ágnes Kiss

- *PIC/S Expert Circle on Human Blood and Tissue member*

Dr. Hilda Kőszegi-Szalai

- *European Federation of Pharmaceutical Sciences (EUFEPS):Executive Committe Member*
- *EUFEPS Bioavailability and Bioekvivalence Steering Group member*
- *EDQM vice president (2004-2007)*
- *EDQM hungarian delegation member*
- *EDQM P4 Expert Group member*

Németh Tamás

- *EDQM hungarian delegation member*

Júlia Palotás - Németh

- *OMCL Network contact*

Prof. Dr. Tamás L. Paál

- *The Organisation of Professionals in Regulatory Affairs (TOPRA) Advisory Council* member,
- *European Forum of Good Clinical Practice Ethical Advisory Council* member,
- *Drug Information Association (DIA)* member,
- World Health Organization (WHO)
 - *Uppsala Monitoring Centre, UMC* assessor,
 - *International Regulatory Collaboration on Herbal Medicines (IRCH)* member.

Ágnes Pusztay

- EMACOLEX

Dr. Ferenc Rakiás

- *European Association of Nuclear Medicine (EANM)* member

Franciska Szabó

- WHO *International Regulatory Collaboration on Herbal Medicines (IRCH)* focal point.

12. ACTIVITIES OF MEMBERS OF NIP IN THE UNIVERSITY POSTGRADUATE EDUCATION AND TRAINING

Several NIP specialists used to work in Universities. Some of them still participates regularly, as invited lecturers, into the graduate education provided by other Universities (Semmelweis University, Budapest, University of Szeged, University of Debrecen etc.) as well as in postgraduate training courses (e.g. Health Management).

Professors

Dr. János Borvendég

Dr. Tamás L. Paál

Invited lecturers

Erzsébet Bozsik

Dr. Zsuzsanna Búzás

Dr. Éva Csekey

Dr. Ágnes Gyurasics

Dr. Hilda Kőszegi-Szalai

Dr. István Sándor

13. PUBLICATIONS

2004

- Borvendég János – Polák Gyula – Váradi András, Hatóanyagok Készítmények Terápia – Fókuszban a keringési rendszer, Melinda kiadó és Reklámügynökség, Budapest
- Borvendég János dr., Klinikai gyógyszervizsgálat gyermekeken, Gyógyszereink, 54. évf. 4-5. szám 120-122.
- Eggenhofer J, Emésztőrendszer – kóros motilitás – szerotonin, Gyógyszerek és remények. European Journal of Gastroenterology & Hepatology, VIII. évf. 3. szám 81-84.
- Eggenhofer J, Klinikai vizsgálatok Magyarországon 2004. május 1. előtt és azt követően, Gyógyszereink, 54/6 173-175.
- Kőszeginé Szalai Hilda, Magyar Gyógyszerkönyv VIII. kiadás II. kötet, Medicina Könyvkiadó Budapest
- Kőszeginé Szalai Hilda, A hónap kérdése, Gyógyszerészet, 48, 485-487.
- Vné dr. Bogdán Mária, Gyógyhatású készítmények a gyógyszerárban (Bőrgyógyászati készítmények), PharmaGrad, december
- Vné dr. Bogdán Mária, A székrekedésről másképpen, PharmaGrad, június
- Vné dr. Bogdán Mária, Influenza vagy meghűlés?, PharmaGrad, március

