

A strategic action plan for the Greek pharmaceutical industry

PILLAR 1: Research, Development and Innovation			
POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.1 Developing policies for linking academic research centres and the private sector</p>	<p>1.1.1 Creating R&D clusters in cooperation with other stakeholders</p>	<ul style="list-style-type: none"> • Investment Law 4146/2013, Article 22. Key financing tool for the establishment, expansion and modernisation of firms: <ul style="list-style-type: none"> ○ Creation of investment clustering schemes is fostered. ○ Clusters must be comprised of at least five companies in the Attica region and in the prefecture of Thessaloniki and at least three in the other prefectures of the country; they must operate in the form of a consortium, for which companies from EU Member States are eligible. Universities, research institutes and legal persons in private law may participate in an investment cluster with a share of up to 20% each. ○ The minimum amount of investment required for a cluster is set at €200,000 and the maximum at €20,000,000. ○ The level of support to clustering schemes may reach up to 50% of the project . 	<ul style="list-style-type: none"> • Exploring mature partnerships, embryonic networks, etc. which could develop into clusters. M/Ministry of Development, Secretariat General for Research and Technology • Joining of forces between existing networks and provision of additional services to members. M/Ministry of Development, Secretariat General for Research and Technology <ul style="list-style-type: none"> ○ Advice from specialist patent lawyers with knowledge of international environment ○ Partnerships with specialised universities and institutes, e.g. Johns Hopkins University. • Identifying Greek success stories of innovative businesses, e.g. CBL Patras, that can serve as a guide for promoting innovative initiatives and a dissemination of knowledge. S/ Ministry of Development, Secretariat General for Research and Technology

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.2 Developing/revising the legislative framework for the protection and commercialisation of intellectual property rights on research results</p>	<p>1.2.1 Enhancing the operation of transfer technology offices in universities</p>	<ul style="list-style-type: none"> • Operation of an innovation and liaison office under Law 4009/2011, Article 60, with the task to: <ul style="list-style-type: none"> ○ support and facilitate the patenting of intellectual property rights of the higher education institution and members of the relevant academic community; ○ promote communication and cooperation of researchers and members of the academic community with industry for the commercialisation of the results of research carried out at a higher education institution. • Creation of spin-offs under Law 2741/1999 Article 23, Law 2843/2000, Article 34, Presidential Decree 17/2001 and Law 2919/2001, Article 11. <ul style="list-style-type: none"> ○ A university has the option to participate {through the Special Account of Research Funds – ELKE) in a spin-off or, alternatively, license the use and exploitation of intellectual property (discovery , invention , research results) by signing agreements for technology transfer, concession, etc., setting out in detail the terms and conditions of the licensing and the financial remuneration. 	<ul style="list-style-type: none"> • Establishing contracts for technology transfer or licensing etc., specifying in detail the terms and conditions of transfer/licensing and the financial counterpart. M/ Ministry of Education <ul style="list-style-type: none"> ○ Compensation on royalties basis or up for payment and not in the form of equity holding in the spin-off, as this would put constraints on future operation, e.g. narrow definition of purpose, ambiguity of university compensation in case of a new patent without its involvement • Activation of transfer technology offices within all academic institutions. S/ Ministry of Education, Universities <ul style="list-style-type: none"> ○ Evaluation of staff (key performance indicators) ○ Evaluation of structures (processes, results) ○ Staffing with qualified personnel, e.g. patent lawyers with knowledge of procedures, costs, etc. ○ Operation of technology liaison offices on the model of other European countries

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.3 Preserving and utilising the research potential</p>	<p>1.3.1 Creating research units within hospitals and linking existing units with the research cluster</p>	<ul style="list-style-type: none"> • Organisational and procedural rules on the conduct of clinical trials at public health structures. Joint Ministerial Decision 18910, Article 18. <ul style="list-style-type: none"> ○ Consent of the hospital’s governing body and scientific committee is required. • Ceiling on salaries of civil servants under Law 4024/2011, Article 31. <ul style="list-style-type: none"> ○ the salary of any employee in the broader public sector may not exceed the maximum amount applicable to central government employees of the same educational level and employment contract type. • Creation of Centres of Excellence under Law 4009/2011, Article 75 (universities and their schools and departments). Criteria: <ul style="list-style-type: none"> ○ excellent quality and effectiveness of teaching and research work; ○ efficient structure and organization of curricula, linking teaching and research; and ○ high-quality support services. 	<ul style="list-style-type: none"> • Systematic performance measurement of pharmaceutical research and innovation at national and regional level by institutional bodies, e.g. Hellenic Statistical Authority (ELSTAT). S/EKT, ELSTAT, Secretariat General for Research and Technology • Encouraging research structures (National Health System, legal persons) through incentives to conduct clinical studies. S/Ministry of Health <ul style="list-style-type: none"> ○ Improving and upgrading infrastructure for clinical studies • Deregulating the salaries of NHS and university researchers and physicians involved in clinical studies on medicinal products for human use. S/Ministry of Health <ul style="list-style-type: none"> ○ Possibility of an additional fee for participation in research projects, by lifting or easing restrictions on the earnings of civil servants . • Creating full-time jobs in hospitals for clinical researchers in charge of clinical trials and research activities. M/Ministry of Health • Reducing red tape under the existing legal framework (Joint Ministerial Decision 18910 on clinical trials, Article 18) in order to minimise unnecessary administrative procedures. S/Ministry of Health <ul style="list-style-type: none"> ○ Utilisation of information technology

