

AIFA AND HOSPITAL SUPPLY DURING THE COVID CRISIS: THE COLLABORATION BETWEEN REGIONS, COMPANIES, AND AGENCY

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CONTEXT

The current epidemic environment is marked by new therapeutic demands, a high level of dynamism in treatment scheme suggestions, both *on label* and *off label*, and specific organizational needs in the provision of care. Furthermore, the epidemic's widespread nature requires a particular timeliness in the definition and application of the provisions.

The sudden increase in demand for normally low-spread drugs, such as some antivirals (which, at the time, had not yet been evaluated in comparison to COVID therapy), triggered a backlash on the distribution network, which also concerned the territory where the availability of some of the products had encountered unexpected difficulties, at the height of the crisis, which began around mid-March. The AIFA had to respond by rapidly authorizing the import of large quantities of the products required by the protocols, which, however, gradually changed, modifying the expected needs in a sudden way.

In parallel, with the increasing occupation of intensive care units, the demand for drugs such as anaesthetics, whose production has critical aspects that make it difficult to increase availability. The increase in complexity was due to an uncoordinated demand by the territory, which meant that individual hospital facilities were competing for supplies, generating problems so that the stocks of the areas still unaffected by the virus could hardly be made available to the network, in prevision of the emergency.

"COMMUNITY EXPERTS" MODEL

The AIFA has provided an organizational response that has proven effective in response to the new needs given by the pandemic, forming a "community of experts". An operational network that has involved the referents of the regions with the task of supervising, monitoring, and collecting timely the territory's needs, acting as transducers between them and the institutions, and allowing them to carry out timely interventions (ensuring, for example, the supply of hospitals by companies through the regions), and providing real-time support by pharmaceutical companies, interfaced with the AIFA through the network managed by the industry associations, Assogenerici and Farindustria.

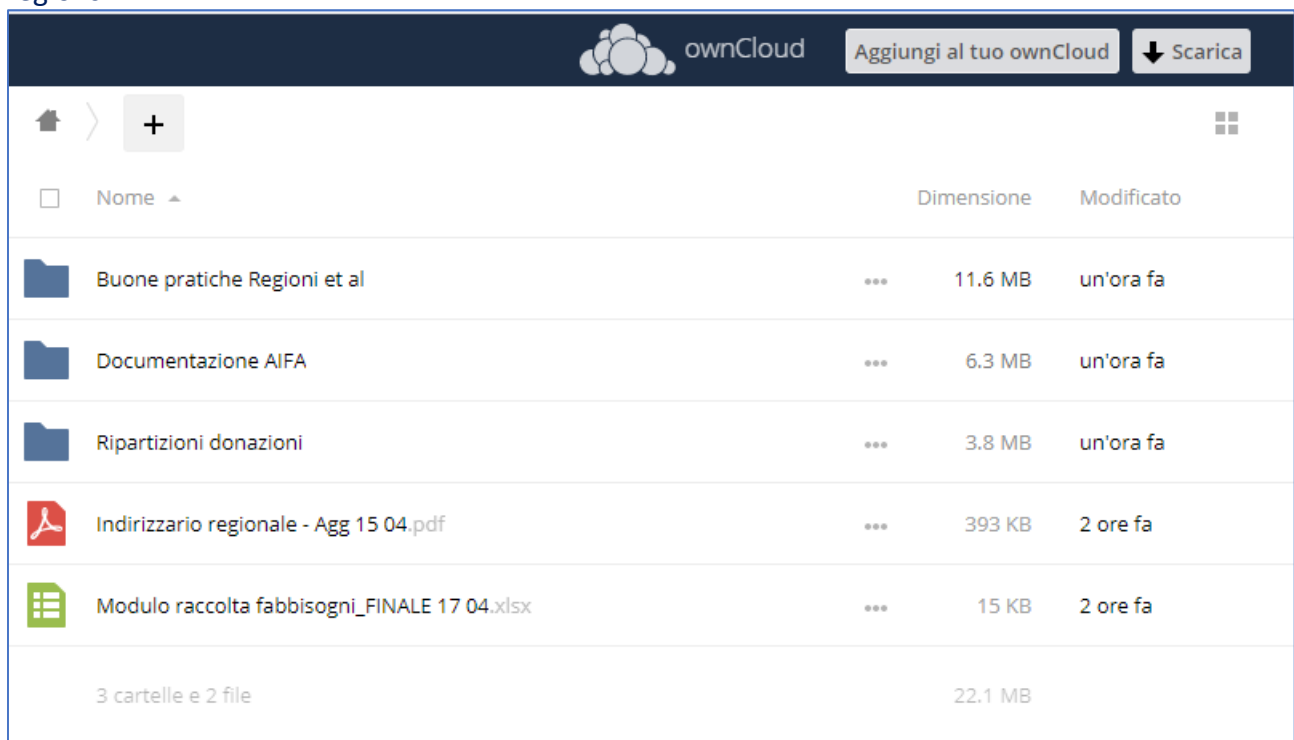
This operating mode has allowed us to rationalize the communication and information flow, avoiding duplication of activities and ensuring the availability of reconnaissance powered by timely and detailed data and information provided in real-time.