2005

- Borvendég János dr., Surrogate versus klinikai végpont, Gyógyszereink, 55. évf. 1. szám, 12-14.
- Borvendég János dr., Antidepresszánsok és alvászavarok, Gyógyszereink, 55. évf. 2. szám, 60-64.
- Borvendég János dr., Hogyan olvassunk klinikai jelentést, vagy arról szóló közleményt? Gyógyszereink, 55. évf. 3. szám, 95-98.
- Borvendég János dr., Klinikai gyógyszervizsgálatok etikai vonatkozásai, jogi szabályozásuk a 35/2005.(VIII.26.) EüM rendelet szerint, Gyógyszereink, 55. évf. 4. szám, 136-138.
- Borvendég János dr., Irányelv antidepresszánsok klinikai vizsgálatára, Gyógyszereink, 55. évf. 5-6. szám, 181-183.
- Bozsik E., Paál T., A Formulae normales új kiadása — összefoglalás elsősorban orvoskollegák számára. (The new Edition of the Formulae normales [Model prescriptions] — summary, mostly for physicians), Gyógyszereink, 55(2), 43-51.
- Eggenhofer J., 24/2002.(V.9.) EüM. vs. 35/2005.(VIII.26.) EüM. rendelet, Gyógyszereink, 55/4 135-136.
- Eggenhofer J., NO ACID – NO ULCER. A savelválasztás gátlásának útjai, European Journal of Gastroenterology & Hepatology, IX. évf. 4. szám 121-124.
- Eggenhofer J., A gyógyszerkifejlesztés lépései, PharmaGrad, december, 14-17.
- H. Kőszegi-Szalai, The role of the European Directorate for the Quality of Medicines in the assurance of the high quality of medicines in Europe, EUFEPS Newsletter, 1.
- Kőszeginé Szalai Hilda, Gyógyszerminőség hazánkban az EU csatlakozás után, Gyógyszereink, 54 (6), 164-166.
- H.Kőszegi Szalai, H.De Jong, Harmonisation of the texts of the European Pharmacopoeia with the rules governing medicinal products and with the texts of other prominent compendia, EUFEPS Newsletter, 4.
- Kőszeginé Szalai Hilda, Az Európai Gyógyszerminőségi Főigazgatóság (EDQM, European Directorate for the Quality of Medicines) szerepe a gyógyszerek megfelelő minőségének biztosításában, Gyógyszereink, 55 (5-6) 179-180.
- Medgyesi György, Stabil vérkészítmények a VIII. Magyar Gyógyszerkönyvben, Focus Medicinae, *7*, 15-17.
- Csóka, T.L. Paál, Regulatory aspects of drug dissolution testing. Eur. J. Pharm. Sci., 25(Suppl. 1), S-223
- Paál T., Csekey É., *The Compassionate Use of Medicines in Hungary*. Regul. Affairs J., 16(9), 651-652.
- Paál T., Magyarországon forgalomba hozatali engedéllyel nem rendelkező gyógyszerek rendelése, (Prescription of medicinal products without valid marketing authorisation in Hungary) Gyógyszereink, 55(3), 83-88.
- Paál T., Egy magisztrális gyógyszerkészítési tévedés margójára. Gyógyszereink, 55(3), 93-94.

- Paál T., The New Hungarian Medicines Act., Regul. Affairs J., 16(11), 797-798.
- T. Paál, Hypericum perforatum L. (a.k.a.) St. John's worth – White cell disorders, WHO Signal, November, 4-6.
- Vné Dr. Bogdán Mária, Gyógyhatású készítmények (egészségmegőrzés), PharmaGrad, december
- Vné dr. Bogdán Mária, Természetes eredetű szerek aktualitása a gyógyszerteráiban, PharmaGrad, szeptember
- Vné dr. Bogdán Mária, Természetes eredetű szerek (növényi anyagok) aktualitása a gyógyszerteráiban, PharmaGrad, március

