Pan American Health Organization
Regional Office of the World Health Organization

Guidelines for the Development of Pharmaceutical Services in Primary Health Care

Washington, June 2011.

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ACKNOWLEDGEMENTS

The drafting of this document began since the year 2008 with the coordination and support of the Pan American Health Organization/World Health Organization (PAHO/WHO), Medicines and Health Technologies Project (MT) in the area of Health Systems and Services based on Primary Health Care (HSS).

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The production of this document had its beginnings in the workshop on "Pharmaceutical services based on Primary Health Care (PHC)", carried out with the financial support of the European Community and the technical support of PAHO/WHO, from March 31, to April 2, 2009, in Santo Domingo, Dominican Republic. The objective of this event was to set out the framework for the establishment of regional guidelines for the development of pharmaceutical services as an integral part of health services based on PHC. Nineteen professionals from different countries participated in this meeting, among them, doctors, pharmacists and nurses, from Ministries of Health, Social Security, Academy, Non-Governmental Organizations (NGO) and PAHO/WHO. Their key collaboration and contributions achieved the objectives.

The Coordinating Group established task forces with other professionals for the development of the Guide to Pharmaceutical Services in Primary Health Care. These involved, namely: Alexander Suazo – Primary Health Care Chief, *Ministry of Health, Dominican Republic;* Gemma María Elizondo Herrera, *Sub-Chief, Pharmacy, National Geriatric Hospital*, Dr Blanco Cervantes, *CCSS;* Marta Nelly Cascavita, *Farmacia y Suministro Ltda, Colombia;* Ilvar Muñoz, Lecturer,

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Two versions of the document reviewed in meetings held respectively in San José, Costa Rica from November 18-20, 2009 and in Porto Alegre, Brazil from May 21-22, 2010.

This document is available in Spanish and English. The contribution of Astrid Alvarado in the review of the Spanish version; the funding for translation into English from the European Union (EU), through the EU/WHO Africa, Caribbean and Pacific Islands (ACP) Partnership on Pharmaceutical Policies and contributions from Adriana Ivama, PAHO/WHO CPC Office for the technical review and Tassia Williams, intern on Medicines and Biologicals at PAHO/WHO CPC Office in the proof-reading of the English version are also acknowledged.

INTRODUCTION

"Nunca el mundo fue tan avanzado tecnológicamente, tan comunicado y al mismo tiempo nunca fue tan desigual en lo social y en lo económico, albergando tanta opresión".
Amartya Sen
"Never was the world so technologically advanced, so interconnected and at the same time never was it so unequal socially and economically, harbouring such oppression".
Amartya Sen

In 2007, when Dr Margaret Chang assumed the post of Director-General, the World Health Organization (WHO), made the commitment to work on Primary Health Care (PHC). Thus, there was the recognition from their constant requests, that Member States have a heartfelt need for health care systems that are more equitable, integrated and fair, with a more comprehensive perspective on the efficiency of the entire health care system [3]. The 61st World Health Assembly, through Resolution WHA._62R_12, reinforces this commitment with a decision by Member States to continue working on strengthening PHC-based health care systems and on a specific mandate to the WHO to support the countries facing this challenge.[4]

In that same year, the Pan American Health Organization/World Health Organization (PAHO/WHO) presented the position paper on "Renewing Primary Health Care in the Americas" [5], after a long process of drafting and consultation with the countries of the region. This document offers a perspective and a renewed vision for the development of health care systems: that of health care systems based on the principles of PHC. In addition to declaring 'in force' the values of: *the right to the best possible standard of health, equity and solidarity, the principles of social justice, sustainability, intersectoriality* inter alia, it proposes to put the strategy on par with the context and current commitments, particularly those derived from the Millennium Development Goals. In addition, to engage the social determinants of health with a view to achieving the highest standard of health [5].

The recent adjustment to the organizational structure of the PAHO/WHO, with the establishment of Management of Health Care Systems based on PHC, shows the Organization's strong commitment to this new approach. The Medicines and Health Technologies project takes its place in this new Management as one of the central components of health care systems.

Specifically in the area of medicines, despite the major efforts made at the global level to ensure access to essential medicines (EM) of guaranteed quality and to the wide dissemination and incorporation of national policies on medicines, with the EM as its fundamental pillar, a large sector of the world's population still does not have access to these essential medicines. Paradoxically, never before have there been so many international resources for medicines, but

the use of those resources follows the same rationale, focusing on the provision of medicines, with a fragmented and segmented focus of health care systems. This leads to inequalities in the access to medicines, to wastage and irrational usage and inadequate supplies of medicines, by those prescribing them and the population, and to health, economic and social consequences.

Due to this reason, there is the need for changes in the approach of the medicines policies and strategies, which until now have been centred on the *medicine* product. The new vision is oriented to the individuals, families and the community (IFC) and their health needs. One must strive to guarantee the comprehensive, integrated and continuous attention to the health needs and problems of the population, both individually and collectively, holding medicine as one of the essential elements, and contribute to its equitable access and rational use.

The values, principles and elements of PHC represent an excellent opportunity to discuss pharmaceutical services, which implies deep reflection on the way persons did work in the last 30 years and the current opportunities to develop quality pharmaceutical services as an integral part of the health care systems and services.

This document presents a proposal for *Guidelines to Pharmaceutical Services based on Primary Health Care*, with a new approach focused on the IFC, where medicine is one of the essential elements, not the only one.

The process of development of these guidelines began following discussions in the PHC Working Group (WG) established by PAHO/WHO, whence came the proposal to develop PHC as a mainstreaming topic, with the incorporation of all the technical areas of the Organization. After the meeting of this Group in August 2008, the Essential Medicines and Biologicals Project (now the Medicines and Health Technologies Project) set out the Terms of Reference for the drafting of a position paper on PHC-based pharmaceutical services. The creation and development of which was entrusted to a Working Group on PHC-based Pharmaceutical Services (WG PS/PHC), made up of pharmaceuticals and PHC experts. These experts came from different sectors like Academia, Ministries of Health, Pharmaceutical Organizations, NGOs working with medicines and PAHO/WHO Advisors.

At the meeting held in the Dominican Republic (April 2009), the WG forged a consensus proposal with respect to the mission, vision, definition and roles and functions of pharmaceutical services which formed the base of the subsequent development of the guidelines, reviewed at the workshops held in Costa Rica (November 2009) and Brazil (May 2010).

The document begins with a background on both PHC and pharmaceutical services. Next, it reflects on the need to change the approach to pharmaceutical services, indicates the direction in which the change should take place, reasons for choosing the principles and proposals of PHC as a model for change and the identification of the critical factors for its implementation. The following chapters outline the development itself of the guide, which begins with the strategic framework: vision, mission, principles and values, roles and functions of pharmaceutical services, and continues with its elements, responsibilities and strategies for implementation of the proposal.

Four conceptual frameworks make up the core of the document: a) philosophy based on PHC proposals; b) operational aspects of the PHC-based pharmaceutical services as part of integrated networks; c) for management purposes, management by process suggested, and; d) pharmaceutical practice based on the concepts of pharmaceutical care.

For the development of the proposal, the best existing practices in some of the pharmaceutical services activities, sought. However, one must bear in mind that this is a process of reflection and collective building, and that a complete and validated model does not exist. Therefore, it is necessary to make use of feedback from the experience, which should be documented and disseminated.

The aim of these guidelines is to support the countries of the Region on the implementation of PHC-based pharmaceutical services. Ministries and departmental or state secretariats of Health, by the academic community, NGOs and all those organizations in civil society that may be working in PHC with the renewed vision proposed by the PAHO/WHO, can use it. Since it is a work in progress, the document is dynamic and there is the expectation that the contributions of everyone will enrich it.

BACKGROUND

Primary Health Care

In 1978, at the Alma Ata Conference, the concept and foundations of Primary Health Care were established. Since then there have continued to be many achievements in healthcare. In the Americas, mortality rates have decreased by 25%; the infant mortality rate reduced by about a third; life expectancy has increased by 6 years; immunization has surpassed 80%, perinatal deaths have decreased by 35% and poliomyelitis has been eradicated from the continent [6].

However, in the same region, there still exist many challenges to overcome. For example, 27% (135 million) of the population (500 million in 2004) do not have regular access to basic health services. Of this population group, 120 million are limited for economic reasons and 107 million by geography; 685,000 children do not have the full range of vaccinations; 46% of the population do not have public or private health insurance (230 million), in the United States alone there are 44 million in this situation; 17% of births are attended by untrained personnel and 30% do not have access to safe drinking water and to basic sanitation (152 million) [7].

In the 1980s, while countries with strong economies organised their healthcare systems according to the social protection model, in developing countries, that decade was characterised by wide social reforms in response to the evident deterioration of the living conditions of large segments of the population. This widened even further the age-old gap between underdeveloped and developed countries [4].

In this decade, the health sector assumed a decided leadership role, engaging other social forces for making commitments on intersectoral improvement. This was done by the XXVII PAHO/WHO Directive Council with the Resolution that gave "*priority to that extremely poor segment of the population in urban and rural areas*", as an expression of the goal of health for everyone. Thus, ratifying in this way a more human-centred perspective in its concepts and thus deepening the contradiction with the tendency towards a system of aid perpetuated without any real achievements [8].

Because of the pressure for greater efficiency and lower health costs, countries have been developing reform processes in their health care systems since the 1970s. Although the principles of universality, equity and the ability to find solutions are present in many documents, they continue to pose a challenge, especially the extent of equity [9]. In the case of PHC, attempts to implement the Alma Ata proposals resulted in many places in an excessively simple interpretation of messages, with localised services that are not solution-based, focusing on the illnesses and not on people in their social context.

In 2003, the celebration of the 25th anniversary of the Alma Ata meeting was a chance to reflect on the results gained with the PHC strategy and to put forward an upgrade of the precepts of the strategy, set in the global context at the beginning of the 21st century. The recently named WHO Director General who pledged to redirect the work of the Organisation towards PHC

took up this proposal again in 2007. The 2008 World Health Report [10] and the resolution WHA62.12 on *Primary Health Care, including the strengthening of health systems* [4], are a product of this effort.

The 2008 World Health Report: "Primary Health Care. Needed now more than ever", aimed at justifying why it is necessary to approach PHC from a more ambitious perspective as a set of principles and values to direct the development of health care systems. It sets out the need to strengthen leadership and management of the PHC renewal process. There is a proposal for change from hospitalisation, marketing and fragmentation towards PHC and points out that for this, a series of reforms are needed: in favour of universal coverage, delivery of health care services, leadership and public policies [10].

It also proposes the establishment of a PHC coalition, aimed at guaranteeing harmonisation and realignment of the international cooperation strategies with partners and donors. In this regard, a network established to exchange experiences in PHC with universities and NGOs. Likewise, there is a convergence of global, regional and local movements, as a means of building synergies. Integration with the Millennium Development Goals [11] and the document "Closing the GAP in a generation" [12]about social determinants, are examples of this convergence.

In Table 1, taken from this document, the main modifications to the PHC proposal are summarised. The idea is to change from a specific approach of activities in the health services targeted to the poor, towards an approach that considers human rights, the social determinants of health, individual autonomy and as such their participation in health decisions, including those on organising the system [5].

Table 1. How the experience has changed the perspective of the movement in favour of PHC

Early attempts to implement PHC	**Current matters of interest for reforms in favour of PHC**
Wide access to a basic package of health interventions and essential medicines for the rural poor	Transformation and regulation of the current health systems, with the aim of achieving universal access and social protection in health
Focus on mother-baby health	Care of the health of all members of the community
Focus on lowering the number of diseases, especially infectious and acute ones	Integrated response to persons' expectations and needs, taking into account all the risks and relevant diseases
Improvement of hygiene, water supply, sanitation and sanitary education in villages	Promotion of healthier ways of life and mitigation of the effects of social and environmental threats to health
Simple technology for non-professional volunteer health workers in the communities	Teams of health workers that facilitate access to technology and medicines and their appropriate use
Participation in the form of mobilising local resources and health-centred management through local health committees	Institutionalised participation of civil society in the dialogue on policies and mechanisms for reporting
Services financed and provided by	Operation of pluralist health systems in a

governments with centralised, vertical management	global health context
Management of a situation of growing scarcity and decreasing resources	Guiding the growth of health resources towards universal coverage
Bilateral aid and technical assistance	Global solidarity and joint learning
Primary care as the antithesis of hospitals	Primary care as the coordinator of an integrated response at all levels
PHC is cheap and only requires a small investment	PHC is not cheap; it requires significant investments, but allows a better usage of resources than the other options

Source: 2008 World Health Report [3]

The Resolution of the World Health Assembly (WHA) 62.12 on Primary Health Care, including strengthening health systems [4], ratifies all the assumptions and proposals of the global report and emphasises four main areas of work. These areas are categorised as fundamental: a) to make up for health inequalities by moving towards universal coverage; b) to place the individual at the centre of delivery of services; c) to integrate health into public policies in all sectors; and d) to institute an integrating leadership in the governing mechanisms in the health sector.

In the Americas region, the Local Health Care Systems (LHCS), established in the 1990s as the "operational strategy appropriate for the application of the basic principles of primary care strategy and its essential components" and as part of these, the development of pharmaceutical services and the use of essential medicines was encouraged. Although the LHCS proposal was established as a focal point in the reorientation and reorganisation of the health sector in decentralisation and at the first level of care, they were not able to overcome the crisis at the time and achieve the expected goals [13].