The collection of data, intended as recognition of needs and critical issues as well as good practices, has also led to the establishment of a national data observatory "real world": the winning strategy was to create a system that shares the problems to allow us to anticipate the solutions.

The model created by the "operational network" has also made it possible to combine knowledge and skills and thus identify and share pragmatically operational solutions in the real world, which are applicable, sustainable, and effectively declined dynamically in response to actual needs, as required by the emergency context.

While reactive activities such as shortage monitoring, donation management, and the establishment of shared allocation criteria may be linked, some of the activities carried out in a shared way have provided insights and perspective solutions. This is well represented by the spread of good practices within the network of the "community of experts", which allowed for the copying of effective practices between the regions, avoiding duplication of activities and optimizing the use of the limited resources available.

The establishment of this network has also allowed the regions to simplify the internal organization for the management of information flows on hospital shortages between ASL and the regions.



One of the sharing tools used during the crisis: the reserved web space in the OwnCloud AIFA, where the documentation of interest with respect to the emergency COVID-19 has been categorised and made accessible to the regional referents.

TOOLS AND INTERVENTIONS

To manage the emergency, the AIFA participated in a series of operating circuits, some of which were built specifically for this contingency:

- AIFA's crisis unit
- Shortage's crisis unit of the competent AIFA's office (in business continuity)
- Operational unit office/Assogenerici/Farindustria (in business continuity to support the regions)
- "Community of experts" [COVID-REGIONS], a circuit with contact people for pharmaceuticals in the regions and autonomous provinces
- "Comitato Operativo Protezione Civile" (participation of AIFA delegate)
- Network "Tavolo Tecnico Indisponibilità" (activated on alerts)
- Theft group involvement (activated on specific reports, in consideration of the risk factor represented by the accumulation of large quantities of drugs of interest to other markets)

The direct intervention by the AIFA was substantiated by a series of specific actions, outlined below for types and examples:

- Import authorization for structures: between January and March, the "import authorizations for shortages" issued to territorial structures have more than doubled.
- Determinations for import by companies: "import determinations for shortages" issued to MA holders were the main tool for managing COVID shortages during the crisis, increasing in number by an order of magnitude.
- Search for Italian and foreign suppliers for products that are more difficult to find.
- Contacts with other administrations for the resolution of specific problems (Central Narcotics Office of the Ministry of Health for the import of products in the table, traceability system of the Ministry of Health for the traceability of imported products, civil protection)
- Administrative and logistical support for specific extraordinary imports by companies and associations
- Support for MA holders in terms of logistical interventions and regulatory simplifications required to ensure the availability of medicines (inclusion of pharmaceutical activities in productive continuity; management procedure Medicinal Oxygen; support for exchange of critical API suppliers)
- Assistance to MA holders and distribution operators interested in assisting with the procurement of specific molecules (Hydroxychloroquine, Lopinavir/Ritonavir, anesthetics).
- Contacts with the distribution network on specific issues (roundups, interruptions, refusals of drug distribution)
- Management of international relations: contacts with the European Commission regarding the activities in progress in Italy and the good practices defined and applied (for example, note to EC on regulatory flexibility in medical gas filling), extraordinary initiatives for non-standard cases (for example, import of experimental drugs from third countries through diplomatic contacts, transport and distribution of donations from third countries, report to EC on good practice in Italy, report to HMA/WGEO on traditional Chinese medicine products found in the distribution network)
- Contacts with foreign countries for mutual support on current and future deficiencies (support to French and Israeli contacts on midazolam supplies; discussion with EMA/Health Canada/WHO of the risks of shortages for specific drugs produced in Italy)
- Contacts with the production network for reports from Civil Protection and other administrations outside the health circuit