2006

- Borvendég János dr., Irányelv bipoláris betegség kezelésére alkalmas gyógyszerek klinikai vizsgálatára, Gyógyszereink, 56. évf. 2. szám 57-59.
- Borvendég János dr., Schizophrenia kezelésére alkalmas gyógyszerek klinikai vizsgálatának irányelvei, Gyógyszereink, 56. évf. 4-5. szám 158-161
- Borvendég János dr., Irányelv az orális antidiabetikumok klinikai vizsgálatára készült CHMP „Note for Guidance on Clinical Investigation of Medical Products in The Treatment of Diabetes Mellitus” c. irányelve alapján, Gyógyszereink, 56. évf. 9. szám 325-327.
- Borvendég János dr., Lipidcsökkentők klinikai-farmakológiai vizsgálata, Gyógyszereink, 56. évf. 10. szám 362-364.
- Borvendég János dr., A vérnyomáscsökkentők klinikai farmakológiai vizsgálatai, Gyógyszereink, 56. évf. 11. szám 406-408.
- Bozsik E. dr., Módosított hatóanyagleadású terápiás rendszerek, Gyógyszereink, február
- Bozsik E dr., Kőszeginé Szalai H. dr., Gyógyszeres csomagolóanyagok minőségének hatósági követelményei, Gyógyszereink, augusztus
- Eggenhofer J., Generikus készítmények, PharmaGrad, március, 16-17
- Eggenhofer J., Gyógyszerek egyenértékűsége, PharmaGrad, június, 14-16
- Eggenhofer J., A ritka betegségek gyógyszere, PharmaGrad, december, 8-9
- Eggenhofer J., Bemutatjuk gyógyszereinket, Gyógyszerismertetések, Gyógyszereink (Minden megjelent számban.)
- H.Kőszegi-Szalai, Adaptation of the European Pharmacopoeia to the current legal and regulatory environment in Europe, EUFAPS Newsletter, Vol 15 3/06 5-7.
- T. Paál, Teucrium chamaedrys L. and Teucrium scorodonia L., Wall germander and Woodland germander – Hepatitis and other liver disorders, WHO Signal, March, 10-17.
- Hoogmartens, J., Shaohong, J. Paal, T. et al., WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. WHO Tech. Rep. Ser. 937, 85-106.
- Paál T., Medicines for the Poor in Hungary, Regul. Affairs J., 17(9), 597-598.
- Paál T., Generikus gyógyszerek (Generic medicines), Orvostovábbképző szemle 13(10), 13-23 .
- Vné Dr. Bogdán Mária, Gyógyhatású készítmények a gyógyszerteráiban (egészségmegőrzés), PharmaGrad, március

2007

- Borvendég János dr., Gyermekgyógyászati kezelésének hiányosságai, ezek okai, az Európai Tanács és Parlament intézkedései a problémák orvoslására, Gyógyszereink, 57. évf. 2. szám 64-67.
- Borvendég János dr., A krónikus obstruktív tüdőbetegség COPD kezelésére alkalmazott gyógyszerek klinikai vizsgálatának irányelvei, Gyógyszereink, 57. évf. 3. szám 107-108.
- Borvendég János dr., Irányelv tervezet a potenciálisan nagy rizikójú gyógyszerek I. fázisú klinikai vizsgálatára, Gyógyszereink, 57. évf. 4. szám 149-153.
- Borvendég János dr., Parkinson kórban alkalmazott gyógyszerek klinikai-farmakológiai vizsgálata, Gyógyszereink, 57. évf. 5-6. szám 175-178.
- Borvendég János dr., Az epilepszia kezelésére alkalmas gyógyszerek klinikai vizsgálatának irányelvei, Gyógyszereink, 57. évf. 7. szám 215-219
- Borvendég János dr., A demencia kezelésére alkalmas gyógyszerek klinikai vizsgálatának irányelvei, Gyógyszereink, 57. évf. 8. szám 262-267.
- Borvendég János dr., A gyógyszerek törzskönyvezése és forgalomba hozatala az európai unió országaiban. LAM (Lege Artis Medicinae), 17 (8-9) 599-604
- Bozsik E dr., A FoNoVII. alkalmazását segítő áttekintés, Gyógyszerészet, november
- Eggenhofer Judit, Biológiai készítmények, biohasonlóság, hasonló biológiai készítmények, Orvostovábbképző Szemle, XIV. évf. 7-8. (július-augusztus) 12-18.
- Eggenhofer Judit, Testsúlycsökkentő szereink, PharmaGrad (március) 7-9.

