COVID-19:
FARMAINDUSTRIA'S PRIORITIES, ACTIONS AND OUTCOMES

APRIL 13th, 2020

farmaindustria

Introduction

Since the outbreak of the coronavirus crisis, and more specifically since the state of alarm was declared, Farmaindustria has focused its efforts on supporting member companies in the continuity of their business processes, paying special attention to the supply of medicines to hospitals and pharmacies, manufacturing, clinical trials, regulation, and all changes brought about by the emergency legislation.

A key element to this effect has been the increased frequency of meetings with the most affected Farmaindustria's Working Groups (Manufacturing and Traceability, Legal Affairs, Human Resources, Clinical Research, Hospital Market, Spanish Regions) and the creation of ad hoc groups, such as Supply for Hospital Pharmacy (outpatients).

The Governing Bodies have also increased the frequency with which they meet. The Vice-Presidents Group meets every Monday and the Council meets every Thursday. The Board of Directors also held an extraordinary meeting. Statutory Groups are updating all other member companies that do not participate in the Governing Bodies.

The Newsletter* is shared with all member companies and almost 2,000 individuals are authorized to access Farmaindustria's intranet. The Newsletter has been published daily for the last four weeks with real-time information regarding updates as they occur, Farmaindustria's actions and outcomes.

The speed at which events are unfolding makes it difficult at times to have a comprehensive view of the impact the crisis is having and of the support activities provided by the Association. This summary has been prepared specifically in order to provide member companies with an updated, complete picture of these priorities and actions, which will be regularly updated.

** The hyperlinks of the newsletters and memos available along this summary can only be accessed by Farmaindustria's members.*

1. Supply of medicines. Hospital pharmacy

OBJECTIVES

- **Guarantee the continuity of supply of hospital medicines**

ACTIONS	OUTCOMES / FOLLOW-UP
Regular contact with the Spanish Medicines Agency (AEMPS) and the General Direction of Pharmacy of the Ministry of Health (DGCBSF) in order that companies can adjust **supply according to past records**	• Ministry of Health Order SND/293/20 (newsletter **1,234**): maximum of 2-month medication for patients, limited to 1 month for some medicines. • Ministry of Health Order SND/276/20 (newsletter **1,231**): daily information on used of ICUs medicines and others used to fight COVID-19. Services provided during weekends and holidays (newsletter **1,235**). • Memo from the AEMPS regarding Chloroquine and Hydroxychloroquine (newsletter **1,231**). • Letter from the President of the Spanish Society for Hospital Pharmacy supporting procurement according to past records. (newsletter **1,230**).
Regular contact with the Spanish regions urging them to maintain **hospital orders according to past records**	• Communication alerting the Spanish regions of possible consequences on supply if requests for hospital procurement exceed past records. • Alignment and awareness outreach to Spanish regions, some with nuances (newsletters **1,232** & **1,233**). Feedback to DGCBSF.
Engagement with the Spanish regions concerning the **dispensing** of hospital medicines **to outpatients**	• Status report compiling instructions and communications issued by Spanish regions with the measures for the dispensing of hospital medicines to outpatients (newsletter **1,239**).
Setting-up and regular meetings of the **Hospital Supply Ad Hoc Group**	• Monitoring of hospitals supply due to the increase in orders. • Proposal to support the NHS to secure vulnerable patients access to hospital medicines. • Industry positioning regarding home delivery of hospital medicines (newsletter **1,242**).
Tracking of the supply to the new **IFEMA Hospital**, hotels and other medical wards	• Coordination with Madrid Health Services (SERMAS) to provide information to suppliers and guarantee logistical aspects of the IFEMA Hospital (memos **CAM/4bis/20**, **CAM/4bis1/20** & **CAM/4 bis2/20** and newsletters **1,230** & **1,231**). • Monitoring of spaces set up for patients hospitalisation in Madrid and Cataluña (memo **CAT/2bis/20** and newsletters **1,236** & **1,241**). • Follow-up of similar initiatives in other Spanish regions: Andalucía, Castilla y León, Galicia, Murcia, Valencia y País Vasco (newsletter **1,238**).