The Americas region was also a pioneer in the revision of PHC; the main policy frameworks for the development of the work of a renewed PHC were:

- PAHO/WHO Resolution of the Directive Council (DC) 44.R6/2003: Primary Health Care in the Americas: Lessons Learned over 25 years and Future Challenges (2003) [14];
- PAHO: Resolution DC 46.13/2005 Regional Declaration on the New Orientations for Primary Health Care, Montevideo (2005) [15];
- Declaration: "Towards a health strategy for equity, based on primary health care". Buenos Aires (Argentina), August 17, 2007. [16];
- Panel "Addressing the Determinants of Health and Strengthening Health Systems" (2008) [17].

Similarly, the *Health Agenda for the Americas* [2], formulated and approved by the Health Ministries in the Americas, established a joint commitment between all the countries of the Region with a view to respond, during the next decade, to the health needs of the population. This also included rescuing human rights principles and values, universality, accessibility and inclusion, health equity and social participation. This agenda sets out ten areas of action necessary to overcome the situation, among which are included the use of knowledge, science

and technology, access to quality health services, including access to medicines, strengthening management and development of health workers.

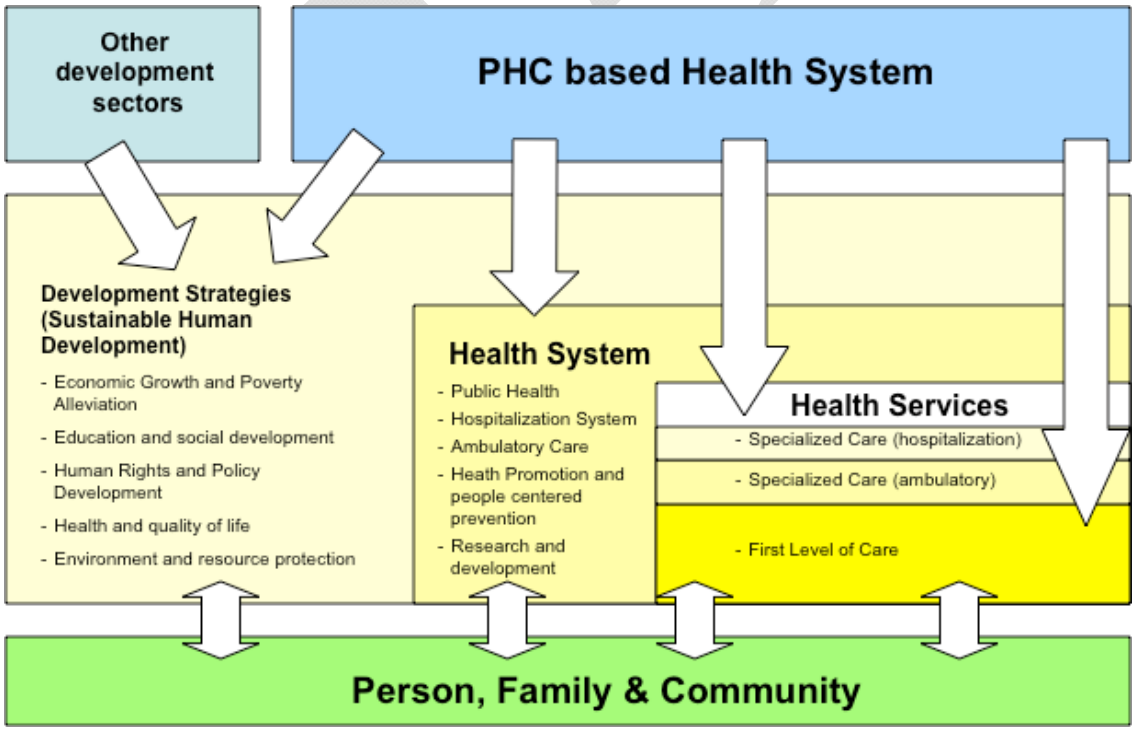
During the reorientation process of PHC within the region, a Position Paper [5] drafted, with wide consultations to define the programme directions and strategies for PHC. The drafting of the document relied on the participation of Ministries of Health, Social Security Institutions and Universities published in March 2007 with a wide distribution in English, Spanish, Portuguese and French.

According to PAHO/WHO, a PHC-based Health System involves a broad approximation to the organisation and the operation of the Health Systems that make the right to having the highest attainable standard of health their main objective, while maximising equity and solidarity.

In this context, it is essential to consider the health needs of the individual, the family and the community. PHC is a strategy for the organisation of health systems, but it is also the connection with other development strategies through intersectoral actions, like the promotion of healthy cities and spaces, environment and economy related education, health promotion, prevention of traffic accidents, healthy communities and basic sanitation, among others.

According to this renewed concept, PHC ceases to be understood selectively as the first level of care and is now considered strategically as a set of principles and values that guide the development of health systems [5, 18]. Figure 1 shows a representation of a PHC-based health system and allows the visualisation of how the levels of care work together with this strategy.

Figure 1. Representation of a PHC-led Health System



Source: PAHO/WHO. [19]

The values, like social goals, provide the base, the principles form the basis of health legislation, evaluation and generation/distribution of resources and the elements provide the structural and functional base for the programmes (operational). Figure 2 details and shows graphically the integration among those different components.

Figure 2. Values, principles and essential elements in a PHC-based health system

Source: PAHO/WHO, 2007 [5]

Following the position paper, there were a series of proposals developed that aimed to provide the tools for putting PHC in operation. Several stood out: a) the paper on "Integrated Health Care Service Networks" containing concepts, policy options and a road map for their implementation in the Americas [20]; b) strategies for the development of PHC teams, what the work teams are seeking to define, and to recognise the importance of multidisciplinary groups [21] and, c) Training in Medicine oriented towards Primary Health Care, that seeks to strengthen the capacities of future doctors to better understand their role in the face of the people's growing needs and to contribute to the development of PHC-based health systems. [2].

Also in 2008, the first course on PHC Renewal to develop PHC competencies was carried out, in which 88 policymakers, managers and providers from 20 countries participated.

Of the elements proposed by PAHO for the renewed PHC, the decision made was to detail some of them, due to their importance to its implementation**: first contact and comprehensive, integrated and continuous care**.

With **first contact**, attempts were made to guarantee a match, in every new instance, between user needs and the relevant services.

For **comprehensive care**, it is understood that the health system is organised to provide a range of services (including health promotion, prevention, treatment and rehabilitation) adequate to respond to health needs. For this, **integrated care** of available resources in the entire health system is needed, bringing **continuity** to the care, without interruption, of persons in the resolution of their needs over time and in different places, establishing a continuous link with the health team.

These elements reflect care centred on the person, not the illness, and seeks to cover all their health needs, reinforcing the importance of the actions of different disciplines within a team, since a variety of knowledge, skills, and practices were needed in order to offer care for all health needs.

The organisation of integrated health service networks (IHSN) facilitates the operation of PHC. Defined as [20] "a network of organisations that provides or makes arrangements to provide equitable and integral health services to a defined population, and that is ready to report on its clinical and economic results and on the state of health of the population it serves".

Pharmaceutical Services: from medicines to people

Since the creation of the World Health Organization (WHO), the constitution of which recognises enjoyment of the highest attainable standard of health as a fundamental right of human beings, medicines considered as priorities in attaining this right. Over thirty years ago, in 1977, was the launch of the concept of essential medicines (EM)[i] and shortly thereafter, in 1978, at the World Conference on Primary Health Care in Alma Ata, EM considered as one of the eight elements necessary to achieve the goal of health for all.

Since then, EM has made up one of the pillars of the formulation and implementation of national pharmaceutical policies, with a public health and legal approach. During this period, numerous efforts have been made and major resources invested, by both the countries and the different international organisations and financing agencies, to guarantee access to essential medicines in health services. In this first instance, there was the accomplishment of work from the perspective of providing medicines without yet having a concept of pharmaceutical services.

The conference of experts in Nairobi in 1985 defined the concept of Rational Use of Medicines as one where *"patients receive medicines appropriate to their clinical needs, in the dosage corresponding to*

[i] According to the last definition in 2002, essential medicines are those that satisfy the priority health needs of the population; they are selected bearing in mind prevalent illnesses, evidence of safety and efficiency and comparative cost effectiveness. Essential medicines must be available in the health services at all times in adequate quantities in the appropriate pharmaceutical forms with guaranteed quality and at a price that individuals and the community can afford.

their individual requirements, during an appropriate period of time and at the lowest possible cost to them and the community"[22].

This concept represents a framework of performance, in the sense that it outlines very clearly that it is not enough just to provide medicines. It is also necessary to use them appropriately and for this, there is the need for the reorganisation of services.

Several projects and initiatives developed in recent decades in low-income countries with the objective of improving the health situation and broadening access to medicines. However, this continues to be one of the greatest challenges. Although the WHO reports that between 1977 and 1997 there was a significant increase in the number of persons that had access to essential medicines [23] , a large segment of the population still does not have access to those medicines according to what can be deduced from the few available studies [24] [25].

Even when there is access, it is not equitable and achieved at a cost to households, as shown in the studies carried out in 21 countries in the region in 2008, which shows that the households themselves paid for 78% of total expenses on medicines. The differences between the countries were very significant: as the out of pocket expenses per capita for medicines in Brazil was US$152. Argentina, had US$163, more than twice the cost observed in Central America and the Andean Region, with less that US$70, and more than 20 times the cost observed in Bolivia (US$7.50) [26].

Regarding equity in access to medicines, the studies available from three countries: Honduras, Guatemala and Nicaragua, show that the probability of being excluded from access to medicines increases when there is exclusion from health care. This probability varies between 6.1 times in Nicaragua and 3.7 times in Guatemala, with Honduras' figures (5.3 times) lying in the middle. The same study identified the social determinants related to access to medicines and health services, showing a major inequity, with illiteracy, unemployment, lack of health insurance and socioeconomic situation being factors in what determines exclusion or self-exclusion from both services. [24].

Other problems observed in several countries, refer to the lack of coordination among different agencies and donors, fragmentation and segmentation of the supply systems that compromise their sustainability and the orientation of those systems towards activities related to the product and its distribution and not as much to rational use.

In search of strategies that allow a change in this vision, since the WHO is making efforts to bring pharmaceutical policies and health systems and services closer together. Access to medicines and technologies clearly defined as one of the six building blocks to strengthen health systems [27].

The Millennium Development Goals (MDG) represents an important framework for the coordination of intersectoral work. Six out of the eight MDGs, seven out of the 16 objectives and 18 out of the 48 indicators relate directly to health, although in a broader sense, they all have a relation to health. Specifically, Objective 17 establishes that "In cooperation with the pharmaceutical companies, giving access to essential medicines in developing countries". Although this objective focuses on the product, it is quite relates to the development of PS.

The WHO strategy on medicines for the period 2008 – 2013 incorporates the orientation towards PHC and sets out as a priority making use of scientific and operational evidence to support the renewal of PHC and the increase in national PHC programmes through the identification and promotion of best practices. The selection of EM based on evidence remains the cornerstone for supply, financing, refunding, quality insurance and rational use of essential medicines in PHC [28].

Conceptual framework of pharmaceutical services at the global level

Referring specifically to **Pharmaceutical services**, in the 60s, the United States, in the hospital setting, developed the concept of clinical pharmacy, related more to the professional practice and focusing on medicine and individual therapy. It is defined by the American College of Clinical Pharmacy (ACCP) as *"a discipline of health science in which pharmacists provide care to patients that optimises therapy medicinally and promotes health, wellbeing and prevention of illnesses"*,[29].

A critical review of clinical pharmacy brought some pharmacists to identify that the principles that said everything should have the patient as the focus were not successful, so the majority of pharmaceutical practice was directed towards the health team and the medicine and not to the interaction between the pharmacist and the patient. In this context, Hepler and Strand [30] proposed a new form of pharmaceutical practice defined as ***pharmaceutical care*** (PC), or, the *"responsible provision of pharmacotherapy with the aim of achieving specific results that improve the patients' quality of life"*.

Meanwhile, the WHO, after a series of meetings, developed the Series on "The Role of the Pharmacist in the Health Care System", considering this professional as key to the development of pharmaceutical services in the context of health care systems.

At the first meeting in New Delhi (1998), discussions held about important topics, such as the field of operation for the pharmacist in the area of health [31].

The second meeting in Tokyo, Japan (1993) [32] on the role of the pharmacist emphasised the importance of "contributing to satisfying the social need to have available effective, safe and economical health care", in order to minimise "the negative effects on the patient and community". It also highlighted the importance of the "team work method", which is vital if one wants to obtain an optimal performance from limited resources – both human and financial – to meet the care needs of any country" [32]. Similarly, in this meeting, the concept of Pharmaceutical care proposed by Hepler and Strand in 1990 was ratified [30] and the Declaration of Tokyo drafted.

In that sense it considered Pharmaceutical care is defined above, as:

A sum of attitudes, behaviours, commitments, concerns, ethical values, functions, knowledge, responsibilities and skills of the pharmacist in the delivery of pharmacotherapy, with the objective of achieving definite therapeutic results in the health and quality of life of the patient.

But this was not enough for the pharmacists' practice in the context of health care, so the following was added: "*Although this definition focuses on the chemical therapy applied to the patient, the Group preferred to extend the character of the recipient of pharmaceutical care to the public in its totality and at the same time to recognise the pharmacist as a health care provider who can actively participate in the prevention of illness and the promotion of health, along with other members of the health care team. Therefore, in this report, the functions of pharmacists are divided into those that refer to the patient and those that relate to the community.*"

The recommendations of these two meetings gave the input for the approval of resolution WHA 47.12 of 1994. This is about the role of the pharmacist, where pharmacists are asked to collaborate with the objectives of guaranteeing quality, access, and rational use of medicines, and to give support to the development of pharmaceutical care. Also, Member States and pharmacists' associations are to define the role of the pharmacist in health care and make better use of their skills in the health system; and the WHO Director General was asked to support countries in developing pharmaceutical services and regulation of medicines [33].