- Eggenhofer Judit, A Helicobacter pylori eradikáció gyógyszerei, PharmaGrad , (június) 7-9.
- Eggenhofer Judit, Antithrombotikus szerek, Gyógyszereink, 57/1 16-23.
- Eggenhofer Judit, Variációk egy-egy témára, Gyógyszereink, 57/2 68-72.
- Eggenhofer Judit, Bronchodilatátorok, Gyógyszereink, 57/3 110-115
- Eggenhofer Judit, Az asthma bronchiale kezelésében alkalmazott glükokortikoidok, Gyógyszereink, 57/4 154-157.
- Eggenhofer Judit, Antiparkinson szerek, Gyógyszereink, 57/5-6 179-185
- Eggenhofer Judit, Antiepileptikumok, Gyógyszereink, 57/7 220-228
- Eggenhofer Judit, A demencia és az Alzheimer-betegség gyógyszerei, Gyógyszereink, 57/8 268-273.
- Eggenhofer Judit, Biológiai készítmények, biohasonlóság, hasonló biológiai készítmények, Gyógyszereink, 57/9-10 299-304
- Eggenhofer Judit, Hatóanyagok, amelyek hasonló biológiai termékekben szerepelhetnek, Gyógyszereink, 57/9-10 305-309.
- Eggenhofer Judit, Nem-szteroid gyulladásgátlók mint lázcsillapítók, Gyógyszereink, 57/11 346-351
- G. Gigler, K. Móricz, M. Agoston, A. Simó, M. Albert, A. Benedek, G. Kapus, S. Kertész, M. Vegh, J. Barkóczy, B. Markó, G. Szabó, E. Matucz, I. Gacsályi, G. Lévy, L.G. Hársing, G. Szénási, Neuroprotective and anticonvulsant effects of EGIS-8332, a non-competitive AMPA receptor antagonist, in a range of animal models. Br J Pharmacol, Jul 2; 17603549
- Poór Rita, Antiparkinson szerek felhasználása 2006-ban Magyarországon, Családoctorosi Fórum, 04
- Poór Rita, Nemszteroid gyulladáscsökkentők felhasználása Magyarországon az elmúlt tíz évben, Családoctorosi Fórum, 05
- Poór Rita, Antidepresszánsok fogyási adatai az elmúlt öt évben Magyarországon, Családoctorosi Fórum 06.
- Poór Rita, A diabetes mellitus gyógyszeres kezelésének alakulása az utóbbi tíz évben Magyarországon, Családoctorosi Fórum, 08.
- Poór Rita, A peptikus fekély gyógyszereinek fogyása az elmúlt öt évben Magyarországon, Családoctorosi Fórum, 09.
- Virányi, M.; Pálkó, L., Gadolinium-tartalmú kontrasztanyagok alkalmazásához csatlakozó nephrogen systemás fibrosis, Gyógyszereink, 57(2) 73-74.
- Virányi M, A gadolinium tartalmú MR-kontrasztanyagok ritka mellékhatása: a nephrogen systemás fibrosis, Magyar Radiológia, 81(1-2), 294-295.
- Bogaert, M., Carne, X., Druml, C., Fabris, N., Glasa, J., Klingmann, I., Lafolie, P., Paál T., Wells, R.: The Procedure for the Ethical Review of Protocols for Clinical Research Project sin the European Union. Int. J Pharm. Med., 21 (1), 1-113.
- Paál T., A pyrazolonok vényhez kötése Magyarországon, Gyógyszereink, 57 (1), 3-6.
- Paál T., Regulating Medicines Supply. Regul Aff. J. – Pharma, 18(2), 87-91.
- Paál T., A gyógyszerétáron kívül forgalmazható gyógyszerekről, Gyógyszerészet, 51(5), 309-313.
- Csóka i., Bozsik E., Erős I., Paál T., Regulatory aspects of semisolid dosage form design. Eur. J. Pharm. Sci., 32(1 Suppl.) S9
- Németh T., Kőszeginé Szalai H., Paál T., Magisztrális gyógyszerkészítés a XXI. században – hogyan biztosítható a megfelelő minőség európai szinten? Gyógyszerészet, 51, 675-677.

Paál T., *Törzskönyvezés (Registration)*. In: Dinya E.(szerk.): Humán gyógyszerfejlesztés (Development of human medicines). Medicina, Budapest 2006. pp. 521-544.

Borvendég J.: Reflections on twentieth-century psychopharmacology, T.A. Ban, D. Healy, Eshorter *The History of Psychotropic Drug Regulation in Hungary* 2004, Animala Publishing House, Budapest, 2004 pp 103-105.

Borvendég J., *Klinikai vizsgálatok jogi és hatósági szabályozása* (Legal and official regulations of clinical trial) In: Dinya E (szerk), Humán gyógyszerfejlesztés, (Development of Human Medicines), Medicina, Budapest, 2006. pp. 334-377.