2. Supply of medicines. Community pharmacy

OBJECTIVES

- **Guarantee the continuity of supply throughout the pharmaceutical supply chain**

ACTIONS	OUTCOMES / FOLLOW-UP
Weekly teleconference between **AEMPS and medicines supply chain stakeholders** (pharmacists, wholesalers, generics and Farmaindustria)	• AEMPS coordination with supply chain stakeholders, with paramount cooperation for solving problems (every Monday afternoon) (newsletters **1,231** & **1,226**). • Agreement between pharmacists and Spanish Red Cross for home delivery (newsletter **1,234**).
Contact with health authorities of the Spanish regions regarding **electronic prescription and approvals**	• Communication requesting that the extension of treatment for chronic patients does not imply greater dispensing of medicines, warning of possible supply problems if stockpiling is favoured. • Alignment and awareness outreach to Spanish regions, some with nuances (newsletters **1,232** & **1,233**).
Compilation of **instructions and communication with Spanish regions**	• Status report on the prescriptions renewal for chronic treatments and medicines subject to prior approval in the Spanish regions (**web**, BICCAA **270** and newsletters **1,229** & **1,230**).

3. Supply of medicines. Actions at European level

OBJECTIVES

- **Coordinate the Spanish and European action with regard to supply of medicines**
- **Facilitate transport of medicines and PPE at borders**

ACTIONS	OUTCOMES / FOLLOW-UP
Regular meetings of the **Steering Group** (EMA, EFPIA and other European associations of pharmaceutical manufacturers) focusing on shortages	• Adoption of a European single point of contact (SPOC) for companies to notify anticipated shortages (newsletters **1,225**, **1,228**, **1,230** & **1,241**). • Regular information on European actions to member companies (newsletters **1,235**, **1,238** & **1,240**).
Weekly meetings with EU **Commissioners of Health, Interior Market and Crisis Management**	• Setting-up of priority green lanes for medicines and PPE (newsletters **1,225**, **1,228** & **1,230**). • Statement by the European Council on five lines of action (newsletter **1,234**). • Regular information on European actions to member companies (newsletter **1,235**).
Contact with the Spanish Tax Agency's **customs authorities**	• Implementation and follow-up of the Protocol for Notice of Arrival of Medicines and PPE (newsletters **1,232** & **1,233**). • Publication of a **Q&A** by the Spanish Tax Agency on the importation of medical equipment and PPE. • Adoption of extraordinary measures for the implementation of the EU preferential agreements (newsletter **1,236**). • Publication of explanatory notes on customs procedure for donations of imported material (**23 March** & **2 April**).

4. Manufacturing and supply chain

OBJECTIVES

- **Guarantee continuity in manufacturing sites**

ACTIONS	OUTCOMES / FOLLOW-UP
Weekly meetings of the **Manufacturing and Traceability Working Group**	• Monitoring the situation at the 80 medicines and raw materials' manufacturing sites in Spain.
Collaboration with the Spanish authorities for the **supply of PPE to** the pharmaceutical industry's **workers**	• Participation in surveys on availability and demand of PPE conducted by the Ministry of Industry to mobilise national production. • Option of using the Health Silk Road with China for the importation of EPP for manufacturing sites (memo **OIF/12bis30 /20** and newsletter **1,236**). • Communication with member companies regarding list of suppliers via working groups.
Collaboration with the Spanish authorities for the supply of **tests for workers**	• Request health authorities to prioritize tests in pharmaceutical production plants.
Collaboration with the Spanish authorities to consider the pharmaceutical industry as an **essential sector**	• Coordination with the Ministry of Industry (newsletter **1,231**). • Pharmaceutical industry as an essential sector by Royal Decree RDL/10/2020 (newsletter **1,235**).
Collaboration with the Spanish authorities and other stakeholders on **access to API**	• Option of using the Health Airlift with China for API (memo **OIF/12bis30/20** and newsletter **1,236**). • Coordination with the AEMPS and the Spanish chemical industry associations to identify API manufacturers for essential medicines.

5. Clinical trials and research

OBJECTIVES

- **Guarantee the continuity of on-going clinical trials**
- **Facilitate the approval of new clinical trials against Covid-19**
- **Mobilise the Spanish scientific community to research against Covid-19**

