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INFARMED Annual Conference 2005

# Focus on the challenges of medicines regulation


The Institute's annual conference met in Lisbon and gathered many national and international experts. The meeting focused on the challenges to medicines and health technologies regulation and was attended by more than 700 participants. page 4

17th DIA Annual EuroMeeting

# INFARMED and DIA organize joint symposium

The Portuguese medicines regulatory agency, INFARMED and the Drug Information Association, DIA, organize on March 6, a joint satellite symposium on "Medicines Regulatory Affairs in Portugal". The session will count with the participation, as speakers, of representatives from INFARMED, DIA, industry association, medical and pharmaceutical societies as well as patient organizations. A special representative from the EMEA will present the main consequences resulting from the new EU pharmaceutical legislation.

# Website: 27 million visits in 2004

page 3


# Clinical Trials: Portugal is ready

After the approval of the law on Clinical Trials last August, in line with the EU Directive 2001/20/CE, Portugal has just operationalized the new central ethics commission for clinical research which is now ready to start working. page 5

## editorial

*At INFARMED we are very happy to issue for the first time a special edition in English of our quarterly newsletter INFARMED NOTÍCIAS. The issuance of the current edition takes place on the day of the joint satellite symposium organised by INFARMED and DIA aside to the 17th Annual EuroMeeting of the Drug Information Association. This occasion represents a crucial opportunity for us at INFARMED to present to an international audience the activities under development on the medicines regulatory sector in Portugal. I am confident that this type of initiatives can only reinforce mutual knowledge on the regulation of medicines, particularly bearing in mind the important consequences resulting from the new EU pharmaceutical legislation.*

*A special cover in this edition is given to the INFARMED annual conference held on January 25 and 26 in Lisbon. For us this meeting was also extremely relevant as it gathered a large number of national and international experts who have presented their best knowledge and experience on the various perspectives related to the regulation of medicines and health technologies. Some of the conclusions achieved in this conference are presented in this edition.*

Rui Santos Ivo
President of INFARMED

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Instituto Nacional da Farmácia e do Medicamento

# Strategic objectives and activities for 2005

The Portuguese regulatory agency, INFARMED has identified a set of strategic objectives, which will lead the Institute's activity in 2005.

### The Institute's Strategic Objectives for 2005

1. Reinforce INFARMED's regulatory function in protecting public health through the development of risk management systems.
2. Promote access to validated information to INFARMED's partners, stakeholders, healthcare professionals and citizens, by involving patients' and consumers' associations, as well as scientific and professional societies.
3. Develop and promote the rational use of medicines in the National Health System.
4. Improve the quality of services provided by enhancing internal efficiency and by reinforcing a performance management culture, based on an integrated quality management system.
5. Consolidate INFARMED's position within the European and international medicines regulatory systems.
6. Strengthen competitiveness and internationalization of the pharmaceutical sector; and promote R&D activities in the industrial field.

In practice, these strategic orientation lines are already being put into place in a wide variety of daily tasks and activities, such as:

- Strengthen the strategic role of INFARMED in the European medicines regulatory framework in increasing the agency's participation in the Mutual Recognition Procedure as Reference Member State;
- The reinforcement of information instruments to healthcare professionals, stakeholders and the public;
- Optimisation of internal procedures through procedural reengineering to maximise efficiency and performance thus meeting the expectations of all partners and entities of the sector;
- The reinforcement of communication, information and transparency policies;
- Public release at www.infarmed.pt of reimbursement and pharmacotherapeutic evaluation reports;
- Continue the monitoring and evaluation of the medicines policy;
- Development of an integrated information system that will meet both internal and external needs;
- Preparation of proposals through a consultative process towards the reform of the medicines reimbursement system in accordance with governmental guidelines, ensuring that the more incapacitating conditions and the most vulnerable patients have facilitated access to medicines;
- Reinforce the quality control process by INFARMED of medicinal and health products.

Executive Board of INFARMED (Manuel Neves Dias, member, Rui Santos Ivo, president, Alexandra Bordalo, member, and António Faria Vaz, vice-president).

## New Medicines Act Working Document

After an internal reflection phase INFARMED, in conjunction with the Ministry of Health, has released for comments and suggestions to its partners a draft version of a Working Document that will set the basis for the new medicines act. The new piece of legislation envisages consolidating in one single document all the norms and rules related to human medicines thus rationalizing and harmonizing the current legal framework and the transposition of directives 2004/24/CE and 2004/27/CE.