The third WHO meeting on the role of the pharmacist held in Vancouver, Canada in 1997, is of great importance because the knowledge and skills a pharmacist should have were discussed and established, specified as "the seven-star pharmacist". Discussions held on the need to change pharmacists' basic education [34].

As a tool to put this mission in practice, based on the development of pharmaceutical education and practice, the paper: *Developing pharmacy practice: A focus on patient care* [35] was drafted by the International Pharmaceutical Federation (IPF) in collaboration with the WHO.

Development of pharmaceutical services in the Americas region

In the Americas, discussions on pharmaceutical services form part of the discussions generated in the context of the Local Health Care Systems (LHCS). In this sense, the PAHO/WHO called a meeting of experts in Quito in 1989 where they discussed the topic of medicines in LHCS. Their conclusions became an important reference for the development of medicines policies and strategies to organise pharmaceutical services, aiming the guarantee of access to quality and safe essential medicines, which today is still considered to be relevant [36].

In that same meeting, a definition of **pharmaceutical services** approved, is as follows:

Pharmaceutical services are an integrating part of health services and programmes and represent a process that includes:

- Supply of medicines at each and every one of the constituent stages;
- Maintenance and control of quality;
- Safety and therapeutic effectiveness of medicines;
- Follow-up and evaluation of usage;
- Procurement and dissemination of information about medicines; and

- Life-long learning in the other members of the health care team, the patient, as well as the community to ensure the rational use of medicines [36].

This definition focuses on the curative aspects and a review in the context of the renewed PHC strategy was considered necessary.

In Central America, Ara and Marchand [37] reported that in the specific case of Primary Health Care and the use of essential medicines, the *"articulation between training technical personnel and keeping staff in the health services trained is based on the fact that part of the specific work is immersed in the experience of users. In their demands in terms of needs, there is knowledge and skills for better care* (and self-care) *of the population that assumes therapeutic responsibilities at the local level.*

Colombia, meanwhile, started a movement for the conceptual and methodological development of pharmaceutical services, as well as the development of practical applications. This was with a view to integrate those concepts and methods in the set of actions in health care and within a new ethic of social responsibility. Thus, confronting attitudes that then, as even now, dominated by concepts based on health care routine and market ideologies, incapable of making proposals of wide coverage for the population [38].

In Costa Rica [39], in the Andean region [40] and later in other parts of the Americas Region, the implementation of the supply of medicines seen as scientific practice. It dealt with in its complexity and integrity as a system, a demand to access full knowledge of its dynamics and from there to apply concepts and methods to its implementation in a specific social scenario: the health care systems and within these, the pharmaceutical services, a demand for accessibility to the most essential services.

In Brazil, there was the incorporation, of the strengthening of ***pharmaceutical services*** (Assistência Farmacêutica) [41] into the framework of the national policy on medicines (1998) as one of its essential guidelines. This initially, was to have an action setting similar to the PAHO definition of pharmaceutical services. In 2004, there was already the revision and incorporation of this concept into the National Policy on Pharmaceutical Services (BRASIL, 2004) with the following definition:

> *Pharmaceutical services must be understood as a public policy that paves the way for the formulation of sector policies, which should include policies on medicines, science, and technology, on industrial development and on human resource training. Among others, therefore guaranteeing the intersectoral aspect inherent to the country's health care system (SUS) and whose implementation involves both the public and private health care sectors.*
>
> *Pharmaceutical services cover a set of actions directed towards the promotion, protection, and recovery of health, for the individual as well as the society, using medicines as an essential supply and seeking to achieve access to and rational use of them. This set of actions includes the research, development and production of medicines and health supplies, for their selection as well as the programming, procurement, distribution, dispensation, quality guarantee of products and services, and the follow-up and evaluation of their use, in the perspective of...*

What we can extract from this historical review and proposed concepts, are different orientations and a comprehensive area of work, first having medicine as an end-goal, then as a health supply and finally as a tool to improve the quality of life.

During the aforementioned workshop held in Santo Domingo in 2009 on PHC-based Pharmaceutical Services [42], an analysis of Deficiencies and Strengthens was carried out. There was the identification of progress made in several areas of pharmaceutical policies, such as the strengthening of regulations in different countries, the development of strategies to improve access, the strengthening of medicine storage systems and strategies for promoting rational use. However, it also pointed out weaknesses and challenges to be confronted, such as:

- Lack of guarantee of universal health care coverage, including coverage for medicines;
- Lack of clarity about the concept of pharmaceutical services by health professionals and renewed PHC;
- The orientation of health policies is directed towards the product;
- Insufficient human resources in pharmaceutical services, as well as inequitable allocation, especially of professionals trained for the paradigm shift;
- Practical training of pharmacists oriented more to the product than to the Health Care System, making team work and integration into the community more difficult;
- Weak steering role to deal with fragmentation/verticalisation of the health care system, which has a great effect on PS;
- Scarce infrastructure and equipment;
- In many countries, the legislation considers the pharmacy as a business and not a health service;
- Actors, mainly donors, with a "medicines" oriented rationale with resources most of the times oriented towards the products;
- Distorted commercial advertising, replacing pharmaceutical advice, leads to challenges with the rational use of medicines;
- There are no financial resources to implement a model for PHC-based pharmaceutical services;
- Prevailing culture among patients who only believe doctors and hospital centres.

The Santo Domingo meeting was a milestone in this process since it allowed for a deep discussion on the situation described above and on the results shown in the few available studies, as well as on the rationale of the pharmaceutical services (PS) in recent decades. Nevertheless, they also analysed, in a constructive way, the opportunities to develop quality PS as part of the health care systems and services, sharing the foundations and principles of renewed Primary Health Care, as well as the proposed instruments for developing health care services.

CHANGING THE PHARMACEUTICAL SERVICES

"If you want different results
do not do the same thing"
A. Einstein

Challenges to change

"The growing expectations of society for health and health care, means a demand for services that are more focused on the IFC, a higher quality of health care within the community and a more effective participation in decisions" [4]. Therefore, changes to pharmaceutical services also have to fulfil these expectations.

We live in a globalised and 'post-Modern' context, with structural changes and the difficult balance in the face of many contradictions. Beck [43], in this context launches the concept of "risk society." According to this author, we are faced with the contrasts of modernity and industrial society, production of riches and risks, inequity, disasters, illnesses and so many other global threats and different political and social dynamics.

In these times, the risks are different, going further beyond our possible sensorial perception [43], like, for example, the physical-chemistry formulas of toxic elements in foods, nuclear threats, pandemics, among others.

At the same time that we face recurring risks of overproduction, industrial development, and progress, we still have old risks, like hunger, poverty, inequity and a lack of access to health care (related to the processes of rationalisation and conflicts in social guarantees). The "new" risks transcend their place of origin, the dangers of very developed productive forces, of globalisation and the old institutions have difficulty absorbing and confronting them.

There is therefore a need to adapt the health care systems and the PS to the social trends that cause demographic transitions, to the economic crises and collapses and the multicultural societies, where forces of change are identified such as cultural and ethnic diversity, heterogeneous societies, and risks such as inequity, social exclusion and so many others.

Such forces demand recognition and different types of communication and action [44, 45], new technologies that convert the act of prevention, diagnosis, and treatment of illnesses into an art. Apart from this, biotechnological medicines are emerging (more than 600, a third of them for cancer, a quarter for infectious diseases, the immune system and AIDS, to cite a few), as well as the development of new technologies for the search for active principles, including advances in genomics [46].

Whither change

This is not simply about change, but changes designed to face the problem described and the challenges outlined.

Elimination of difficulties in access

The PAHO/WHO [47] recommends the identification of the limitations to accessibility, interaction and the achievement of consensus for their elimination. It is proposed that pharmaceutical services be reoriented in such a way that they contribute to the **elimination of barriers caused by social determinants of access** to health care, while confronting difficulties of socioeconomic, geographic, socio-cultural and of course organisational order. PS must be a right for all strata of society, both in the urban centres and the rural areas, without the ability to pay being a restrictive factor.

Incorporation of pharmaceutical services as components of national pharmaceutical policies

For this, it is essential that the incorporation of pharmaceutical services be a key component of **the national pharmaceutical policies and regulatory frameworks**. Their updating and adaptation would therefore be necessary.

Thus, equal access to PS must be included at the starting point of the formulation, implementation, and evaluation of public policies in the field of pharmaceuticals, as an integrating part of the health policies and of the social macro policies, guided by PHC. It is equally important to involve the different actors, in an intersectoral way, incorporating the different levels of health care, considering the integrated and integral networks of health care services.

On the other hand, regulation must also have a different rationale, once it is necessary to broaden or incorporate a component of regulation of services (mission, function, activities and necessary conditions) and not only focused on medicines and the establishments that make, consign, distribute and dispense them.

Although the pharmaceutical services do not have a direct responsibility in the design and implementation of some of the strategies of pharmaceutical policy, they require the development of those strategies in the countries. Some are key in the success of the services, for example: the strengthening of the regulatory authority, the regulation of prices, the implementation of strategies for generic medicines, the implementation of public health strategy, innovation, and intellectual property and the collective purchase of medicines.

Pharmaceutical services (PS) based on the individual, family, and community

For the reorientation of this model, it is essential to understand that the expression of PS at the local level in the **health care facility** and based on the individual, family, and community, with the understanding of the biological and social determinants of health, instead of the hospital and illness.

Quality PS must begin with an appropriate diagnosis, prescription based on evidence, with the choice of the most appropriate medicines, at the appropriate dosage; the **quality of**

dispensation, providing the information and support to achieve the therapeutic objectives for the patient, including not only the rational use of medicines, but also the promotion of healthy lifestyles and self-care.

For this, consideration must be given, not just knowledge about medicines, their pharmacology, International Non-Proprietary Name (INN) or generic names, concentrations, instructions to patients on the how to take them, but also to the socio-cultural context, the social determinants and health illness process and the quality of the **processes** and of the **pharmaceutical products**.

Management with comprehensive and integrated care, committed to the achievement of health care results

The rationale of changes to the management of PS must be lead to them to provide comprehensive and integrated care to those who need it for the promotion, recovery, and preservation of their health. Therefore, management and planning of PS, as part of IHCSN, must take into account the perception of reality of each one of the social actors, seek to interpret this report and based on that, design future scenarios of change. The IHCSN can give sustained care, both preventative and curative over time and at different levels of the health care system.

Training of Human Resources for PHC-based PS

It is impossible to promote the reorientation of the PS model without the reorientation of training and life-long learning for human resources; a human resource, that should be familiar with the socio-cultural and economic context, with the topics related to policy making, regulation, management and service delivery in the health care and pharmaceutical services.

In this new human talent will live the transforming force of these pharmaceutical services and the same health care systems that they change with their direction and leadership. That is why it is required that pedagogical projects for pharmaceutical careers be able to reconcile knowledge, abilities and attitudes, in such a way as to train these professionals to develop and place existing technologies at the service of the health and well-being of the population.

This professional must be capable of providing service, making decisions, communicating, being a leader, manager, life-long learner, and educator [34]. He/she must be able to work in teams, as interdisciplinary and intersectoral cohesion is paramount. To this end, educational institutions must promote life-long learning, with adequate conditions and resources, using active methodologies of teaching and learning, with a highly qualified staff.

The background presented in the previous chapter that clearly describes the problems identified, along with giving an outline of where PS should go, also allows for the establishment of the path to arrive at the desired situation, as shown in Table 2.

Table 2. Frameworks of the change in pharmaceutical services towards the renewed PHC principles.

No	Current situation	Desired situation
1	Individual, incomplete and fragmented care	Comprehensive and integrated care of the individual, family and community, humanised and committed to attaining health care results
2	Care focusing on the illness	Care focused on health, including promotion and prevention
3	Pharmaceutical service focused on medicines	Pharmaceutical service focused on IFC
4	Periodic care	Continuous care
5	Individual work	Working in teams
6	Unequal access to pharmaceutical services	Equity and universal coverage
7	Difficulties in geographic access to pharmaceutical services	Better distribution of health care networks
8	Inefficient, segmented and fragmented supply systems,	Single Supply System
9	Same service for everyone	Service adapted to patient needs
10	Segmented and fragmented services	IHCSN services
11	Lack of protocols	Definition of norms, guides and processes
12	Insufficient human resources in quantity and quality	Adequate and sustainable human resources
13	Product-centred professional training	Service-centred professional training
14	Product-centred policies	Service-centred policies
15	High out of pocket expenses on medicines	Sustainable financing
16	Working exclusively with the health care sector	Intersectoral work

Source: own drafting

Critical factors to success (CFS) for the strengthening of PHC-based Pharmaceutical Services

For the implementation of PHC-based pharmaceutical services, the following CFS has been identified:

The theoretical and methodological reference and tools are fundamental for establishing a framework for the direction of the change and how to get there. To this end, this position paper and guidelines on the development of PS in PHC have been drafted.

As next step, it is essential to begin the process of **change management**, for which it is necessary to have institutional and political support. The support and involvement of governments, professional associations, health teams and the population, among other possible stakeholders. What is important to highlight here is not an isolated change, therefore, establishing alliances

with the stakeholders is fundamental. In the same way, it is a change that goes beyond the limit of pharmaceutical services and of the very health care services and systems. It is therefore necessary to promote intersectoriality. A key activity is advocacy of the new model and the validation of the proposal in relation to its feasibility and viability.