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.3 Preserving and utilising the research potential</p>	<p>1.3.1 Creating research units within hospitals and linking existing units with the research cluster</p>		<p>(automation, databases)</p> <ul style="list-style-type: none"> Expanding the institution of excellence centres within the National Health System and establishing centres of clinical excellence and researcher networks. L/Ministry of Health. Utilising existing structures, e.g. Biomedical Research Foundation - Academy of Athens (BRFAA). M/Secretariat General for Research and Technology Constantly updating legislation to keep it abreast of developments in science and technology (e.g. genomics) and in line with EU law. L/Secretariat General for Research and Technology, Ministry of Health
	<p>1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector</p>	<ul style="list-style-type: none"> Restrictions, i.e. incompatibility of the status of a teacher in a higher/technological education institution with employment in the private sector or participation in a business company, Law 2530/1997 Article 6 and Law 4009/2011 Article 24 without prejudice to paragraph 6 of Article 23, Law 2741/1999 Article 23, Law 2843/2000 Article 34, Presidential Decree 17/2001 and Law 2919/2001 Article 11 regarding the creation of spin-offs. In particular, university teachers are prohibited: <ul style="list-style-type: none"> from being employed as consultants or with administrative or teaching or research tasks, or from participating, under any relationship and for any duration, in a provider of 	<ul style="list-style-type: none"> Changing the institutional framework, in terms of: <ul style="list-style-type: none"> relaxation of employment restrictions for university teachers clarification of rules governing the participation of researchers and university teachers in the financial results of research that has translated into innovative business activity. S/ Ministry of Education Amending legislation on setting up a corporation to the effect that contribution of capital in the form of intangible assets (e.g. patents) can be freely negotiated/agreed by the contracting partners.

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.3 Preserving and utilising the research potential</p>	<p>1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector</p>	<p>educational and research services which is not part of the public sector;</p> <ul style="list-style-type: none"> ○ establishing or participating, under any relationship or capacity, in any business or company or joint venture or for-profit corporation contracted by the university to which they are affiliated or any other university to carry out any study or programme or implement any project or procure goods or services; and ○ holding another permanent position in the broader public sector, as defined in paragraph 1 of Article 1B of Law 2362/1995 (Gov. Gaz. A 247); exempted from this prohibition are university faculty members, members of the judiciary and church officials; ○ the status of rector, alternate rector and dean is incompatible with any professional employment outside the education institution as well as with any salaried position in the public or private sector. <ul style="list-style-type: none"> • The participation of teaching and research staff (faculty members) in a university spin-off is permitted following a decision of the university's senate (amendment to Article 11 of Law 2919/2001), provided that such members do not hold a significant management or administrative position (e.g. CEO, Executive Manager) at the university or the spin-off company and have completed three years of service since their appointment as faculty members. 	<p>S/Ministry of Finance</p> <ul style="list-style-type: none"> • Expanding internship schemes to more professions, e.g. pharmacists and chemists in pharmaceutical manufacturing companies. S/ Ministry of Education, Universities • Encouraging the hiring of students after the end of internship by lower social security contributions for the first year. S/Ministry of Labour • Employment in research in private-sector as qualification for academic career advancement. M/ Ministry of Education • Encouraging employment of PhD holders in private companies. M/Ministry of Labour <ul style="list-style-type: none"> ○ Exempting businesses from employers' contributions for R&D staff • Employing researchers/university faculty members in the private sector (on contractual, project-specific basis). S/Ministry of Education • Funding of academic research by the private sector (e.g. scholarships to Ph.D. candidates). .S/SFEE, PEF • Rewarding innovation, supporting entrepreneurship and identifying innovative proposals in the field of healthcare through competitions/contests, e.g. SFEE Innovation Project. S/SFEE, PEF • Encouraging business ventures from university graduates, through joint actions of SFEE/PEF and