The new Statute will introduce alterations to the norms applicable to the community procedures of authorisation, such as the new decentralised procedure, a new definition of generic medicine and specific authorisation rules including a harmonized regime for data exclusivity, norms on parallel imports, exceptional authorisations, new labelling rules, including Braille provisions and consumers test, reinforcement of pharmacovigilance rules in complement to the single authorisation renewal. It also introduces new and specific norms on the publication of medicines evaluation reports. The draft version of the document is currently available at www.infarmed.pt and the public consultation is taking place until the 25th March 2005.

## Market Surveillance Operations Group met in Lisbon

The Market Surveillance Operations Group (MSOG) on medical devices, held a meeting, organised by INFARMED, on 16 and 17 February in Lisbon under the auspices of the European Commission. 17 countries were represented. Activities developed in 2004 as well as the Plan for 2005 were discussed. Guidance documents for Class I and Custom made devices, Guidance notes for Distributors and Importers as well the role of Authorised Representatives were reviewed. Medical Devices have an increasing role in health care treatment. Member States are encouraged to take all necessary steps to ensure that medical devices are placed on the European market according to the Medical Devices Directives ensuring the compliance with the essential requirements, safety, quality and performance. The MSOG, which is chaired by INFARMED, was created to reinforce the cooperation between Member States to build an European Network of enforcement activities on Market Surveillance.

INFARMED's website

# More than 27 million visits in 2004

The website of INFARMED registered in 2004, more than 27 million visits. This number of visits is, in fact, remarkable when comparing with the 3 million visits registered in 2002 and approximately 15 million in 2003.

This figure is the result of the large variety of information available to all interlocutors and stakeholders along with an important set of tools available on-line.

As a result, INFARMED's web page is currently a reference communication and information tool for healthcare professionals, health institutions like hospitals and health centres, the pharmaceutical industry, associations, patients and general public.

www.infarmed.pt

Quality and rational use

# Professionals visit INFARMED Quality Control Laboratory...

As foreseen in its plan of activities, INFARMED organised in 2003 and 2004 numerous visits to its Official Medicines Control Laboratory by nearly 300 healthcare professionals. These visits mainly focused on the process for medicines quality control in Portugal. Given the high appreciation by healthcare professionals, the institute is organising a new programme for 2005.

## ... and participate in information sessions

The institute has also organised information sessions to healthcare professionals throughout the country. These information sessions were attended by more than 700 health professionals and focused on the promotion of generic medicines, the rational use of medicines and in assisting healthcare professionals with appropriate prescribing information, thus contributing to an adequate cost-effectiveness balance.

## INFARMED prepares for the future

As part of a medium term strategy to be developed by INFARMED, the Institute is carrying out a number of activities aiming at this overall objective.

The Executive Board has commissioned two external evaluation studies designed to develop a new organisational model and to implement a new Information System in order to respond to internal and external needs.

These processes have just been concluded and are now under internal evaluation by a specific team set up within INFARMED.

This process is being conducted in conjunction with the ongoing activities at EU level, namely the EMEA Road Map 2010 and the European Regulatory Network Strategy being developed by Heads of Medicines Agencies.

The Institute intends to start the implementation of this process early this year, as part of its goal to implement a Quality Management System for INFARMED.

This process includes the following components:

- New Organisational Model;
- New Information System aimed at internal and external customers;
- New Statute for INFARMED
- INFARMED Strategy for 2010
- Quality Management System
- Coordination with strategy for the EU Regulatory Network and EMEA Road Map 2010

## Compounded medicines
## A new framework

During 2004 legislation has been passed on compounded medicines with a view to reinforce the quality of these medicines prepared in community and hospital pharmacies in accordance with magistral and officinal formulas.

The new legislative acts integrate new guidelines on good manufacturing practices, required equipment, recognised pharmacopoeia and formularies, non authorised substances, pharmacist responsibilities, criteria applying to starting materials suppliers including manufacturers, importers and wholesalers. The new framework also sets the pricing definition formulas and reimbursement.