ACTIONS	OUTCOMES / FOLLOW-UP
Continuous contact with the AEMPS, Ethics Committees in Medical Research Group (CEIm), the Spanish Data Protection Agency (AEPD), hospital centres and patient organisations to **continue on-going clinical trials**	• Follow-up with the AEMPS and CEIm on clinical trials in progress. • Implementation and distribution of recommendations from the AEMPS (**briefing note** on extraordinary measures) as well as follow-up of EMA and other member states guidelines (newsletters **1,223**, **1,225**, **1,228**, **1,230** & **1,242**). • Ministry of Health Order SND/293/20 (newsletter **1,234**). Home delivery for participants in clinical trials. Instruction of Galicia (memo **IV/9bis4/20**). • Proposal to the AEMPS and AEPD to enable sponsors to remotely monitor with sourced data verification for certain types of clinical trials (newsletters **1,224** & **1,242**). • Proposal to the 50 hospitals participating in the Best Project for the implementation of digital tools management to conduct clinical trials (newsletter **1,238**). • Communication with patient representatives on the status of clinical trials in progress.
Engagement with Spanish authorities in order to **approve faster new clinical trials** against Covid-19	• Coordination with the AEMPS to expedite timelines. Response from the Agency within 48-72 hours. • Setting-up of the Covid Commission to coordinate clinical trials in hospitals. • 19 clinical trials (7 from industry sponsors) approved by the AEMPS by April 7th to research medicines against Covid-19 (newsletter **1,228**).
Contact with the Ministry of Science & Innovation and the Centre for the Development of Industrial Technology (CDTI) regarding **research projects**	• Report on the pharmaceutical industry's efforts in R&D projects in the fight against Covid-19: new treatments, vaccines, testing kits (newsletter **1,233**).
Interaction with member companies and the Spanish scientific community to promote **participation in European collaborative initiatives** for Covid-19 (IMI and European Commission)	• Wide distribution of IMI call regarding the development of therapies and diagnostic methods to fight Covid-19. Important Spanish participation. • Wide distribution of the European Commission call to share compounds libraries and use supercomputation to shorten the R&D process (newsletters **1,231** & **1,239**). Important Spanish participation.

6. Regulation and pharmacovigilance

OBJECTIVES

- **Adapt regulation to the exceptional crisis situation**

ACTIONS	OUTCOMES / FOLLOW-UP
Regular contact with the **AEMPS**	• Postponement of risk analysis submission for nitrosamines (newsletter **1,233**). • AEMPS' response accepting the postponement of all non-urgent monitoring activities.
Regular contact with **EFPIA** and other national associations	• Follow-up of the international regulatory situation (newsletter **1,234** & **1.241**).

7. Human resources

OBJECTIVES

- **Analyse and share exceptional labour laws with member companies**
- **Channel volunteering initiatives carried out by employees of member companies**

ACTIONS	OUTCOMES / FOLLOW-UP
Compilation, analysis and monitoring of the **new labour regulation** due to Covid-19	• Joint analysis of the information, its enforcement and its impact on the pharmaceutical industry. • Provision of updated regulatory information to members on working hours (memo **IE/12/20** and newsletter **1,227**), provision of essential services (memo **IL/5bis2/20** and newsletter **1,235**), movement of workers according to the Ministry of Health Order SND/307/2020 (memo **IL/5bis3/20** and newsletter **1,236**), prevention of occupational risks (newsletter **1,233**), initiatives to maintain the industrial activity and jobs (memo **IE/12bis4/20** and newsletter **1,237**) and European Commission guidelines concerning the free movement of critical workers (memo **II/5bis6/20** and newsletter **1,237**).
Regular meetings of the **Human Resources Working Group**	• Joint analysis of the information, its enforcement and its impact on the pharmaceutical industry.
Identification and channelling of **volunteering initiatives**	• Compilation of all the volunteering initiatives carried out by employees of pharmaceutical companies (internal survey). • Contact with health authorities in Madrid and Cataluña to channel volunteering (newsletters **1,229** & **1,233**).

8. Legal affairs

OBJECTIVES

- **Analyse and share exceptional legislation affecting the pharmaceutical industry with member companies**

ACTIONS	OUTCOMES / FOLLOW-UP
Compilation, analysis and monitoring of **new regulation** due to Covid-19	• Updated regulatory information to members on public procurement, jurisdictional, administrative, fiscal and electronic certificates (memo **IV/8bis/20** and newsletters **1,225**, **1,227**, **1,228**, **1,230**, **1,231** & **1238**). • Updated regional regulatory information to members (memo **IV/9bis3/20** and newsletter **1,236**).
Regular meetings of the **Legal Affairs Working Group**	• Joint analysis of the information, its enforcement and its impact on the pharmaceutical industry.