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p style="text-align: center;">1.3 Preserving and utilising the research potential</p>	<p style="text-align: center;">1.3.2 Establishing a set of incentives to attract and retain researcher jobs in the private sector</p>	<ul style="list-style-type: none"> • Restrictions on the remuneration of faculty members: <ul style="list-style-type: none"> ○ According to Law 3833/2010, allowances and bonuses to faculty members may not exceed 100% of the regular monthly salary of their position. In addition, the sum of regular monthly salaries of faculty members and bonuses derived from: ○ programmes co-financed by the EU and national resources (Ministry of Education, Operational Programme Education and Lifelong Learning, Territorial Cooperation , Digital Convergence, Public Investment Programme, etc.) should not exceed the monthly salary of a Ministry Secretary-General, i.e. €4,750.00; and ○ international programmes or private funds should not exceed the total of the monthly salary of the President of the Supreme Court i.e. €6.138,80. • Establishment of the National Council for Research and Technology (NCRT) by Law 3848/2010, Article 46. The NCRT is the supreme advisory body of the State, responsible for the formulation and implementation of a national policy for research, technology and innovation. • Law 3653/2008, Article 4. The National Programme for Research and Technology (NPRT) is a set of actions aimed to systematically and effectively promote basic and applied research, 	<p>universities (cf. the joint SEV-NTUA action “Starting up together”). S/SFEE, PEF, Universities</p> <ul style="list-style-type: none"> • Maturing plans of students into business plans through a short-term boot camp with entrepreneurs and executives of pharmaceutical companies. M/SFEE, PEF, Universities • Promoting a flexible and fast tool to provide seed capital finance to promising young scientists with innovative ideas that have the potential to translate into new medicinal products. L/SFEE, XPHM. OPEIΣ • Utilisation of the Research Potential Activity of the FP7 Capacities Programme, with a budget of EUR 340 million, for trans-national two-way secondments of research staff; acquisition and development of research equipment; organisation of workshops and conferences to facilitate knowledge transfer; evaluation facilities for research centres. S/Ministry of Development, SFEE, PPPs

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
		<p>innovation and technology in the country.</p>	
<p>1.3 Preserving and utilising the research potential</p>	<p>1.3.3 Creating joint SFEE/PEF-University postgraduate programmes, focusing on research and business development</p>	<ul style="list-style-type: none"> • Legal framework governing postgraduate programmes at higher education institutions and interdepartmental postgraduate programmes specified by Laws 2083/1992, 3549/2007 and 3685/2008. • Structure, operation, quality assurance and internationalisation of higher education institutions specified by Law 4009/2011 as amended by Law 4076/2012. 	<ul style="list-style-type: none"> • Creating postgraduate specialisation programmes (e.g. across university departments): <ul style="list-style-type: none"> ○ in the fields in biomedical engineering, clinical engineering, clinical research, pharmaceutical medicine, pharmacotechnology ○ interdisciplinary. L/Ministry of Education, Universities ○ Involvement of the pharmaceutical industry in the development of postgraduate curricula in universities. S/SFEE,PEF, Universities • Inclusion in the curricula of medical and pharmaceutical schools of subjects such as: <ul style="list-style-type: none"> ○ innovation, technology , ICT, licensing, commercialisation of knowledge ○ research methodology/ethics ○ business administration, preparation of feasibility studies, business planning, access to finance. M/Universities, Ministry of Education • Organising business seminars as part of undergraduate and postgraduate programmes, e.g. on patents. M/Universities,SFEE,PEF(IP) • Co-organising entrepreneurship summer school at