Annual Conference 2005

# INFARMED gathers national and international experts


"The president of INFARMED, Rui Santos Ivo, speaking at the opening session of the Institute's Annual Conference 2005. Seated, Manuel Neves Dias and António Faria Vaz, member and vice-president of the Executive Board, the Minister of Health, Luís Filipe Pereira and Alexandra Bordalo, member of the Executive Board of INFARMED"

The Portuguese National Institute of Pharmacy and Medicines, INFARMED, held its 2005 annual conference on 25th and 26th January dedicated to the theme "From the health system to the citizen – Challenges to the regulation of medicinal products and health technologies".

The Minister of Health, Luís Filipe Pereira opened the conference followed by the President of INFARMED, Rui Santos Ivo who presented the main achievements of INFARMED and progress made in the sector in recent years.

The meeting had the contribution of a wide spectrum of national and international experts (91) as speakers. Participants from various institutions at both national and international level, such as stakeholders, National Health System institutions, the European Commission, the European Medicines Agency, EMEA, the World Health Organization Europe and from different European national medicines agencies such as Spain, France, Italy, Netherlands, Denmark and Poland were present.

The two-day meeting assembled seven hundred participants distributed among healthcare professionals, pharmaceutical industry, health institutions, patients and the general public.

The meeting was held in a crucial moment when important changes are being introduced to the medicines regulatory sector on national and international levels. These changes are scientific and regulatory spurring from the new EU pharmaceutical legislation

General overview of participants at the conference. On the first row, Luís Cunha Ribeiro, president of the National Institute of Medical Emergency, Pedro Nunes, president of the Medical Society, J. A. Aranda da Silva, president of the Pharmaceutical Society and J. Pereira Miguel, director-general of Health and High Comissioner for Health.

presenting new challenges and important consequences at European and country levels. For INFARMED, this requires the development of expertise in more areas of competence and a continuous effort to support technicality in this ever more evolving, demanding and challenging area.

| Panels | Conclusions |
|---|---|
| **Health System and Medicines** – *Recent developments in Portugal* | • Medicines life-cycle from research to quality control shall be under the responsibility from the national regulatory agency<br>• Effective regulation requires observance of three levels: public health, economical and scientific<br>• Latest developments in Portugal: better access, revision of prices and reimbursement systems, more and better information to healthcare professionals in support to clinical decision and reorganization of hospital pharmacies<br>• Priorities: Reinforce access and promotion of the rational use of medicines, including the continued development of generics |
| **Pricing and Reimbursement Systems** | • Future policies should promote efficiency and maintain equity through selectivity in reimbursement, the promotion of generic medicines, to improve prescription profile and the use of medicines, to increase negotiable terms of "paying" entities and in implementing reference pricing systems |
| **Medicines policies and regulations in France** | • Reimbursement system based on two positive lists – one for community pharmacies and another for hospital-pharmacies<br>• Committee of transparency produces opinions after evaluating added therapeutic value<br>• Committee of transparency is integrated in independent entity named Haute Autorité de Santé and is part of the global reform of the French health sector |
| **Rational use of medicines:** Instruments and Strategies | • National network for the promotion of the rational use of medicines – QualiMED<br>• To develop a national information system on medicines; to support all the activities that promote the rational use of medicines and to implement a rational prescription programme |
| **Pharmacovigilance, Risk Management and Communication** | • Significant progress has been achieved by regulatory authorities in issuing information for healthcare professionals as well as on the development of communication channels |
| **Clinical Research Development** | • Clinical research in Portugal is at a mature state with progressively more groups operating although it can be characterized as an evolving process<br>• A better characterisation of the patient groups in a given institution are needed also for epidemiological assessment |
| **Pharmacoepidemiology and Pharmacoeconomic studies** | • The inadequate use of medicines brought the need to implement strategies to assist patients to have the maximum results from medical prescription<br>• For that end the development of pharmacoepidemiology and pharmacoeconomics and the medicines observatory of INFARMED are essential |
| **Pharmaceutical research in Portugal: New Therapeutics** | • Demonstration of the profitable advantage of R&D in industry through good examples<br>• Need to increase the involvement of the national-based pharmaceutical industry in R&D activities – biotechnology and new therapies<br>• Need to diversify approaches including in the area of pharmaceutical CRO's |
| **New Perspectives in the Medical Devices European System** | • MDD review, the changes of the medical devices regulation<br>• SWOT Analysis made by the European Commission and Eucomed about the European System<br>• Market Surveillance importance to wholesalers and users |

## Clinical Trials: Portugal is ready

The Portuguese parliament passed the law on Clinical Trials in August 2004. Among other aspects this law drawing from Directive 2001/20/CE establishes a new central ethics commission for clinical research (CEIC). This commission was established last January by the Ministry of Health and is now becoming operational to start receiving and evaluating clinical trials. The new commission will be located near INFARMED premises. The new commission will assume a key role in the clinical trials authorisation process being provided with technical and scientific independence.