In the sense of promoting the institutionalisation of the change and creating the necessary mechanisms, it is essential to establish the **appropriate political and regulatory frameworks**, as well as the mechanisms for monitoring, evaluation and the mechanisms that guarantee their enforcement.

Human resources must be of sufficient numbers, with adequate competence and must be committed to the proposed changes. It is important that the pharmaceutical services (PS) have a team under the pharmacist supervision and this PS team can be integrated to other professionals and be part of the multiprofessional health care team. The services must have the resources, such as financing, infrastructure, and equipment, among others, necessary for implementing the proposed changes.

Finally, it must also be clear that the proposed path can take some time; it will require hard work to overcome possible conflicts arising from different interpretations of PHC. As PAHO suggests [19], it is necessary to strike a balance between the competing forces: care in health care units vs. hospital care; professionals who give general care vs. those who specialise; horizontal approaches vs. vertical ones; promotion and prevention vs. treatment and rehabilitation; public sector vs. private. For the pharmaceutical professional, the required transformation is also very deep and will definitely occur gradually, as there can be achievement in changing teaching and life-long learning with greater intensity.

PROPOSAL OF THE MODEL FOR PHC-BASED PHARMACEUTICAL SERVICES

The conceptual framework presented in this chapter serves as a basis for organising and understanding the elements of PHC-based pharmaceutical services. The information presented is therefore an ideal and desired approach, which must be adapted to each country according its conditions.

Definition, Mission, Vision, Values and Principles of PHC-based Pharmaceutical Services

Definition- Pharmaceutical Services

"Set of actions in the healthcare system that seeks to guarantee comprehensive, integrated and continuous care for responding to the health needs and problems of the population, both individual and collective; having medicines as one of the essential elements, contributing to their equitable access and rational use at health facilities. These actions, developed by the pharmacist or under his/her coordination, as part of a healthcare team, with community participation, aim to achieve defined health outcomes leading to improvement of the quality of life of the population."

Mission

Contribute to the individual and collective healthcare of the population, through the active involvement of the pharmaceutical staff as part of the healthcare team with the community. Comprehensive, integrated and continuous pharmaceutical services, committed with the achievement of the equitable access to quality medicines and other essential health supplies and ensuring their rational use, including alternative and complementary therapies, in a health system based on APS, to reach its highest level of health.

Vision

Pharmaceutical services, of social importance, integrated in the PHC-based Health Care System that respond to the needs of the individual, family and community, with well defined roles and functions that promote healthy lifestyles, access to and rational use of medicines, contributing to the right to the enjoyment of the highest attainable level of health.

Values

The right to the highest attainable level of health without distinction based on race, gender or religious, political, sexual preferences, or economic or social situation is expressed in many national constitutions and is outlined in international treaties, among them the founding charter of the World Health Organization (Fuenzalida-Puelma and Connor 1989). This means legally defined rights for citizens and officials of the State and other concerns, and in such a way as to achieve maximum efficiency and effectiveness, at the same time minimising possible harm to health. The right to health and other rights are irrevocably joined to equity and in turn reflect and help to reinforce social solidarity [48].

Equity as it relate to health care refers to the absence of different injustices in the state of health, in access to health care and to healthy surroundings, and in the treatment received in the health care system and in other social services. Equity has intrinsic value because it is a requirement for persons' capacities, freedoms and rights [49]. Equity is a cornerstone of social values: the way in which a society treats its less fortunate members reflects the value that it places on human life, whether explicitly or implicitly. To simply appeal to values or a moral conscience of society may not be enough to prevent or reverse inequalities in relation to health care. This means that citizens must be capable of correcting inequities through the exercise of their moral and legal rights to health care and other social rights. Making equity one of the central values of the PHC-based health care system, aims to ensure that the health care policies and programmes are pro-equity. The reason behind this position is not only to achieve a greater efficiency, cost-effectiveness or quality, but also, in a fair society, quality should be considered a moral imperative and a legal and social obligation [5]. *"Equity is the adaptation of a unique norm that does not allow a perfect levelling of expected cases (...)"*, the unequal treatment corresponds to recognition of the inequality of the situation" [50, 51]. In other words: adapting the provision of pharmaceutical services according to the need of the population.

Solidarity is the degree to which the members of a society work together to define and achieve the common good. In local and national governments, solidarity manifests itself in the formation of voluntary organisations and unions, as well as multiple other forms of citizen participation. Social solidarity is one of the means by which collective action can overcome common problems; health care and social security systems are mechanisms through which solidarity can be expressed between individuals of different classes and generations. PHC-based health care systems require social solidarity for health care investments to be sustainable, to provide financial protection and the spreading of risk, and to allow the health care sector to work together with other sectors and actors, whose cooperation is necessary to improve health care and conditions that influence it. Participation and reporting is necessary at all levels, not only to achieve solidarity, but also to guarantee that its maintenance over time [5].

Principles

The principles approved for the Renewed Primary Health Care are adopted for the Pharmaceutical Services[i], namely:

- Responsiveness to peoples' health needs
- Quality-oriented services.
- Government accountability
- Participation
- Sustainability
- Intersectoriality

Essential functions of pharmaceutical services

Initial reflections on the essential functions of PS

The proposed definition of pharmaceutical services has a direct impact on what the professional who deliver those services do. From a role with a marked emphasis on administrative tasks dealing with logistics of medicines and curative care, the direction of PS is required to move towards the PHC framework. In other words, it is required that the functions carried out and the new ones proposed focus on health and lifestyle, with IFC as the focal point. This approach is applicable to both public and private pharmacies, as well as to the health care systems in general wherever there is the provision of pharmaceutical services.

In the case of private pharmacies, it is an opportunity to reorient their role, integrating themselves into the network of services and into the health care systems in order to be an effective health care establishment. This orientation is practicable due to its wide availability and because it assumes the professional conduct of the pharmacist and his team.

In having PHC as a framework, PS must make a firm commitment to the values of PHC and specifically, as well laid out in the beginning of the paper, to the implementation of policies that promote equity of access to PS, whether described as socioeconomic, geographic, socio-cultural and or organisational in nature. This vision is in sync with the line of policies proposed by the WHO for the development of PHC, which identifies the need to make up for health care inequities, moving towards universal coverage, with the development of the integrated network of services [4].

In the case of public pharmaceutical services, it is also an opportunity to reorient their activities. They must have an idea of the epidemiology of illnesses in the population under their care,

[i] To see the meaning of each principle please refer to the document: **Renewing Primary Health Care in the Americas. A position paper form the Pan American Health Organization.** Washington DC, PAHO 2007. Available at: http://www.paho.org/english/AD/THS/PrimaryHealthCare.pdf

their bio-psycho-social characteristics and from there, they can plan logistics based on evidence-based pharmacology.

Pharmaceutical services must give emphasis to actions directed to the IFC such as dispensing, pharmacotherapeutic accompaniment and health education, among others; always having as the focus, the individual and collective therapeutic results. Wherever possible, private and public services require integration into the IHCSN.

Another group of functions in pharmaceutical services that traditionally have not undergone enough development is the **human resources** training for PHC-based PS, considering all the professionals involved in the different PS processes, not just pharmaceutical professionals and pharmacy assistants. Human resources must possess adequate attitudes, knowledge and skills, in addition to observe ethical norms, treating persons with dignity, and respect [2].

In conclusion, the traditional activities related to the logistical aspects of the provision of medicines form part of the services, but no longer as an end in themselves, but as a means to achieve the final objective of PS: the achievement of specific health care results with a view to attaining the highest possible standard of health for the population.

Roles and Functions

In a didactic manner, the functions and roles of PS have been organised on 4 groups that are summarised in Table 3 and described below.

Table 3. Roles and functions of PHC-based Pharmaceutical Services

1. Functions linked to public policies, organisation and management of pharmaceutical systems and services	a) Participate in and carry out the formulation, implementation and evaluation of pharmaceutical policies, within the area of influence of the service; b) Participate in the development and updating of the legislation and setting of norms for pharmaceutical services and complying with active legislation (including ethical/bioethical aspects); c) Plan, implement, manage and evaluate pharmaceutical services in ways that are integrated into the IHCSN and the health care system; d) Promote access, quality, safety and Rational Use of Medicines (advocacy); e) Administer and manage the supply of medicines and other essential supplies; f) Contribute to the protection of health and safety of the population and the environment; g) Manage the availability and promote rational use of medicines and other essential supplies in situations of disaster mitigation and prevention and sanitary emergencies;

	h) Implement and coordinate or participate in Pharmacy and Therapeutic Committees (selection of medicines) or other committees related to pharmaceutical services.
2. Functions linked to medicines	a) Formulate, compound and store extemporaneous preparations, parenteral solutions, reconstitution of cytostatics and other formulations required for the services; b) Repacking and carrying out the appropriate conditioning of medicines and other essential supplies; c) Implement the necessary measures to guarantee the quality of medicines throughout the supply chain; d) Implement the necessary measures for the appropriate regulation of waste from medicines and other essential supplies;
3. Functions directly linked to the patient, family and community, in service and in the community	a) Develop and support programmes and activities for prevention of illnesses and for health promotion, protection and rehabilitation; b) Dispensing medicines; c) Develop activities for the promotion of rational use of medicines aimed at the public and the other members of the health care team; d) Carry out pharmaceutical care, including pharmacotherapeutic follow-up; e) Develop and participate in pharmacovigilance programmes.
4. Functions linked to research and knowledge management	a) Participate in the design, monitoring and evaluation of clinical trials, promoting and respecting bioethical principles; b) Promote and participate in the design, monitoring and evaluation of health research; c) Manage, provide information and develop competencies related to medicines; d) Promote life-long education of human resources in pharmaceutical services and on health care teams.

Source: own drafting

Functions related to public policies and the organisation and management of pharmaceutical systems and services

a. **Participate and carry out the formulation, implementation and evaluation of pharmaceutical policies in the area of influence of the service**: PS should participate in and promote the formulation, implementation and monitoring/evaluation of policies, regulations, norms and protocols in the area of pharmaceutical services. Therefore, in the end contributing to knowledge and experience so that these policies give priority to the needs of the population, the priorities of the region and the weaknesses of the health care system as it relates to medicines and pharmaceutical services. PS should define its policy and regulations within the political and legal framework of the country and the institution in which it sets up;

b. **Participate in the development and updating of legislation and setting of norms for pharmaceutical services and complying with active legislation (including ethical/ bioethical aspects):** Although legislation and regulation are the responsibility of the regulatory area, PS should support this work and mainly comply with established norms, according to ethical principles and reporting;

c. **Plan, implement, manage and evaluate pharmaceutical services in a way that is integrated into IHCSN and the health care system**: with the definition (of an organisational and functional structure linked to the IHCSN) with goals to achieve of the necessary economic, technological and human resources. Also with, permanent monitoring of critical indicators to make necessary adjustments in the face of the permanent changes that arise in the healthcare system. The management of PS should be carried out with a view to guarantee access to, quality of and rational use of medicines. The coordinating pharmacist of the pharmaceutical service will be responsible for a management model and will have initiative and enough knowledge of the health care system in his country, with the aim of referring persons who seek his services to the different levels of care, according to their health needs. It is important that PS be integrated into the Strategic Public Health Programmes so as to avoid fragmentation or duplication of roles and wasting of resources;

d. **Promoting access, quality, safety and Rational Use of Medicines (advocacy**): It is a function of PS to influence decision-making processes, development and implementation of pharmaceutical policies for the promotion of access to, quality and rational use of medicines – one of the main functions of PS. It is related to the Coordination or Secretariat of Pharmacy and Therapeutic Committees, promotion to strengthen the use of generic medicines, carry out actions to avoid the influence of publicity and propaganda and promote rational prescribing, among other actions;

e. **Manage the supply of medicines and other supplies: Traditionally, the proposed system was maintained, which focuses on the supply cycle of medicines with their elements of**: selection, procurement, donations, storage and distribution, use and disposal. Here it is proposed to address supply using another organisational rationale, with a renewed vision, with a comprehensive and integrated approach into the IHCSN;

f. **Contribute to the protection of the health and safety of the population and the environment**: The regulation of these aspects is a function of the competent health authority. Every essential function of regulation serves to provide feedback to the others. PS should comply with active sanitation norms and contribute to the guarantee of quality, both of the products provided and of the protection of the health of its users, in an effort to minimise and avoid health risks. One of the main actions of feedback on the services towards regulation is the participation in pharmacovigilance programmes so as to identify, monitor, document and notify the ARN of any suspicions of adverse events related to medicines, contributing to the guarantee of sanitary safety;

g. **Managing the availability and promoting the rational use of medicines and other essential supplies in situations of disaster mitigation and prevention and sanitary**

emergencies: PS should assume its role of participating, collaborating in some regions where the presence of health care professionals is scarce. In addition, there is the need for involvement in leading the formation of teams for identification, prevention and care of disasters with active participation from the community. Through an effective management of donations of medicines, PS prevents other damages related to the use of products of questionable quality, due to, in the majority of cases, the storage and distribution conditions of the medicines.

h. **Implementing and coordinating or participating in Pharmacy and Therapeutic Committees (selection of medicines) or other pharmaceutical services related committees:** This is a function developed in collaboration with other Areas or Units, in some of them PS coordinates and promotes its operation; in others, its role is as participant.

