

PROTOCOL SIGNED BETWEEN

THE MINISTRY OF SOLIDARITY AND SOCIAL SECURITY, THE PORTUGUESE ASSOCIATION OF PHARMACEUTICAL INDUSTRY, INFARMED – National Authority of Medicinal and Health Products, I.P. and the UNION OF PORTUGUESE *MISERICÓRDIAS*

The 19th Government, through the Ministry of Solidarity and Social Security, created the Social Emergency Program with the purpose of alleviating the impact of the economic and financial crisis on the life of the citizens facing financial difficulties.

Through the Social Emergency Program, social action programs are developed aiming at improving the life conditions of the families and to promote equal opportunities for childhood, youth, active aging, dependence, health, immigration and other vulnerable situations.

The *Medicinal Products Bank* was created with the aim of promoting the access of the most deprived sectors of the population to health and medicinal products, especially by supporting the elderly with low income and high health consumptions, encouraging the use of medicinal and health products which are not part of the distribution chain and which are under full therapeutic and security conditions.

The Portuguese Association of Pharmaceutical Industry (APIFARMA), aware of its social responsibility role, namely in times of economic crisis, welcomed the challenge of the Ministry of Solidarity and Social Security to be an active partner of a bank to collect medicinal and health products, which may be provided, free of charge, to patients with low income.

INFARMED – National Authority of Medicinal and Health Products, I.P. (INFARMED, I.P.), as the body of Ministry of Health with the mission of regulate and supervise the sectors of medicinal products for human use and health products, according to the highest public health protection standards, joins the *Medicinal Products Bank* program.

The Ministry of Solidarity and Social Security, APIFARMA, and INFARMED, I.P., agree to generate a program enabling the Pharmaceutical Industry companies to donate to Private Social Solidarity Institutions (PSSI) with a medical and pharmaceutical service, as well as

those providing inpatient care, the medicinal and health products, with a sell-by date not less than 6 months, so as to be used in perfect conditions of quality and safety by the users of those institutions.

The safe, equitable and efficient operation of the *Medicinal Products Bank* suggests the existence of a social institution as the central unit for the supervision of the program operation, in charge with the management of the relations with the pharmaceutical entities, checking, monitoring and assessing the acquisition process of the medicinal products, disclosing the program and releasing, when required, the duly recommendations to its partners. Taking into account the universe of social responses in health care provided by *Misericórdias*, the Union of Portuguese *Misericórdias* appears as the entity in charge with the construction of a cohesion and Good Practices approach within the scope of *Medicinal Products Bank*.

Accordingly, the Ministry of Solidarity and Social Security, APIFARMA, INFARMED, I.P., and the Union of Portuguese *Misericórdias* sign a Protocol of cooperation governed by the following clauses:

Clause 1 **Object**

This Protocol aims at operating the *Medicinal Products Bank* created by the Ministry of Solidarity and Social Security, within the scope of the Social Emergency Program, with the purpose of supporting people with lower income and encouraging the use of medicinal and health products which are not part of the distribution chain and which are in full therapeutic and safety conditions.

Clause 2

Commitment of the Ministry of Solidarity and Social Security

The Ministry of Solidarity and Social Security undertakes to:

- a) Promote the required conditions for the creation of the *Medicinal Products Bank* namely to constitute or enable an entity for the fulfilment of the purpose provided for in the previous clause and under the provisions of clause 4;

- b) Disclose the *Medicinal Products Bank* among the Private Social Solidarity Institutions (PSSI) with a medical and pharmaceutical service, as well as those providing inpatient care.

Clause 3

Commitment of the Pharmaceutical Industry

1. APIFARMA undertakes to support the operation of the *Medicinal Products Bank* program, developed by the Ministry of Solidarity and Social Security and to disclose it among its associated Pharmaceutical Industry companies.
2. The companies associated with APIFARMA joining the *Medicinal Products Bank* undertake to:
 - a) guarantee that the distribution of medicinal products is carried out according to Good Practices for the Distribution of Medicinal Products, provided for in Decree-order no. 348/98, of 15th June, and that the distribution company is the holder of an authorization for the Wholesale Distribution of Medicinal Products, according to the provisions of article 94 and following of the Medicinal Product Statute;
 - b) send to the electronic platform provided for in clause 6, every month, information on the medicinal and health products which they can provide, as well as the respective quantities;
 - c) supply the medicinal and health products through the *Medicinal Products Bank*;
 - d) supply only medicinal products with a valid marketing authorization or registration in Portugal;
 - e) guarantee that the medicinal and health product available have a sell-by date not less than 6 months;
 - f) guarantee the quality and safety of the available medicinal and health products.