The new commission will comprise an executive committee and will work closely with local ethics committees and the Clinical Trials Department of INFARMED. Dr António Barros Veloso, a physician specialist in internal medicine and former Director at the Lisbon Civilian Hospitals, is the first chairman of CEIC.

The new legislation also gives new roles to INFARMED as competent authority, including the responsibility to authorise clinical trials conducted in Portugal, the conduct of GCP inspections, the manufacture and use of experimental medicines, amongst many other activities.

## INFARMED promotes OTCs usage

The National Institute of Pharmacy and Medicines prepared last November a document establishing a set of actions to adjust and solve various aspects related to OTCs. The document identifies the establishment of an individual health and self-medication primary care programme, the reactivation of the consensus working group on self-medication, the revision and update of all self-medication clinical situations, publication of the list of all products OTCs and subject to medical prescription as well as the indications approved for each INN. During the process INFARMED will consult various partners such as the National Pharmacies Association, the Pharmaceutical Industry Association, the General-Directorate for Health and the Medical and Pharmaceutical Societies.

# INFARMED and Industry engaged in working group

The Portuguese medicines regulatory agency, INFARMED and the Pharmaceutical Industry Association, APIFARMA have been engaged since July 2003 in the discussion of technical matters of the sector within a technical working group of representatives of both entities. Periodically the boards of INFARMED and APIFARMA meet to evaluate the work carried-out by this group.

The main objective of this working group is to promote dialogue and cooperation between the regulatory agency and the industry association on topics of common interest in order to foster a rapid and comprehensive decision making process. In nearly two years of activity the work of the working group has proven to be of great value to the whole national medicines sector namely in introducing greater transparency and efficiency into the system.

**Some issues worked by the INFARMED/APIFARMA technical working group**

- Agreement and public release at www.infarmed.pt of activity monthly indicators on the evaluation of National MA applications and Reimbursement requests. These indicators include namely the number of processes evaluated and evaluation time periods.
- Preparation of the project on the release at www.infarmed.pt of provisional information received from pharmaceutical industry on possible rupture of stocks and on additional information on therapeutic alternatives available, if necessary.
- Definition of a harmonised manufacturing authorisation document.
- Debate on questions related to the Common Technical Document for marketing authorisations.
- Discussion of the procedures related to the electronic submission of Clinical Trials; Implementation at www.infarmed.pt of a Clinical Trials forum of discussion and information.
- Debate on the decision on the release at www.infarmed.pt of reimbursement and pharmaco-therapeutic evaluation reports.
- Debate and interpretation of the legal framework for the conversion of bibliographic to generic medicines.
- Debate and interpretation of technical and legal requisites for the conversion of prescription medicines to OTCs.

## INFARMED establishes new R&D office

INFARMED established in 2004 a new R&D office to act as contact point with the industry and academia to support the increase in R&D at the national based pharmaceutical industry.

The new R&D office provides technical and regulatory assistance related to the establishment of R&D infrastructures and project development according to the principles of good practice. Since the start of its activity it has been supporting 3 new projects related to biotechnology and advanced therapies.

## Publication of Evaluation Reports

As part of INFARMED policy on increasing transparency and developing new tools to promote the rational use of medicines INFARMED is initiating the publication of the evaluation reports of new reimbursed substances.

This new measure has been taken after a process of discussion with APIFARMA and is considered to be a major step to increase the transparency in the reimbursement process for new medicines and is also a major contribution to better inform health professionals on new reimbursed products, thus promoting the rational use of medicines. This activity is part of an integrated strategy aiming at the development of the quality use of medicines, which includes the recent creation of a new Committee for the Rational Use of Medicines, which will produce, amongst other activities, therapeutic guidelines.


# Quality Certification of Medical Devices Department

In 2004 the Department of Medical Devices implemented a Quality Management System and in December last year was certified under the ISO 9001:2000. Since 1993 INFARMED has been developing activities on the medical devices area but only in 2003 a Medical Devices Department was created.