Functions related to medicines

a. **Formulate, compound and store extemporaneous preparations:** This is generally done in response to an individual prescription as a way of resolving the problems of supply of some medicines that are not available as required, different from the industrialised or for seldom occurring illnesses. Some examples are formulations for paediatrics, products for dermatology, parenteral nutrition, cytostatic reconstitution and other injectable medicines in general, among others.

b. **Repackaging of medicines and other essential supplies**: For the adaptation of the quantity dispensed to the user, as well as directing them in the prescription. It is required to guarantee the efforts to preserve the quality of medicines, including user information and the prevention of errors in use.

c. **Implementing the necessary measures to guarantee the quality of the products throughout the supply chain**: This entails the operational conditions in the selection of medicines. Additionally involved are procedures to guarantee quality during the procurement and preparation, storage and distribution, the provision of information and supervision of the preservation of quality of the products during their time in the internal consumer units of the institution, to the home, supporting and educating the final users.

d. **Implementing the necessary measures for the adequate regulation of waste from medicines and other essential supplies:** Although this problem reduces to a minimum when there is adequate management, there is the need to regulate expired or spoiled medicines, or the waste from the production process. This procedure, if done inappropriately, carries a potential risk to the environment and people, such that pharmaceutical services should set out an appropriate plan for the regulation of waste, supporting, informing and educating other health care professionals and users about this procedure. That is one more opportunity to mobilise intersectoral action to achieve feasible mechanisms for disposal, taking into consideration local laws and conditions.

Functions directly related to individuals, the family and community, in central and isolated areas

These activities should be carried out in accordance with the different levels of care and complexity of services into which they are integrated, be they public or private. It is suggested that the introduction of PS into the different strategies of organisation and services delivery be explored and broadened, such as family health programmes and different services, delivery modalities as home care[i] services, among others.

a. **Developing and supporting programmes and activities for the prevention of illnesses and promotion of health to users and the community**: Promotion and participation in cross-cutting programmes for the promotion of health and healthy lifestyles and activities designed to obtain results in specific groups of users. Some examples are campaigns for vaccination, education on the use of medicines in schools, etc. These are the work methods explored and linked to different levels of care or carried out in an intersectoral way. It is important to have the focus in the health of the family and the community, strengthening social networks and empowering the community.

b. **Dispensing medicines**: As the routine activity, this needs accompaniment by the promotion of rational use of medicines to users and member of the healthcare team;

c. **Developing activities to promote the rational use of medicines to users and professionals**: PS has an important role in this area. Along with those two elements, information and counselling are crucial components in guaranteeing the rational use of medicines.

d. **Carrying out pharmaceutical care, including pharmacotherapy follow-up:** A set of activities that goes beyond the delivery of medicines and even their effect. It deals with the extent of health care objectives and the improvement in the quality of life of the population, including carrying out pharmacotherapeutic follow-up. In this function, in which professional interact directly with users; they must be aware of their role and the purpose of their job.

e. **Developing and participating in pharmacovigilance programmes**: PS should organise pharmacovigilance programmes within health care services, stimulating the participation of health care professionals and carrying out retroactive boosting of other professionals who carry out notification of the RAM. It is essential that institutional pharmacovigilance programmes be linked to the national ones and be in harmony with the regulations and activities developed by the National Regulatory Authority.

[i] Set of continuous activities, ambulatory in nature, that is planned and carried out in the home by a multi-professional health care team. In some cases, at-home interaction takes place, which is care of persons who are clinically stable, who require a level of care that goes beyond the ambulatory method but who can be looked after at home.

Functions related to research, production and knowledge management

a. **Participating in the design, monitoring and evaluation of clinical trials, promoting and respecting bioethical principles:** Pharmaceutical services should be capable of becoming involved in clinical trials of medicines. In some countries' legislation, this is part of the pharmacist's professional scope and in many institutions that carry out clinical trials, pharmaceutical services are responsible for preparing the medicines to be given to the patients and to compile data on use. Besides this, the PS is responsible for monitoring and control quality and safety of medicines, along with the other members of the health care team. Apart from the operational aspects, PS can participate in the design of the study, and in the analysis and interpretation of the data;

b. **Promoting and participating in the design, monitoring and evaluation of health research:** Perhaps the most accessible research initiatives and of most tangible credit for the services are related to the studies on the use of medicines, availability, access and the impact of interventions to solve problems, etc. Such studies are important sources of evidence for decision-making, both in the institutional and national context. They can contribute to improvements in the quality of service and care of the patient, as well as the reorientation of sectoral policies. The role of the pharmacists in these regard are highlighted in the manual on development of pharmaceutical practice developed by FIP and WHO [35];

c. **Managing, providing information and developing competencies related to medicines:** In this context, PS should generate information-based knowledge, adapting its language to receivers, whether they be patients, their families, other professionals or members of the health care team, without losing sight of the details of previous knowledge, culture and identity, making the receivers of the message participants and not objects. Through direct contact with persons who access services, in close connection with the members of the health care team, PS have the challenge of providing a dynamic updating of knowledge in relation to the health conditions of the patients and the therapies – not just pharmacological ones - adapting it to the local reality. In relation to this component, it is logical that PS function as object and subject as it relates to a life-long learning and evidence-based dynamic;

d. **Promoting life-long education of human resources in pharmaceutical services and the health care team[i]:** PS should promote training of the Service team in the areas related to the necessary competencies for excellent service provided. At the same time, contribute to the training and continued, life-long education of the other health care professionals in all the aspects related to the functions and activities of PS.

As it can be seen, the functions of pharmaceutical services are very broad; from administrative to clinical functions and they must be developed in the context of the health care systems. The level of execution depends on the level of complexity of the services; there are functions carried out by the pharmacists and his team, integrated into the health care system and others, as

[i] See Chapter "Human Resources as a factor for success in changing PHC-based PS". p. 54.

matter of necessity, along with other health care professions. The era of only *dispensing* medicines is an outdated practice in the framework of making the most of capacities to develop useful functions in society.

These functions, along with the mission, values, concepts and philosophy for change, are the basis of development of the model of pharmaceutical services outlined in the following chapters.

ELEMENTS OF PHARMACEUTICAL SERVICES

Management, service delivery to users and human resources, seen as central elements for changing and are discussed below.

Organisation and management

Initial aspects of the management of services and health care actions

It can be said that every change process and use of resources towards a specific purpose requires planning and management. In this section there is brief discussion about some of the general management principles and their importance, how management fills the work of health care professionals in their different functions, the importance of participatory management, general characteristics of a management system, and the main functions of management.

Once there is the understanding of management and achievements made, there exists the ability or capacity to use resources in the best possible way to achieve results. It is, therefore, a strategic process in all health care actions.

Therefore, all professionals need to know and practise management, since they require an optimal handling of assigned resources to carry out the proposed objectives, making decisions to resolve possible problems according to their level of autonomy. Where the managerial knowledge and abilities complement the role that each professional plays, a managerial or administrative level requires a higher level of knowledge and solid, structural managerial abilities, and a lower level of technical speciality; the opposite case is the professional who responds on account of his technical speciality. His managerial knowledge or abilities will be at an intermediate or operational level, but his technical knowledge or abilities should be at a higher level. (Figure 3).

Figure 3. Technical and managerial knowledge and abilities required at the organisational level of professional behaviour.

Management from an integrating and participative perspective

The different actors, from their professional, personal experiences and introduction into the system, have different viewpoints. There can be excellent current interventions and processes, but if they are not coordinated, the overall result may be disastrous. For example, if a known medical specialist decides to implement a modern and complex treatment, but does not coordinate with the available resources, the measures and support activities and continuity of the treatment, or the patients' conditions to access the necessary resources, the result will be the failure to achieve health results, as well as wasted resources.

One organisation is not definitively equal to the sum of its parts. It is important to have a known vision, mission, objectives and institutional policies that are within agreement. Specific work plans for every service should be synchronised with the others based on the strategic objectives of the organisation, which in turn aligns with the development plan of its town, province, municipality or country.

The organisation of the system based on IHCSN allows for the optimising and organising of resources and the care process, avoiding unnecessary and costly duplications. In the case of pharmacotherapy, we can take as an example the challenges faced to guarantee continuity of the treatment of a patient who is hospitalised and later returns to ambulatory care with a set of medicines that are unavailable in units at the primary level. Only the functioning of services in integrated networks will adequately address the problem. This means that the Network is responsible for guaranteeing results in a determined territory, where the health care resources of this area be planned as a whole, as well as the response to problems out of the reach of the territory. Similarly, many problems require an intrasectoral and multidisciplinary approach.

The traditional organisational structure of health care systems in the Americas should overcome the non-integrated arrangement of subsystems directed at specific strata of the population,

which has led to their further segmentation and fragmentation and has deeply affected their performance.

Management systems

In relation to the *management system*, there are different approaches. An exhaustive presentation is outside of the scope of this document. The decision made to present the proposal for management by process by considering that it brings important contributions to health care work; most of all to the change that is proposed.

The SESCAM *[Health Care System of Castilla-La-Mancha, Spain]* [52] systematised the main differences between traditional or functional management and management by processes (Table 4).

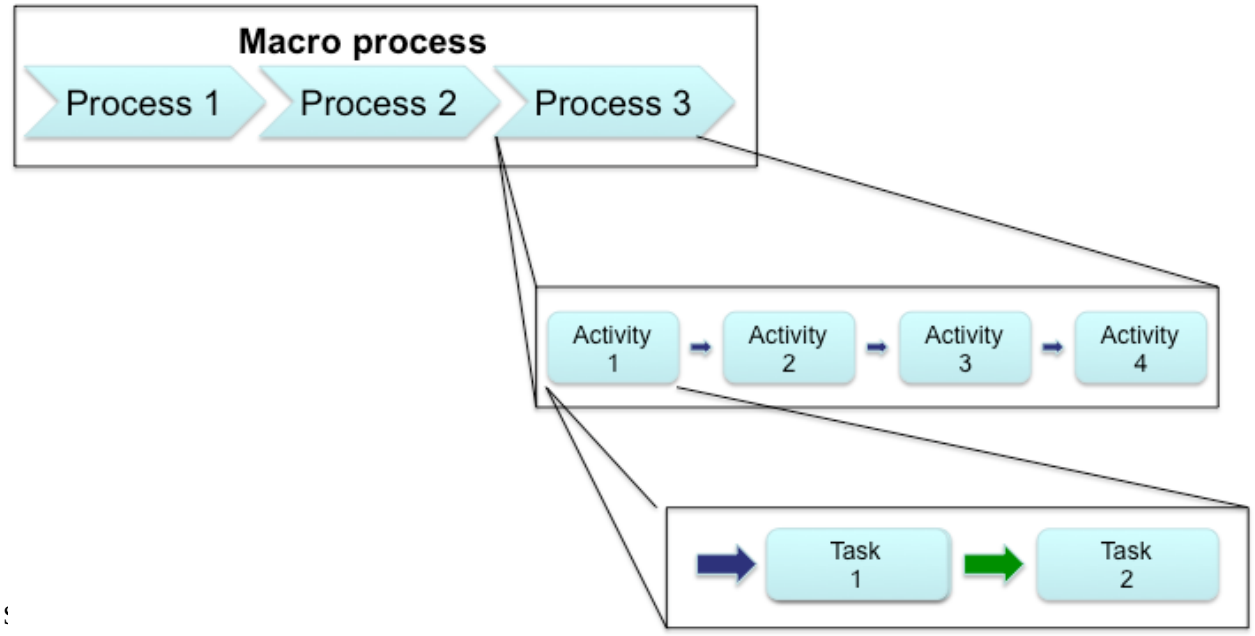
Table 4. Differences between traditional management and management by processes

Traditional management	Management by processes
Organisation by department or area	Organisation oriented towards the processes
The departments determine the carrying out of activities	The value added processes determine the carrying out of activities
Authority lies with departmental heads	Authority lies with those responsible for processes
Principle of hierarchy and control	Principle of autonomy and self control
Internal orientation of activities towards the head or department	Outward orientation of activities towards the internal or external client
Principles of bureaucracy, formality and centralisation in decision-making	Principles of efficiency, flexibility and decentralisation in decision-making
Exercise of control of command based on vigilance	Exercise of command by exception based on support or supervision
Principle of efficiency: to be more productive	Principle of efficiency: to be more competitive
How to improve on what we have been doing	Who are we doing this for and what should we do
Improvements have a limited scope: the department	Improvements have a transfusional and generalised scope: the process

Badía apud [52]

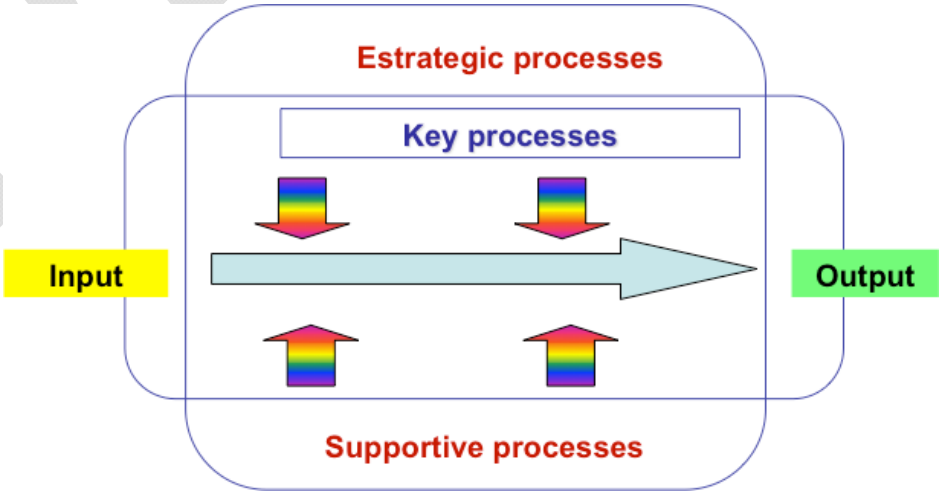
In institutions different levels of organisation identified that go from the general to the specific; levels that are observed in the structure presented in **Figure 4**.