9. Code of Practice, scientific conferences and meetings and medical rep visits

OBJECTIVES

- **Follow up on restrictions to medical rep visits and attendance to scientific conferences and meetings**
- **Adapt functions of the Code of Practice to the current situation**

ACTIONS	OUTCOMES / FOLLOW-UP
Follow-up of **Spanish regions**' actions	• **Report** including instructions and statements from the Spanish regions restricting medical rep visits and attendance to clinical & training sessions and scientific conferences & meetings due to Covid-19 (prior to confinement of the state of alarm).
Adaptation to the Self-regulation System for Covid-19 **donations**	• Note on the VAT treatment of the free delivery of PPE and medicines (memo **IE/12bis3/20**).
Adaptation of activities of the **Code Control Bodies**	• Development and distribution of the memo **USD/04/20** on the activity of the Control Bodies (the Jury, the Code of Practice Committee and the Code of Practice Surveillance Unit) in the wake of the Covid-19 crisis.

10. Communication

OBJECTIVES

- **Inform society of the pharmaceutical industry efforts in the fight against Covid-19**

ACTIONS	OUTCOMES / FOLLOW-UP
Development and distribution of **briefing notes** on the: – Pharmaceutical industry's commitment against Covid-19 – Status of research against Covid-19 – Production and supply of medicines – Continuity of clinical trials – Donation and volunteering activities	• **Open letter from Farmaindustria's President** regarding the commitment to research, supply and manufacture as well as the continuity of clinical trials. Around 850 impacts in the media achieved during the first weeks of the crisis. • Communication on **R&D progress** led by the pharmaceutical industry as much in medicines as in **vaccines**. • Interviews and videos showcasing the continuity of **medicines supply** by Farmaindustria's member companies. • Participation in TV programs to inform on the efforts the pharmaceutical industry is doing to guarantee supply and research (**Tele5**, **TVE1**, **TV Castilla y León** and **TV Balear**). • **Testimonials in first person** as well as through member companies on the daily work of manufacturing sites in Spain. • Press release and diffusion in social networks of the **coordination activities with the AEMPS** to secure clinical trials continuity guaranteeing patient safety. • Communication concerning the **pharmaceutical industry support through donations** and other related initiatives. • Information on the **pharmaceutical industry's employees volunteering to join the NHS** to reinforce the healthcare workforce.
Reinforcement of **internal communication** and member companies' common narrative	• Sharing of information with Farmaindustria's member companies concerning figures, common narrative, key messages and positioning during the crisis. • Invitation to companies to participate in Farmaindustria's initiatives with the aim of launching joint messages regarding **supply, sector commitment, solidarity**, etc.
Dialogue with society in **social media**	• Reinforcement of **information** and interaction with **specific actions** linked to the core messages from the pharmaceutical industry in the context of the crisis. More than 170,000 reactions achieved on social media platforms in which Farmaindustria participates. • **Increase in the number of followers** in two renowned platforms as LinkedIn (more than 30,000) and Twitter (more than 31,400).

11. Economic impact

OBJECTIVES

- **Facilitate updated information regarding the estimated impact of the healthcare crisis on the economy and the pharmaceutical market**
- **Monitor regulators actions in P&R issues**

ACTIONS	OUTCOMES / FOLLOW-UP
Compilation and analysis of **external estimations regarding the impact** of the crisis on the Spanish economy. Definition and update of scenarios	• Updated internal reports on the economic impact of the crisis. • Communication to Farmaindustria's members of economic analysis with projections of the crisis impact on the GDP, employment and public deficit (newsletter **1,241** and hyperlinks: **BBVA**, **Caixabank**, **CEOE**, **Deutsche Bank** and **FUNCAS**). Maximum uncertainty; scenarios built according to the duration of the state of alarm. • Submission to CEOs of Farmaindustria's member companies of a comprehensive confidential report by International Financial Analysts, including estimates of GDP loss.
Analysis of the crisis impact on **pharmaceutical expenditure**. Revision of forecasts	• Update expenditure forecasting model, considering demand-side changes: increased Covid-19 medicines consumption, decreased consumption in other segments due to the focus of resources on Covid-19 (in progress). • Revision of companies' forecasts from previous years in order to improve forecasting capacity at a sector level (in progress).
Follow-up on **pricing and financing** activities: Interministerial Medicinal Product Pricing Committee (CIPM), P&R, Order of Reference Pricing	• CIPM meeting postponed with no new date, originally scheduled 1 April (newsletter **1,233**). • Suspension of administrative processes deadlines by Royal Decree 463/2020 of 14 March (newsletter **1,225**). • Focus by the DGCBSF on supply of medicines, healthcare material, tests, and PPE, with pricing and financing issues being set aside temporarily.