The certified activities, developed by the Medical Devices Department are: Registration and validation of medical devices and in vitro diagnostic medical devices; Evaluation of medical devices clinical investigation; Market conformity surveillance; Training and information activities conception and development; Conformity evaluation of non-active medical devices by the Notified Body.

The Quality system was developed accordingly to the main concern of INFARMED: to look for improvement of the activities and to satisfy partners' needs.

# Partnership to boost exports

A three-year strategic partnership has been developed between twelve Portuguese companies, the industry association, APIFARMA, the national institute for the external promotion of the Portuguese economy, ICEP, and the medicines regulatory agency, INFARMED to boost exports in the national medicines sector until 2007.

The principal target is to promote the image and internationalisation of medicines manufactured in Portugal. The project envisages to promote and reinforce the image and quality of Portuguese medicinal products namely through the representation of the national-based industry in international fairs and meetings and in unifying the external image of the involved companies under one single country brand called – Farma Portugal. The project has been presented in two occasions to various public and private institutions as well as to an important number of foreign diplomatic representations and Portuguese diplomatic officials followed by visits to the companies involved.


Angola

# INFARMED integrates assistance programme

The international cooperation has been for several years a strategic area of INFARMED's activities. In privileging cooperation schemes with Portuguese speaking countries, the National Institute of Pharmacy and Medicines was asked to participate in an international project for the development of the health sector in Angola. This project, designated PASS Programme, resulted from an international call for tender, launched in 2003 by the European Union and won by a consortium that includes a Portuguese owned company, Partex-Ige.

INFARMED will collaborate specifically in the pharmaceutical domain through the participation of experts in the areas covered by the project, namely in the inspection, quality control and medicines registration. This project will also allow for the establishment of a direct partnership between INFARMED and the National Directorate of Medicines and Equipments of Angola (DNME) thus complementing the activities to be developed by the PASS programme.

### Cooperation with Cape Verde

The signature of a Cooperation Protocol between INFARMED and the National Pharmacy Directorate of Cape Verde in January 2004 reinforced the partnership between the two entities. Cape Verde is one of the Portuguese speaking countries that have had a long lasting cooperation scheme with INFARMED.

An action plan for 2004 was established following the signature of the protocol towards the implementation of most of the actions there defined, namely training to pharmacists from Cape Verde in the medicines and inspections sectors, regulatory support and exchange of information in relevant areas. The action plan for 2005 will give continuity to the work done in 2004 with special focus on Pharmacovigilance, Inspection and Quality Control activities.

## Meeting of Iberoamerican medicines authorities

Following the successful 5th Meeting of the Medicines Competent Authorities of Iberoamerican countries (EAMI), which gathered in Brasilia from 29 to 31 March 2004, 21 countries, Portugal decided to host the next meeting in 2006 in Lisbon. This decision follows the wish of the delegations present in Brasilia to follow-up on the work done in the 5th EAMI, the first meeting after a 3-year interruption. This Iberoamerican group also includes observers from Portuguese speaking countries and Macao.

In hosting the 6th EAMI in 2006, Portugal namely through INFARMED will contribute towards the continuity of these meetings and a fruitful exchange views therein.

## Cooperation with Spanish counterpart

A delegation from INFARMED visited the Spanish medicines agency, AEMPS on February 1, 2005 with a view to strengthen cooperation between the two agencies in many areas and also to promote the exchange of information on prices and reimbursement. These are extremely important topics if we consider the close relation between the two Iberian countries and its similarities.

Other topics were also under discussion as the preparation of the forthcoming meeting of the secretariat of the group of competent authorities of Ibero-American countries along with possibilities for the exchange of training through internships between both agencies.

## Mutual recognition: INFARMED strengthens capacity

Over the last 2 years INFARMED sought to reinforce its mutual recognition evaluation capacity as a key element to strengthen the Institute's intervention in the European medicines regulatory environment. Currently, Portugal is Reference Member State for 17 applications.

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## agenda

**JANUARY**

***INFARMED completed 1 n 15 Jan.***
The 12th anniversary of INFARMED has been celebrated during the institute's annual conference.

***INFARMED Annual Conference 2005***
The annual conference of INFARMED took place on 25 and 26 January in Lisbon.

**FEBRUARY**

***EU Heads of Medicines Agencies met in Reykjavik***
The EU Heads of Medicines Agencies met in Reykjavik on February 23 and 24.