Figure 4. Structure by processes



The macroprocess is the set of processes that are generally identified as the *raison d'être* of the organisation. They are classified as managerial or strategic macroprocess, which are those that are responsible for giving direction or instructions of the organisation, defining the institution's strategies (including the functions of direction like planning, managing, evaluation, etc.). Operational or key macroprocess, is the set of processes that are directed to the provision of health care to the final client. These processes give account of the mission of the organisation and the support macroprocess, which is the set of processes that support the carrying out and delivery of the service or product (Figure 5). These types of processes are related and interconnected, forming a map of processes.

Figure 5. Types of processes



Source: adapted from Aberloa y Sellés [53]

A process is a set of interrelated work activities that require certain inputs and particular tasks that involve benefit to obtain specified results [52]. The outputs of a process make up the inputs of other processes, such that this approach allows the treatment of an organisation as a whole, thus valuing interrelations.

Figure 6. Chain of interrelated processes

176/SC 2/N 544R [54]

Pharmaceutical services should be capable of identifying the health care work processes in which they should be directly involved, as well as its internal processes, so as to prioritise them in the most rational way.

Sanz, Calvo et al. [55] consider that the main factors for the identification and selection of processes are:

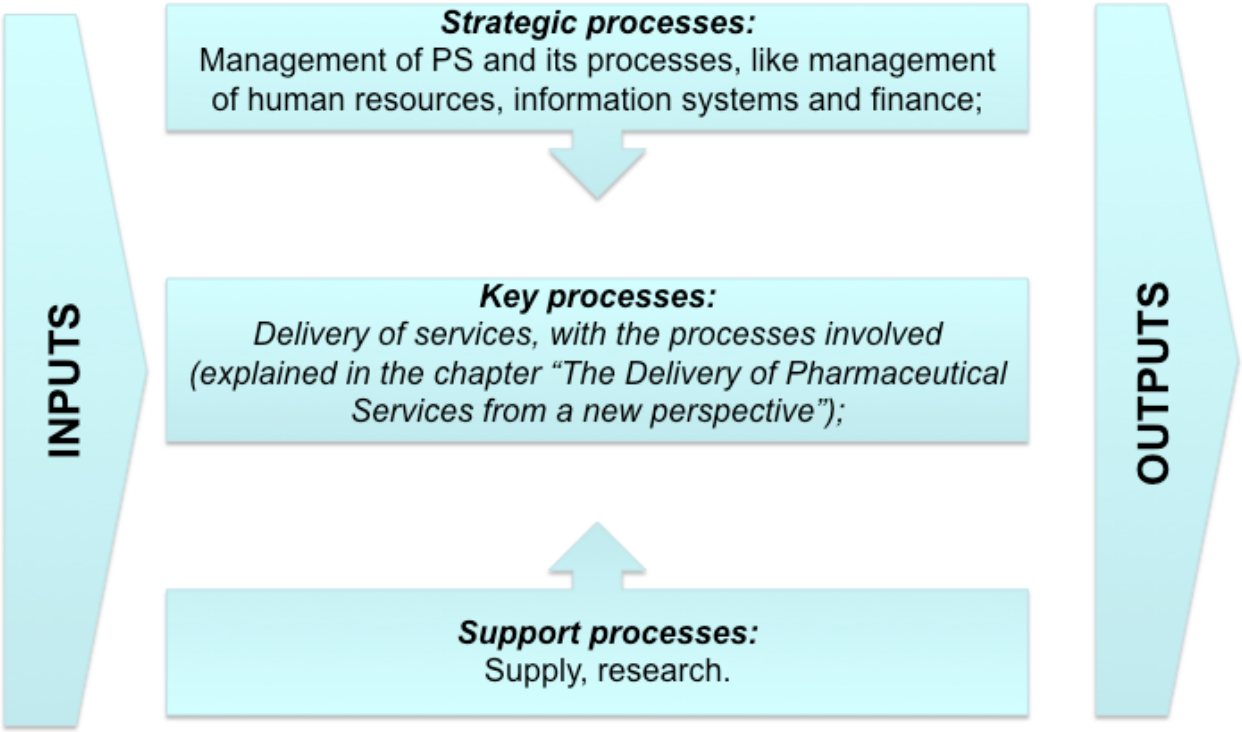
- Effects on the quality of the product/service;
- Influence on critical factors to success (CFE);
- Influence on the mission and strategy;
- Compliance with legal or regulatory requirements;
- Influence on client satisfaction;
- Economic risks and risk of dissatisfaction;
- Intensive use of resources.

The phases to structure a management by processes system outlined below [53]:

- Identify the objectives of the organisation and its preferred activities;
- Identify and select the key processes for the business and their importance in a processes map, identifying their interrelation;
- Designing the processes;
- Setting up a systematic management of process to achieve the maximum effectiveness;

Figure 7 presents an example of processes in pharmaceutical services. It is noted that this document is developed, considering the delivery of service as a key process. However, support and strategic process can be considered differently according to the conditions in each country.

Figure 7. Examples of processes in pharmaceutical services.



Source: Own drafting

Finally, activities and tasks are linked, sequential events, whose integration defines a process.

In order for a particular set of activities be considered as a specific process, the following criteria must be considered [52]:

- It has a clear mission or purpose;
- There are inputs and outputs and the clients, providers and final product can be identified;
- It is likely to be broken down into operations or tasks;
- It can be standardised by applying the management by processes methodology (time, resources, costs);
- Responsibility for the process can be assigned to one person.

Management by processes will allow the organisation of pharmaceutical services and will allow its professionals to get involved in integral health care actions (promotion, prevention, cure and rehabilitation) in a transversal and integrated way, keeping the IFC and health care results as a priority.

General characteristics of a management system

In adopting the definition of pharmaceutical services outlined in this document[i], the attributes that characterise the PHC-based health care system are accepted. This approach differs broadly from the traditional pharmaceutical practice, and therefore requires important adjustments to the manner of carrying out and managing the services.

Mendes Junior and Bonfim [56] propose some characteristics to describe a management system, that, with some adaptations, apply quite well to the characteristics of a management system for pharmaceutical services, as can be seen in Table 5.

Table 5. Characteristics of a management model

Governance	Set of regulations and practices inherent to the models that are capable of *"empowering"* the system, as well as allowing the systems to be responsible in the face of the demands of society and higher organisations.
Professionalisation	The management must count on sufficiently technical regulations that are appropriate to the organisation's objectives, working with the means/resources, as well as the management of results. These regulations should be applied by adequately trained and competent professionals in a way that produces the best results.
Financing	This refers to the economic-financial dimension of management. It includes the volume and equitable distribution of resources; the sources and origins of resources; and the methods of payment applicable to services. It should allow the sustainability of the system or service, maintain the premise of maximisation of resources (efficiency), respecting the dimension of quality of care. In the case of PS, financing of access to medicines and other essential supplies is fundamental.

[i] See section "The conceptual framework that is presented in this chapter serves as a basis for organising and understanding the elements of PHC-based pharmaceutical services. It is therefore about the ideal target that is desired, that must be adapted to every country according to its conditions.
Definition, Mission, Vision, Values and Principles", p. 25

Management of persons	The nature of the health care organisation requires that the management of work be heavily dependent on professionals, since they have the greatest responsibility for the efficiency and quality of the processes and results obtained. The mechanisms for management of persons are therefore highly crucial to the success of the organisation's work. Some elements are desirable in HR management: autonomy for the leaders of the organisation; permanent appreciation of their role; taking care with persons (including the health of the worker); decent salaries; flexible working hours; inclusion of general incentives – environmental, social, etc.; management of competencies; professional development; procedures for conflict management; participatory processes; flexible selection and recruitment with structured procedures in the selection, as well as induction, training and re-induction processes.
Management of supplies	In the case of pharmaceutical services, this is a central theme. There is the involvement of a series of stages with the objective of guaranteeing the availability of medicines and other essential supplies for health care with quality attributes based on the criteria of rationality. It includes the planning of needs, the implementation of procurement best practices; best practices for storage in order to adequately conserve products, the management of inventory with rational use of resources and timely distribution.
Information technology	Technological support through which the information systems operated by registering, processing and generating information that is reliable, integrated, timely, adequate to needs, and within easy reach and comprehension of different users. Its aim is to support the process of making strategic, tactical or operational decisions in clinical and administrative-financial matters.
Organisation of care	This is what best relates the management model with the organisation's mission. It deals, therefore, with the mechanisms, instruments and health care practices that make it possible to carry out the supporting objectives in accordance with standards of efficiency and quality.

Quality of the performance of the health care system	This is achieved with the carrying out of the following attributes ***Effectiveness*** – degree to which the assistance, services and actions achieve the expected results; ***Access*** – capacity of persons to obtain the necessary services and product in the appropriate time and place; ***Efficiency*** – relationship between the health care intervention; product and the resources used; ***Respect for persons rights*** – capacity of the health care system to ensure that services respect the individual and the community and is oriented towards people; ***Acceptability –*** Degree to which health care services offered; are in sync with the values and expectations of users and the population; ***Continuity*** – capacity of the health care system to deliver services in a continuous and coordinated way between different levels of care; ***Safety*** – capacity of the health care system to identify, avoid or minimise the potential risks of health care or environmental interventions;

Source: adapted from PRO-ADESS apud [56]

Main functions of management

The **main functions of management** are planning, action/execution and monitoring/evaluation, generally presented as the PDCA cycle: **p**lan, **d**o, **c**heck, **a**ct, although consideration given that the reality is dynamic and complex, which means that such components are temporary and overlap during operation.

Planning can vary depending on whether the specific approach adopted is strategic or regulatory. However, it must always combine both approaches with an analysis of the context (organisational, political, financial, social and health environment, and its relations and a regulatory approach that consists of establishing rules, agreements and procedures. The more delineated and defined a problem is, the better the regulatory approach can be. However, these situations are rare in health care, which creates the need for the manager to know the tools and methods involved in strategic planning as a method of better addressing the uncertainties of the health care work process.

The **execution or implementation** function, is when the intentions established during planning become actions, in order to obtain the results. Attention paid to ensuring that planned resources are available in the correct quantities and at the right time, and that the processes take place according to the best practices for the context and specific conditions. Of note is the importance that processes be standardised in guides and manuals formulated in a participatory manner, based on reality, adequately distributed and constantly updated. Everyone involved in the

operations of each guide should be familiar with it and use it. Also noted, is the importance of documented health care processes. In addition to constituting a quality requirement, within the health care field is also a requirement for ethical responsibility.

Monitoring and evaluation (ME) are resources of a strategic nature that contribute to the identification of problems, knowledge about the implementation of actions and the extent of the effects or results, so as to facilitate the choice of strategies, corrections to direction of a programme and whether or not to maintain a programme.

Scriven proposes as the logic behind the evaluation, the selection of a group of criteria of value that *"define what is the best, what is desired in service to translate each criteria in measurable indicators that count on the consensus and approval of involved groups"* [57].

The importance of qualitative evaluation is noted. Therefore, the explicative potential of which cannot be supplanted by objective indicators, which are useful for proving trends and making comparisons. Therefore the indicators are not essential, rather the criteria that go in the direction of change. It is convenient, before going into the establishment of indicators, to establish what is going to be understood by efficiency, effectiveness and social impact, which are what, ultimately contrast against each other. It is important that those who might be affected by the findings of the evaluation be involved in this process, as active agents of change.

The professionals involved in pharmaceutical services should know the existing health care information systems in their country and field of work. A health care information system should include data collection, processing, reporting and use of information necessary to improving the effectiveness and efficiency of health care services through better management at all levels of care. Its aim is to provide support to the decision-making process at every level of an organisation [58]. Thus, in addition to knowing and managing existing information in a way that is integrated with the other work processes, it should also propose and feed information to its more specific processes.

Delivery of Pharmaceutical services from a new perspective

In this section, a description given, firstly, of activities related to the key process of PS and then those that correspond to strategic and supporting processes, which are fundamental to carrying out the objectives of the key process.

The delivery of pharmaceutical services, considered, the key process since it allows direct delivery to its final objective – the public – and, therefore, contributes to achieving health care results. Some of the activities, such as medicines dispensing or pharmacotherapy follow-up, geared towards the individual. Others, such as the promotion of health, are geared towards the individual, or groups of individuals; that is, to the family and the community. Therefore, the objective of pharmaceutical services is to achieve the best possible health care results and to improve the quality of life of individuals, the family and the community. These activities carried out in a pharmaceutical establishment or other locations like homes (house calls) or community centres.

As was mentioned at the beginning of this document, the operative and philosophical pillars of action taken from the proposal on renewed PHC dealt with in previous sections and pharmaceutical care, as well as management by processes and IHCSN.

Interacting with the IFC to obtain health care results: The key processes

Pharmaceutical care is a practice that brings with a direct interaction between the pharmacist and the patient or community, in which functions of control carried out over the consequences of the use of medicines based on evidence of current knowledge and on the commitment given by the patient. Due to it, it is necessary that the pharmacist establish a therapeutic relationship with the patient and both work together to resolve problems, complex or not – emphasising that the definition of the complexity based on who perceives and feels the problems. Only with adoption of a patient-based approach and an established therapeutic relationship can the problems related to medicines be resolved, such that it is mutually beneficial to the patient and the pharmacist [59]. In the PHC framework it is important to verify the need for this therapeutic relationship to be take place in an inter-, intra- and multi-professional context. The complexity of actions in pharmaceutical practice that can occur in PS can be limited by working conditions, like infrastructure and management. However, the right thing is for the offering of pharmaceutical services according to the needs of the individual and the community.