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
			international level, jointly by SFEE, PEF and Universities. M/ Universities,SFEE,PEF
<p>1.4 Strengthening the legislative framework, policies fostering the development of clinical research in Greece and licencing of medicines</p>	<p>1.4.1 Utilising existing clinical research infrastructure to attract foreign investment</p>	<ul style="list-style-type: none"> • Introduction of good clinical practice in the conduct of clinical trials of medicines <ul style="list-style-type: none"> Ministerial Decision 89292/31.12.2003 (Government Gazette B 1973), Ministerial Decision 79602/25.01.07 (Government Gazette B 64)και Ministerial Decision 18910/21.03.2013 (Government Gazette 390). Ministerial Decision 119442/30.12.2013 (Government Gazette 3338). • Establishment of a National Ethics Committee Ministerial Decision 69150, Government Gazette 1503/07.10.2004) <ul style="list-style-type: none"> ○ Evaluation of proposals and ongoing monitoring of interventional clinical trials. ○ 3-year renewable term of office. • Article 18 para 2 of Law 2667/1998 established the National Bioethics Commission, an advisory body responsible for monitoring, reviewing and delivering opinions on ethical, social and legal issues increasingly brought about by advances in biology, biomedicine, genetics and biotechnology - 	<ul style="list-style-type: none"> • Developing an institutional framework for the conduct of non-interventional studies which are an essential part of clinical research. S/Ministry of Health • Constant harmonisation of Greek legislation with EU law regarding the conduct of clinical trials of pharmaceuticals. S/Ministry of Health • Review of the institutional framework, organization and staffing of health facilities with adequate infrastructure for carrying out international Phase 1 studies (currently not available in Greece). M/Ministry of Health • Utilisation of incentives for cooperative research groups that can accelerate technology transfer from basic and clinical research to commercial applications and enable all stakeholders to have a better understanding of the problems to be solved and which may occur at various stages of the process. S/Secretariat General for Research and Technology, Ministry of Development

PILLAR 1: Research, Development and Innovation

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>1.4 Strengthening the legislative framework, policies fostering the development of clinical research in Greece and licencing of medicines</p>	<p>1.4.1 Utilising existing clinical research infrastructure to attract foreign investment</p>	<p>http://www.bioethics.gr.</p>	<ul style="list-style-type: none"> • Recognition of clinical trials as scientific and technological research and the relevant expenditures as eligible for favourable tax treatment, to provide incentives for domestic growth and investment in research. M/Ministry of Finance • Staffing the National Ethics Committee with scientific personnel properly trained to approve and supervise clinical trials and address regulatory and bioethical issues. S/Ministry of Health • Expanding the scope of the National Ethics Committee to include non-interventional clinical trials, diagnostic, surgical techniques, etc.; such tasks should be delegated to appropriate subcommittees, to ensure that the Committee’s core responsibility for interventional clinical trials is not affected. S/Ministry of Health

PILLAR 2: Production and Exports

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>2.1 Introducing a favourable tax treatment of production and technological investment by the pharmaceutical industry</p>	<p>2.1.1 Amending tax rules in respect of intangible investment and profits from innovation</p>	<ul style="list-style-type: none"> • Tax breaks for scientific and technological research expenditure of businesses, under Article 3 para 29 of Law 4110/2013. <ul style="list-style-type: none"> ○ Deduction from taxable income for 130% of expenditure on scientific and technological research, as defined by a Presidential Decree following a recommendation by the Minister of Finance and the Minister of Development, Infrastructures, Transport and Networks. • Under Ministerial Decision 1040588/1700/528/0014 (Gov. Gaz. 335/23.04.1997), universities or technology and research institutes are exempted from VAT for their expenditure on R&D equipment in the context of co-financed research programmes. • Tax incentives for strategic investments under Investment Law 4146/2013, Article 11. <ul style="list-style-type: none"> ○ special tax arrangements, such as: a fixed tax regime from a specific period of time after the launch of the strategic investment; tax-free reserves; procedure and time frame for VAT refund; and reduction or exemption from duties, excise taxes and dues or fees of third parties. • Tax incentives for patents (Law 3842/2010, 	<ul style="list-style-type: none"> • Revision of the tax break framework for R&D and technological innovation. S/Ministry of Finance <ul style="list-style-type: none"> ○ Removal or relaxation of the requirement that R&D expenses should exceed the average of previous two years to qualify for tax deduction (instead, R&D expenditure should exceed e.g. 50 % of previous year) ○ Stronger tax incentive, e.g. doubling the tax deduction, with or without a ceiling (tax after deduction should be at least 30% of the initial amount of tax). ○ Royalties should be exempt from withholding tax. ○ Possibility of exemption from social security contributions, as a bulwark against unemployment ○ Application of a lower rate of corporate tax to profits earned from patented inventions and other innovations (cf. Patent Box in the UK). • Creation of Special Economic Zones (SEZ) with special incentives, tax exemptions for corporations located in industrial areas/industrial parks. L/Ministry of Finance, Ministry of Infrastructures