3. The Pharmaceutical Industry companies cannot provide medicinal products containing an active substance classified as narcotic or psychotropic, included in tables I to II attached to Decree-Law no. 15/93, of 22nd January, or any substances mentioned in no. 1 of article 86 of Regulatory Decree no. 61/94, of 12th October.
4. Pharmaceutical Industry companies may not use the *Medicinal Product Bank* to advertise prescription-only medicinal products and subsidized over-the-counter medicinal products.
5. Pharmaceutical Industry companies interested in cooperating with *Medicinal Product Bank* should join this project individually with APIFARMA, in case of the companies associated with the latter, and with the Ministry of Solidarity and Social Security for companies not associated with APIFARMA.

Clause 4

Commitment of the Union of Portuguese *Misericórdias*

The Union of Portuguese *Misericórdias* is the entity in charge with the construction of a cohesion and Good Practices approach within the scope of the *Medicinal Products Bank* and it is incumbent on it, especially:

- a) To disclose the *Medicinal Products Bank*;
- b) To manage the relations with the pharmaceutical entities;
- c) To check, monitor and assess the process of acquisition of medicinal products;
- d) To release recommendations among its partners, whenever deemed necessary and suitable.

Clause 5

Subjects and Conditions of access to the *Medicinal Products Bank*

1. Only Pharmaceutical Industry companies joining the project are allowed to provide medicinal and health products to the *Medicinal Products Bank*, according to clause 3, number 5.

2. Only Private Social Solidarity Institutions (PSSI) with medical and pharmaceutical services, as well as the ones providing inpatient care may access the *Medicinal Products Bank*, provided that, cumulatively:
 - a) they are duly authorized by INFARMED – National Authority of Medicinal and Health Products, I.P., for that purpose, according to the provisions of article 79 of Decree-Law no. 176/2006, of 30th August, in its current version;
 - b) the medicinal and health products are intended to be consumed by its users.
3. The access to *Medicinal Products Bank* requires that the beneficiary PSSI mentioned in the previous number undertake to:
 - a) Use the *Medicinal Products Bank* in the best interest of the users they assist and support;
 - b) Not provide the users they assist and support medicinal and health products with sell-by date expiring within three months;
 - c) Observe the rules provided for in the law for dispensing medicinal products;
 - d) Observe the pharmacovigilance rules;
 - e) To take the responsibility to comply with the rules for the disposal of medicinal products which have not been used, as well as those with expired sell-by date, namely delivering them to *Valormed*;
 - f) To meet the obligations provided for in article 66 (*Ancillary obligations of the beneficiary entities*) of the Tax Benefits Statute.

Clause 6

Tax treatment regarding medicinal and health products' provision within the scope of the *Medicinal Products Bank*

For the purpose of tax benefits regarding donations, as for Corporate Tax and Valued Added Tax, the respective legal system applies.

Clause 7

IT platform

1. To ensure the management of the *Medicinal Product Bank*, the Ministry of Health, through INFARMED, I.P., shall create an IT platform.
2. It is incumbent on INFARMED, I.P., the definition, implementation and management of the IT platform.
3. The IT platform should include the following information:
 - a) Identification of the holder of the marketing authorization or the company responsible for the marketing of the medicinal product;
 - b) Identification of the holder of the registration of the health product or the company responsible for its marketing;
 - c) Identification of beneficiary PSSI;
 - d) Identification of the provided medicinal product, stating the name of the medicinal product, active substance, pharmaceutical form, dosage, packet, sell-by date and batch number;
 - e) Identification of the provided quantities of each medicinal product and health product.
4. Referring to the IT platform the beneficiary PSSI's have access to all information on the medicinal and health products provided by the Pharmaceutical Industry.
5. The model and operation of the IT platform shall be defined by the Ministry of Solidarity and Social Security, by INFARMED, I.P., and APIFARMA, within two months after this Protocol is signed.

Clause 8

Monitoring Commission

1. To carry out this Protocol a Monitoring Commission shall be created and made up of a representative of the Union of Portuguese *Misericórdias*, who shall preside, a representative of the Ministry of Solidarity and Social Security, a representative of APIFARMA, a representative of INFARMED, I.P., and a representative of the beneficiary PSSI's.

2. The Monitoring Commission shall draw up Rules of Procedure detailing its operating regulations.

Clause 9

Coming into force

This Protocol comes into force at the date of its signature.

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Minister of Social Solidarity and Security, Luis Pedro Russo da Mota Soares

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On behalf of APIFARMA

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On behalf of INFARMED, I.P.

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On behalf of *União das Misericórdias Portuguesas*

Lisbon, 9th November 2012