In reality, pharmaceutical care is a professional practice that has changed the focus from medicine to the individual, family and the community. The methods used can be different, but the commitment made to therapeutic results and quality of life is fundamental, with clinical pharmacy as a science kept as the foundation. The methods used ranked according to the needs of the patients; for some, dispensing medicines are enough, for others, pharmacotherapeutic follow-up is necessary or health education as well.

Dispensing medicines defined as the *"professional pharmaceutical act of providing one or more medicines to a patient, usually in response to the presentation of a prescription written by an authorised profession. In this act, the pharmacist informs and guides the patients about the appropriate use of said medicine. There are important elements to this guidance, including, emphasis on following the dosage directions, the influence of food, interaction with other medicines, recognising potential adverse reactions and storage conditions for the product"* [60].

It is, therefore an active process of interaction with the patient, interfacing with the issues of access, quality and rational use of medicines. It should be an activity carried out with agility and precision and very focused on the process of rational use of medicines so that the therapeutic results are the best possible. Given that it is an act carried out directly towards persons, there is the need for consideration given towards principles of humanism. However, in having as a main objective the usage process, there are limitations. Oral information increases the limitations of therapeutic results, since it is normal not to memorise and learn everything said. Therefore, medicines dispensing should be as focused as possible on the patient and not only a process of delivery of medicines and information.

There is a big difference between the simple delivery of medicines and dispensing, as in the first case no information or care given to the user. There was the delivery of medicines, once accomplished by persons with different qualifications and degrees of training. The reality in many countries is that this included unqualified persons, which brings risks to users, mainly due to the increase in problems related to medicines. The ideal, therefore, for PS is the gradual movement from offering a mere delivery of medicines to true dispensing.

Pharmacotherapeutic follow-up is a process of assisting the patient, in which the pharmacist takes responsibility for the user's needs related to the medicines. The pharmacist should detect, prevent or solve any Problems Related to Medicines (PRM) in a systematic, continuous and documented way, having as his/her objective the achievement of specific pharmacotherapeutic results and seeking an improvement in the user's quality of life. In this process, the pharmacists should identify the need to refer or work together with other health care professionals. If necessary, dispensing medicines done with a pharmacotherapeutic follow-up process, as a sub-process. Pharmacotherapeutic follow-up completed in a private area, with comfortable conditions for the patient. To do this, the pharmacist should receive specific training since it is a process that completely changes the approach of traditional practices, focusing on the patient, and, working as a team member.

Another individual activity in pharmaceutical services stems from when a person asks the pharmacist for help in deciding on the use of medicines for a minor health problem, that is, for minor symptoms. This **counselling on responsible self-medication** is part of self-care, involves supporting the user in his decision to use authorised Over the Counter (OTC) medicines, being aware of choice, risks, and care and if the situation requires the intervention of a prescriber, guiding them to a health care service.

Self-care is a function inherent to human beings and refers to all that persons do for themselves with the aim of re-establishing and preserving the health or preventing and treating illnesses [61, 62]. Practices include, among others, adequate food, physical exercise, hygienic measures and stress management. The close monitoring of the use of medicines as a part of self-care, due to the risks and commercial interests involved.

Within this framework are the concepts of **self-medication and responsible self-medication**. Self-medication is defined as the selection and use of authorised over the counter medicines by the user for treatment of illnesses or symptoms that he recognises. In this sense, it forms part of the self-care activities in health care, just like hygiene, nutrition, lifestyle and the influence of socioeconomic and environmental factors. In responsible self-medication, the user treats his illnesses or symptoms with medicines approved, that are available for sale without prescription and that are safe and effective when used in established conditions [62].

Responsible self-medication requires the following: a) Proof that the medicines administered are safe, of good quality and effective; b) Administration of medicines that are indicated only for the treatment of conditions that the person can identify and of some chronic or recurring conditions (after an initial medical diagnosis). In all cases, these medicines should have been designed and carried out specifically for such purpose and will require an appropriate formulation, dosage and administration.

The ideal is that pharmacists and managers of pharmaceutical services develop protocols to support responsible self-medication in their communities and that the regulatory agencies of medicines define and keep updated lists of medicines used without prescription. In the protocols, it is necessary to establish in which situations it is required to guide a person to other professionals or when to consult other professionals for a better chance of responsible self-medication by the user of pharmaceutical services.

Attention paid to the fact that users see many bad practices in relation to medicines as self-care, such as the autonomous usage of prescribed medicines, taking advice on medicines from laypersons, or taking decision to interrupt treatments or alter the prescription. Pharmaceutical services should be capable of mobilising the tools for the promotion of rational use of medicines to evaluate the magnitude of the problem and define interventions in their target population.

The pharmacist is not only a dispenser of medicines; he has, according to WHO, a professional obligation to be a health care dispenser. In his activities of attending to the patient, the pharmacist can identify the need to give **health education** [63]. In reality, many pharmacists' interventions are characterised as health education sessions. Health education is a tool in Health Promotion that basically aims to facilitate behavioural changes towards healthy behaviours and to eliminate risk factors; for example, providing patients with knowledge about the factors related to the evolution of an illness or providing their relatives with guidelines to help care for the patients.

The direct interaction with the individual takes place in the development of these activities which represents an opportunity for identifying the needs of a family or community. Therefore, the professional must be attentive and detect to what extent individual cases are a representation of cases in the community in order to act accordingly. For example, the pharmacists detect that there are many obese patients in his area of work and can propose to the health care team the development of an educational programme for the community about this problem. It is important to point out that the participation of PS in health education can occur independently of other professional actions.

The WHO gives suggestions on strategies for interacting with the community about the rational use of medicines via different methods of communication like theatre, newspapers, radio, etc. This is done within a process that should have principles such as, starting with identifying a need, collective development of the approach (involving both the health care team and target population) and pre testing of materials and evaluation of effects [64].

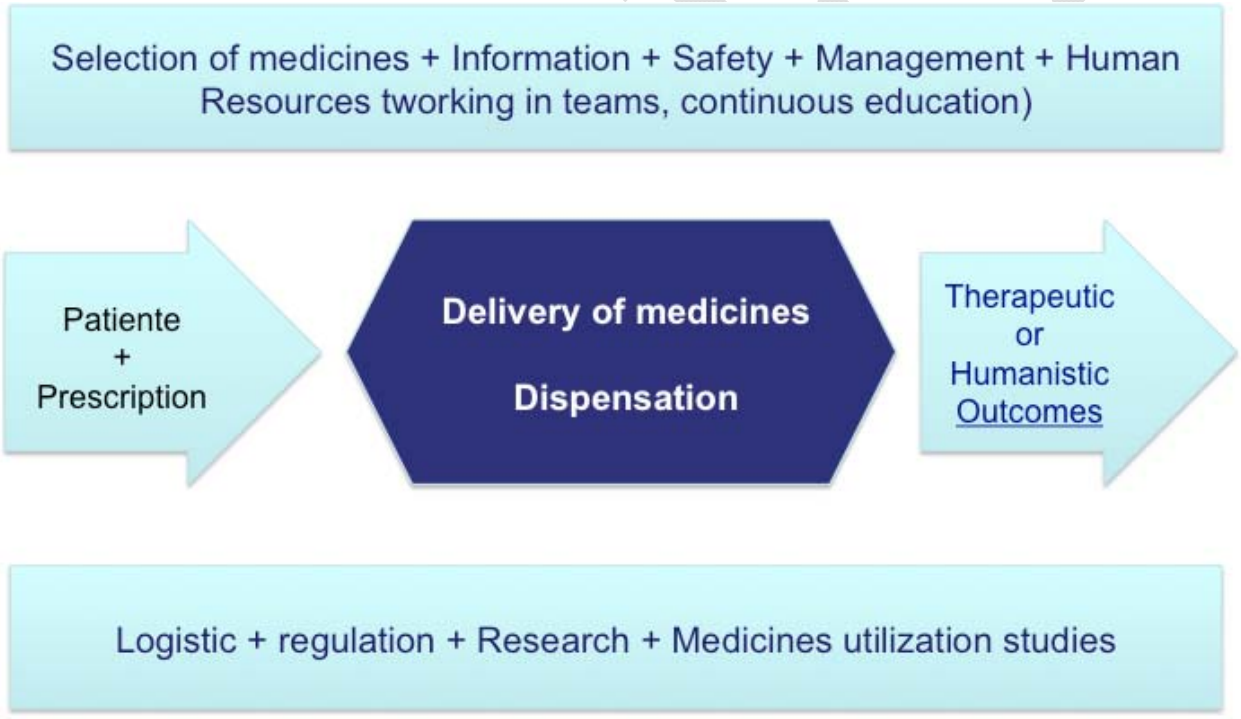
On the other hand, the guarantee of treatment of illnesses followed by additional challenges, such as keeping patients in therapy. Numerous data describe the high incidence of non-compliance. For example, in illnesses prevalent in older patients, and their serious consequences, not to mention the effects they can have on other concomitant illnesses [65-71]). In addition, it has serious repercussions for the health of the patient, leading to an increased percentage of hospital admissions and significantly increases health care costs [63, 72, 73]. Many of the actions carried out in pharmaceutical services can contribute to improving compliance with treatments, be it at the individual or collective level.

To be able to carry out any of the mentioned professional practices, whether individual or collective, it is necessary to take into consideration that the development of supportive action and pharmaceutical services in every country is in different phases. Pharmacists and their managers will have to use their professional discretion to establish priorities, with the aim of reaching the desired objectives as a health care team. On the other hand, plans must be made as to what methods and approaches can be used and if conditions exist to practice them.

Strategic and support processes in pharmaceutical services

As shown in Figure 8, there is a series of elements of strategic and support processes that are interrelated and that contribute to the development of the key process. Following is a brief description of these processes and in separate sections, those related to Human Resources and Regulation expanded upon.

Figure 8. Delivery process in pharmaceutical services



What are the medicines that we should make available for the care of the population?

The first step to answering that question is knowing the epidemiology of the illnesses of the population, whether in a district, city, province or country. From there, selections can be made of first and second choice drugs for the treatment of illnesses, based on the proposals of pharmacology based on evidence. Thus begins the **selection of essential medicines**, a strategic element of obtaining a list of medicines that should be available to care for the community.

With the medicines chosen, it is essential to guarantee adequate information about them. **Information about medicines** should agree with scientific proof, and be provided in the right

way, to the communication level of the individual and community, also being one of the factors that contribute to the rational use of medicines, as well as to the capacity for self-determination. In addition, it is important to find out information about medicines for the health care team, providing as information bulletins or as protocols on the use of medicines. It is also important to be capable of providing information on those medicines that were not selected, to clarify to other health care professionals and users their risks and potential.

With data on incidence or prevalence on the population and social strata, together with the evaluation of pharmacological evidence, it is possible to begin correctly establishing the quantities and resources needed to guarantee access to medicines. From this point, planning can begin on the support process known as logistics [74]

Once identifying the necessary drugs, pharmaceutical forms and their quantities, it is essential to source quality medicines. Not just any medicine bought. **Regulations** established on the quality requirements for registering medicines, which determines those allowed on a country's market, and regulations established for good manufacturing practices. Among the medicines selected, one must look for the pharmaceutical specialties that meet these requirements and not only make selections based on the lowest price. Although in an ideal situation it is guaranteed by the regulatory system, nevertheless, this is not the reality in many countries. This is where concerns about patient safety begin.

As for patient safety, one in every ten patients suffers some harm after receiving care in well financed and technologically advanced hospitals [75] p1. Much less known about the burden of unsafe care in ambulatory centres where the majority of health care services delivered throughout the world. Therefore, it is essential to be able to depend on a programme of quality care and patient safety.

On the other hand, the widespread use of medicines in today's society has engendered a situation where its use increasingly involves a potential risk, one of the main factors being **medication errors**. These occur because of any preventable factor that can cause or lead to the inappropriate use of medicines or harm to the patient when the medicines are under the control of a health care professional, patient or consumer. The causes can be related to "professional practice, health products, procedures and systems, including prescription, verbal order, labelling, packaging and naming, composition, dispensing, distribution, administration, education, monitoring and usage."[76]. Data from the USA show that medication errors are the 5th or 8th cause of death and are associated with a high mortality rate and high direct and indirect costs [77].

Linked to this problem are adverse reactions which can occur with the use of medicines and should be highlighted in order to generate action through **pharmacovigilance** programmes, incorporating a set of activities that refer to detection, evaluation and prevention of adverse reactions and other adverse events associated with medicines. Therefore, for the dispensing of medicines or pharmacotherapeutic follow-up, interfacing with a programme of quality care and patient safety is strategic, as is the pharmacovigilance system, which is going to influence the reduction of injuries, especially incapacitating ones and deaths, as well as the reduction of costs to the health care system and society as a whole.

For all this to function adequately, activities must be planned and organised that are only possible with good management, and as mentioned in the previous chapter, in this document management by processes was chosen.

In good management, the establishment of strategic processes is essential, starting with the management of **human resources**, which are those who make the processes happen. Also required is the implementation of support processes among which a logistics system is essential to guarantee that the medicines are available and of good quality.

Finally, follow-up and evaluation of the impact of the delivery of service must be conducted. Among the available tools, are **studies on medicines use**, that aim to understand the health, social and economic consequences of marketing, distribution, prescription and use of medicines. Many times, it requires, carrying out research, done by the service or in collaboration with universities. The right research should bring managers information about the level of effectiveness and development of the services. It is important that managers encourage research that measures outcomes of the services.

It is important to share both the positive and negative results, of the studies. The culture of only publishing positive results has given a poor contribution, as it could avoid repeating unpleasant experiences and practices that lead to bad results.