PILLAR 2: Production and Exports

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>2.1 Introducing a favourable tax treatment of production and technological investment by the pharmaceutical industry</p>	<p>2.1.1 Amending tax rules in respect of intangible investment and profits from innovation</p>	<p>Article 71).</p> <ul style="list-style-type: none"> ○ Business profits from the sale of goods which have been produced using internationally recognised patents are exempt from income tax for three consecutive financial years. 	<ul style="list-style-type: none"> ● Amendment to Development Law to provide higher percentage of subsidy to manufacturing companies in regions with high industrial concentration, e.g. Attica. M/Ministry of Development ● Removing tax impediments to production for non-resident companies (e.g. VAT charges, requirement to designate a tax representative resident in Greece, implying double taxation, difficulties in tax and accounting treatment). S/Ministry of Finance ● Harmonising Greek legislation with the EU Directive on deliveries of materials from EU countries under consignment arrangements. S/Ministry of Finance ● Setting up a committee of representatives of government and independent agencies to evaluate pharmaceutical companies' intangible investment (purchase of patents, marketing authorisations, clinical studies, etc.) for inclusion in the NSRF and other development programmes. M/Ministry of Finance ● Ensuring that the licensing process starts with the construction phase of capacity development/expansion projects (other than facilities expansion) for existing

PILLAR 2: Production and Exports

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
<p>2.1 Introducing a favourable tax treatment of production and technological investment by the pharmaceutical industry</p>	<ul style="list-style-type: none"> • 2.1.1 Amending tax rules in respect of intangible investment and profits from innovation 		<p>industrial plants. In any case, speedy issuance of necessary licences to avoid hampering investment and the smooth functioning of the market. M/Ministry of Development</p> <ul style="list-style-type: none"> • Introducing tariff and tax exemptions and facilities for foreign firms relocating to Greece, e.g. an update of Law 89/1967 which was in force until 2005. L/Ministry of Finance

PILLAR 2: Production and Exports

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
2.2 Increasing the extroversion and internationalisation of Greek pharmaceutical producers	2.2.1 Amending tax rules in respect of intangible investment and profits from innovation	<ul style="list-style-type: none"> The National Organisation for Medicines (EOF) was established by Law 1316/1983 and is a legal person in public law supervised by the Ministry of Health and Social Solidarity. 	<ul style="list-style-type: none"> Enhancing the role of the National Organisation for Medicines (EOF). M/EOF, Ministry of Health <ul style="list-style-type: none"> Activation of MRP and DCP processes. Speeding up the procedures for the evaluation and supervision of clinical studies conducted in Greece. A supportive/advisory role for the pharmaceutical industry Staffing with qualified human resources (e.g. Directorate of Pharmaceutical Studies and Research). .M/EOF, Ministry of Health
	2.2.2 Establishing a one-stop shop structure for consultancy services to export firms	<ul style="list-style-type: none"> Law3853/2010, Article 2 specified the agencies that may operate as one-stop shops, e.g. General Electronic Business Registry (GEMI), Citizen Service Centres (KEP). Law 4072/2012, Article 3. Operation of Invest In Greece as one-stop shop in the context of the effort to speed up licensing procedures and promote investment. Law 4072/2012. Registry of export enterprises, acceleration of export procedures. 	<ul style="list-style-type: none"> Providing specialised consultancy services for firms seeking to export to new markets (on the model of Enterprise Europe Network - EEP), e.g. coaching, mentoring, training, infrastructure, support services. S/SFEE,PEF,HORIZON 2020 Activation of Enterprise Greece SA (which will result from the merger of Invest in Greece and the Hellenic Foreign Trade Organisation - OPE) to promote exports. S/INVEST IN GREECE <ul style="list-style-type: none"> Participating in international pharma

PILLAR 2: Production and Exports

POLICIES	SUPPORTING MECHANISMS	LEGISLATION	PROPOSALS
2.2 Increasing the extroversion and internationalisation of Greek pharmaceutical producers		<ul style="list-style-type: none"> ○ Extending the opening hours of customs. ○ Electronic submission of documents for exports/imports, issuance of relevant certificates/licences using the Single Integrated Information System. 	<p>and biotechnology events (e.g. CPHI, Bio-Europe on Generics from Greece) to co-promote Greek medicinal products and materials</p> <ul style="list-style-type: none"> ● Specialised training for one-stop shop staff. S/INVEST IN GREECE
	2.2.3 Using the Pharmaceutical Forum (EPHForT) as a network platform for exporters, to promote basic research, clinical research and domestically produced proprietary pharmaceuticals	<ul style="list-style-type: none"> ● Law 4072/2012, Article 39. Export activity award. 	<ul style="list-style-type: none"> ● Developing an electronic platform to encourage the sharing of R&A-related information among companies, universities and research institutes. S/SFEE,PEF,INVEST IN GREECE ● Organising joint events, conferences and workshops between academia and the pharmaceutical industry for the purpose of promoting research institutes, disseminating research results and building mutual trust. M/SFEE, PEF, Universities ● Promoting international best practices in order to support innovative initiatives and strengthen the bonds between industry and research. M/SFEE, PEF