DETAIL ON SOME OF THE ORGANIZED ACTIVITIES

SINGLE POINT OF BUSINESS CONTINUITY CONTACT. The AIFA, in collaboration with Assogenerici and Farindustria, has created a "single point of contact" for the management of the shortages caused by the COVID emergency. In this way, it has been possible to create coordinated public-private actions with evident results in terms of the speed of response to the requests of the regions. These were in turn urged to address the demands of the territory and to speak with the aforementioned working group of AIFA-entrepreneurial associations. This model, which has the same system as that later used by EMA/EC with the "creation of the network of industrial contact points" subject to press release at the end of April, has allowed to intervene in real-time with emergency supplies to all the requests of the territory, with the only limit being the different reactivity between the various regions.

OPERATIONAL SIMPLIFICATIONS. The AIFA, in agreement with the Ministry of Health, the European institutions, industries and regions (depending on the areas), has managed emergency simplification processes compared to procedures that would have risked slowing the flow of essential medicines to our network: interventions with regard to drug labeling, import of narcotic active ingredients, extraordinary releases of lots (oxygen with containers in accordance other than those of the dossiers, drugs analyzed, or products with variations compared to the MA) have ensured the continuity of the availability of essential medicines, and have been managed in a tracked manner and with full protection of patients.

IMPORTS. In view of the shortages related to medicines for the treatment of COVID patients, the AIFA has streamlined the modalities of importing medicines from non-EU countries. To facilitate the understanding of the methods adopted, they have prepared a "vademecum" that provides for four types of imports that cover the cases where the MA holder amounts to medicines that are also in Italy but with foreign packaging, that the holder acts as an importer or that the imported does not have an Italian analogue, and that, in both cases, it is narcotics. The framework of the applicable procedures was then summarized in a text proposed as an order.

MANAGEMENT OF THE DISTRIBUTION OF DRUGS IN SUPPORT OF CIVIL PROTECTION AND THE GOVERNMENT COMMISSIONER. In agreement with civil protection, joint actions have been launched that have ensured the effective distribution of products to the regions and encouraged the resolution of operational issues resulting from extraordinary interventions of the Government Commissioner, effectively managed and shared at the institutional level, allowing to avoid critical issues for patients and difficulties with foreign administrations and companies.

DEVELOPMENT AND PUBLICATION OF PROCEDURES AND CRITERIA FOR THE DISTRIBUTION OF DONATIONS OF MEDICINAL PRODUCTS.

The AIFA has set up a procedure for the donation of drugs for the COVID emergency with the criterion of distribution among the regions based on the data of the current month's civil protection in relation to the total number of infected, hospitalized, in intensive care unit, and home therapy. These criteria, shared with the pharmaceutical representatives of the regions, have guided the distribution in the territory of millions of doses of critical drugs (such as hydroxychloroquine and propofol), donated by pharmaceutical companies and others: the

documentation on criteria and donations was also published on the AIFA website (<https://www.aifa.gov.it/donazioni-emergenza-covid-19>).

ACTION AGAINST EXPORT BLOCKADES. Following the letter with which Assogenerici had asked the AIFA to intervene with foreign governments to unblock the export of active substances of interest in relation to the pandemic, the AIFA contacted the Diplomatic Advisor of the Minister of Health to activate, through the Ministry of Foreign Affairs, the Italian Embassy, which intervened by releasing the supplies in question.

REQUIREMENTS. The AIFA has prepared, in agreement with the industries, the collection of the needs of the drugs connected to the COVID emergency through the "community of experts" of the regions; the result of the research will provide practical support to the programming of the production and possible imports of drugs considered at risk of shortage.