**MARCH**

***INFARMED/DIA symposium***
On March 6, INFARMED organises with the Drug Information Association a satellite symposium on medicines regulatory affairs in Portugal.

***17th Annual EuroMeeting***
The 17th EuroMeeting entitled "Medicines on Changing Times" will take place from 7 to 9 March in Lisbon.

***Portuguese speaking pharmacists***
From the 9th to the 11th March, it will take place in Maputo, Mozambique, the VII World Congress of Portuguese Speaking Pharmacists.

***EMEA Management Board Meeting***
The quarterly meeting of the Management Board of the EMEA will occur on March 10.

***EMEA Anniversary***
The European Medicines Agency will celebrate its 10th anniversary on March 11. A Scientific Conference will take place in London to mark the event.

Portugal

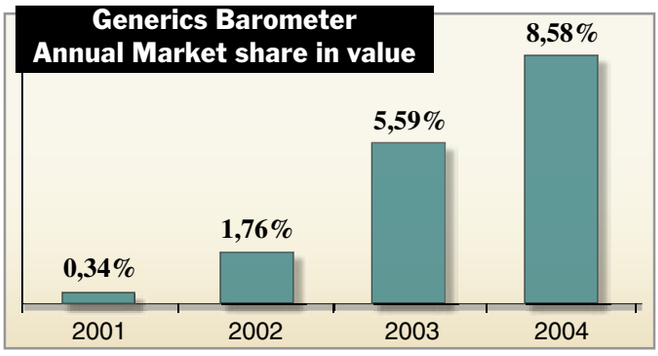
# Generics near 10% in 2004

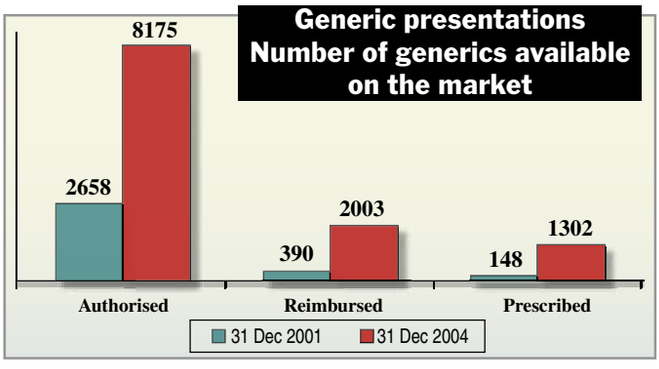
In Portugal generic medicines closed the year with an annual market share in value of 8,58 per cent at a growth rate of 28 per cent. In terms of monthly results, the market share registered in November 2004 was 9,92 per cent, 9,84 in December and 10,76 per cent in January 2005.

As for the generics volume indicator, the market share in 2004 was 5,09 per cent.

Comparatively, by the end of 2001 generic medicines registered a market share of 0,34 per cent. The market witnessed an important growth in recent years main as a result of legislation passed by the Government to promote generic medicines notably the INN prescribing act, including electronic prescribing, the introduction of a new reference pricing system, the adoption of a new model of medical prescription and an intense nation-wide information strategy.

The increased use of generic medicines has contributed to introduce greater efficiency into the National Health System and allowed for significant savings in the expenses with medicines in 2003 and 2004 paving the way for the reimbursement of new and innovative medicinal products.




# Portuguese agency tightens control on advertising

INFARMED established a multidisciplinary team that will work in close articulation with the National Council on Medicines Advertisement to ensure that medicines are correctly promoted in compliance with legislation. This team will monitor if the information contained in medicines advertisings is clear and objective regarding its benefits, usage and effects. This measure responds to the technical and scientific needs of advertising activity and to the challenges related to the information accessibility through different channels, television, radio, press and internet.

This new structure is part of a reorganisation of these activities which also aim at reinforcing the transparency in the filed, namely by publishing any sanctions or decisions taken in this domain.

# Medicines packs: new dimensions proposed

The Ministry of Health recently approved an order containing new rules and principles to which medicines reimbursed by the NHS should comply. The new instrument intends to shorten the relation between the quantities of the product to patient therapeutic needs by establishing two dimensions for packs – a small (app. 20 units) and a large one (app. 60 units). The solutions adopted aim at the harmonisation of a proper relation between costs and rational therapeutic criteria based on scientific evidence, protecting medical and pharmaceutical ethics and the rights of patients.

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