All processes are part of a health care network and their planning depends on the situation and policies of the country. For example, from the selection of medicines, thought given to a policy on developing the national medicine industry, if the country has an adequate industrial park and wishes to have strategic control of the production of some medicines.

Logistical elements of pharmaceutical services

In the delivery of service, it is necessary to implement good procurement practices that guarantee the availability of medicines and health care supplies with the attributes of quality; good storage practices so that products are adequately preserved, for the inventory management with rationalisation of resources and timely distribution. There are activities that require leadership and responsibility of suitable and sufficient human talent, in addition to a reliable and timely information system, adequate infrastructure, conservation and measurement equipment such as hygrometers and administrative inputs. Therefore, there is the description of some important elements in each of these sub-processes.

The **procurement** of medicines and other health care supplies has as objectives: a) obtaining an adequate quantity of more efficient and safe medicines in function of the costs; b) selecting reliable suppliers of quality products and excellent service; c) ensuring punctual delivery; and d) obtaining a competitive price.

There is the division of three stages. The first is planning. This fundamental and determining role in the whole procurement process, involves the formulation of policies, objectives and functions, as well as the definition of the medicines and quantities to procure, and the method of purchasing used. Priority always given to the medicines on the list of essential medicines

approved, by the institution. However, procedures for purchasing medicines that are not listed must be established when a patient requires it and it is duly justified.

The second stage is execution, in accordance with purchasing methods, in compliance with policies, use of variables like minimum levels, point of reposition, maximum levels and quantity to purchase and service records provided by the suppliers.

The third stage is evaluation of the process and its compliance with the different plans, as well as the evaluation of the outcomes. Important aspects of evaluation involve: availability of supplies, prices acquired on the market, opportunity, quality and service given by suppliers.

The clear definition of policies, the objective, functions, estimation of needs, purchasing plan and method, in addition to charting the path for execution and evaluation of the process, brings transparency and trust to participating actors. In forming part of this plan is the quantifying of needs based on historical trends, epidemiology, and market research. Strategic projections results from the management of certain variables like prices, services, population growth, epidemiological profile, competence, economic policies, financing and inflation; complemented by mathematical techniques or statistics that allow forecasts with a minimum margin of error, behaviour of the products and their tendencies through time.

The purchasing plan is therefore an approximation of needs; its purpose is to guarantee availability of quality products, at the right time, in the required quantities and at affordable prices, for an adequate delivery of service. Included in said planning is the adequate management of donations. In cases of emergency, it is necessary to have a contingency plan, to be clear on the supplies received by the institution from donations, as well as coverage for the needs, with the aim of adequate and rational use of resources.

Good procurement practices provide some useful guidelines such as: purchase supplies with an International Non-Proprietary Name (INN) or generic name, stay limited to the list of essential medicines and the formally approved procedures. There is also the inclusion of purchase in large quantities, assess and monitor suppliers, purchase by tender, order based on reliable estimations of current needs, develop mechanisms for prompt/reliable payments and for adequate financial management. It is important to work on written and clear procedures, separate functions, rely on programmes that ensure product quality, carry out annual audits with publication of the results, present regular reports in carrying out purchasing, with indicators compared to goals and standards.

In evaluation, the indicators of results like the use of the basic list of essential medicines in purchasing, variation of prices at the national and international level, percentage of medicines that are unavailable in the delivery of service, among others, are the base line for making decisions with intervening actions.

Storage begins with the receipt of the products, an activity in which a comparison carried out between what was agreed with the supplier in the contract, purchasing order and/or invoice and the supplies received (administrative receipt). Also, reviewing compliance with what is established by active laws, as internal and technical requirements, through the review of documentation (e.g. quality protocol) and of the product (technical receipt). Receipt also

includes verification of the conditions involving the transport of medicine and/or other health care supplies one of the important receipt documents is the technical label of every product that facilitates the qualification of the process, as well as the reporting of administrative and technical defects. This information feeds into the evaluation of the supplier.

Storage carried out in such a way as to conserve the quality of the supplies during their period in the warehouse, storage facility or pharmacy, guaranteeing the conditions given by the manufacturer. Inventory management is also important at this stage, with optimisation of resources, adequate rotation of stock, minimum percentage or absence of stock-out and reliability of the inventory. In addition to relying on adequate infrastructure, it is necessary to implement records and controls of environmental factors, a cleaning and fumigation programme, organisation and arranging of products, signage and demarcation of areas, security and restriction of entry only to authorised personnel.

In inventory management, the online and updated information system facilitates the constant measurement of indicators like the rotation index, age of stock, reliability of stock, measure of breakdowns, loss or leaks for subsequent intervention and improvement.

Distribution covers the movement and transport of medicines and health care supplies, inside the health care institution, from the pre-prescription pharmaceutical service to the correct administration or dispensing to the final user, and externally, between health care institutions with equal different levels of delivery of services. In the first instance, the case of intra-hospital distribution, there are different methods, such as a reserve system by floor and a system for prescriptions of individual dosage for 24 hours. A system of the distribution of medicines in unit doses also exists along with, a mixed system of individual prescription and reserve by floor. The choice is made by the institution after evaluation variables like safety, opportunity and efficiency

In external distribution, in addition to an adequate procedure in listing and packaging the required products by different institutions in the network, the choice, follow-up and evaluation of transport to be used, as well as the establishment of chronograms and delivery schedules, acquire importance in the measurement of the opportunity, conservation of medicines and other supplies and security against leaks.

Additional aspects to be noted include the **traceability** of the products throughout the entire process, so as to facilitate recovery in case of identifying a product with compromised quality, and the **information system**, which brings information on quality and costs of the products to institutions in the network.

The logistical system for medicines is one of the most developed components and relies on several instruments for it implementation. This document does not seek to delve deeply into the subject, however for those who want to know more, it is recommended to consult:

- OPS; COHAN; MSH. ***Practical Guide for Procurement Planning and Management of Strategic Public Health Supplies***. Washington 2006[78].
- Management Sciences for Health; World Health Organization. ***Managing drug supply***. 2 ed. Connecticut: Kumarian Press Inc. 1997. p.161-418[79].

- Contreras, Carmen; Moreno, Carlos. ***Gerencia y Administración de Sistemas de Suministro de Medicamentos Esenciales.*** Cooperativa de Hospitales de Antioquia. 4ta edición 2002 [80]

Activity interfaces in pharmaceutical services

Some of the activities mentioned can be better structured to contribute to a situation of more health and less illness. For this, it is necessary to combine different types of knowledge and professional practices, with it being important to establish sectoral committees, with specific functions and, if possible, detailed with all the actions that are sought to build a health care state for all. According to needs and operational capacity, it is necessary to set up committees with different approaches such as pharmacy and therapy or rational use of medicines, and health promotion, among others. The PS has important contributions in other committees such as the Revision of Clinical Records or the Quality of Health Care Services. Those committees should comprise of adequate technical personnel, possess at its disposal the adequate structure to carry out its tasks and linked with others so that there is no duplication of activities. For example, the Health Promotion Committee begins a programme on physical activities, healthy eating, reducing the use of alcohol and smoking; used by committees that work on hypertension, diabetes and dyslipidemia can also use this.

In all these actions, it could be interesting to incorporate aspects such as traditional medicine and integrating and complementary practices, such as phytotherapy, homeopathy or acupuncture.

The role of community pharmacies

Ambulatory pharmaceutical services usually range from private community pharmacies to public health care pharmacies or a combination of the two. On the other hand, many pharmaceutical practices do not need development within a pharmacy, depending on the structure of the health care system.

Public or private community pharmacies are, above all, health care facilities, although they currently require, in the majority of countries in the region, a great effort to reorient their practices and thus reach acceptable ethical, regulatory and health standards. If they manage to offer adequate services, they are a point of first contact, and, if coordinated by the IHCSN, they can become an important gateway into the health care system. With a significant frequency, these services are the first – and even the only – contact for the user with a health care system.

They therefore occupy a space that represents an opportunity for the health care system to capture and intervene for a significant number of persons, particularly in the area of prevention and health care promotion, as well as in situations of self-care.

Many times, they are the closest health care service and are open to the public for long hours. In addition to seeking treatment, the public seek counselling on issues related to their health or that of a family member. This is an opportunity to get to know, interact and intervene in the

health conditions of the family and its surroundings, sensitising the society to the perceiving health risks, promoting healthy lifestyles and preventing problems in prioritised groups. The potential exists to develop activities for rehabilitative and palliative care, for supporting self-care, for follow-up of bouts of illness or health conditions, watching out for early warning indicators and supporting continuity of treatment and uninterrupted, continuous care, thus contributing to the delivery of integral, integrated and continuous care.

However, frequently, not only the sick population turns to pharmacies, but also persons who, although they do not present any symptoms linked to any health problem, are looking for products that can result in unnecessary, inadequate use or abuse.

It is therefore necessary that the managers of pharmaceutical services, together with managers of health in general, try to propose integration into the healthcare system to private community pharmacies. On the other hand, a necessary change made to the role of pharmacies in public health care services and to resolve what would be a conflict of interest between health care delivery and the payment of fees.

Human Resources as a factor for success in changing PHC-based PS

Human resources identified as a critical factor for success in changing PHC-based PS. This change generated in PS from within, or rather, in its team – by re-establishing the method of organisation, management and delivery of service. From the outside, by changing the relationship between the pharmacist and the multi-professional health care team, re-establishing his professional role and the relationship of PS and its "new" functions with the other services in the institution and its integration in the IHCSN.

The *continuous training and education* of human resources should be in accordance with PHC objectives and the roles and functions of PS. It is essential that learning experiences come from interaction with the other actors in the services and in the health care system and the community, under the principles of a more socially relevant training in health problems and with actions focused on the IFC. These services should serve as practice, for both training and the continuous education of pharmaceutical personnel.

In accordance with the PAHO/WHO [21], the necessary changes in training and continuous education should be oriented towards the competencies of the health care professionals according to the essential elements of the PHC Health Care Systems[i]. They were defined based on an extensive bibliographic analysis:

> *" competencies are characteristics (knowledge, skills and attitudes) of persons, that manifest themselves when they execute a task or carry out work and are related to the successful performance of a work activity, or an activity of another nature"*[2].

these teams are proposed as basic work units. It defines *"Working in teams* as a dynamic, open and participatory process in the technical, political and social building of the change to health

[i] See chapter "Primary Health Care". p. 9

care work for the implementation of the new model of care. Interdisciplinary work and community participation facilitate the definition, development and evaluation of integral health care competencies at the local level, producing a renewal and integration of capacities" [47].

Peduzzi apud [47] suggest various criteria for recognising working in teams, especially: intrinsic communication of work, common assistance projects, flexibility in the internal division of work, technical autonomy of an independent nature.

Generic competencies are "fundamental for the adequate carrying out or development of team tasks, are common and shared by all team members and are those that permit the professionals to adapt to new working conditions, are kept updated and overcome the problems that team members must face in their respective positions". Generic competencies involve communication, information management, management of resources and public health. The profile of the 7-star pharmacist [34] coincides sufficiently with the proposal of generic competencies for PHS:

- Caregiver;
- Decision-maker;
- Communicator;
- Leader;
- Manager;
- Life-long learner;
- Teacher.

It is important to underscore that working in teams and an interdisciplinary approach are in the forefront of putting these competencies in practice. In addition, this worker should understand and respond according to the direction and consequences of globalisation, scientific-technological development, and epidemiological transition and, in a major way, development relevant to the new scenarios in which he will have to learn, learn to be and learn to do.

For this, it is essential that practical contact take place from the beginning of training, from different approaches and at growing levels of complexity, mainly in aspects related to:

- The different contexts of public health;
- The different contexts of professional practice directed towards PHC;
- The other members of the health care team;
- The individuals, family and community;
- The different contexts of clinical and operational research and its application to pharmaceutical practice;

Apart from the generic competencies, mentioned above, specific competencies considered for both the PHC teams and PS teams. The **specific competencies** defined as those that "are part of the functions that must be carried out by an organisational unit like PHC teams, linked to processes and individual and collective contributions depending on knowledge and skills. They are inherent in every profession and dominate the technical aspects".

A matrix has been developed linking the necessary competencies for putting in place the elements and functions of PHC[i]. In addition, specific competencies are necessary for the development of PHC roles and functions. These roles and functions detailed in Table 3.

Humanistic competencies refer to the set of ethical values that develop in the professional for the use and application of acquired knowledge. It is related to professional conduct and its role in social responsibility to the community (work ethic)[ii], as well as attitudes.

Reorientation of pharmacist education

Considering that training and life-long education of pharmaceutical personnel is a key element to change, based on the tenets of the renewed PHC, an important part of the PS implementation strategy is support for the reorientation of pharmacist training based on PHC, since this is a key professional in these services.

In addition to the PHC references and competencies of the 7-star pharmacist already mentioned, there are other important references related to pharmaceutical services. These include: the reports from the Conference of Experts on Rational Use of Medicines held in Nairobi (1985), the series of consultations on the Role of the Pharmacist in the Health Care System held in New Delhi in 1988 [31], in Tokyo in 1993 [32], Vancouver in 1997 [34] and The Hague, 1998 [62], among others.

Likewise, of note are the mission of pharmaceutical practice and the proposal of Pharmacy Best Practices resulting in the Tokyo meeting [81], that were subsequently endorsed by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and consolidated the reference points for the reorientation of pharmaceutical tasks towards people.

The aforementioned 1994 World Health Assembly, through Resolution WHA 47.12 [82] notices these new perspectives. It not only appeals to pharmacists to supply documented and objective information on medicines to the public and other professionals, and to develop pharmaceutical care as a medium of promoting rational use of medicines, preventing illnesses and promoting health, but it also asks them to solicit support for research and training programmes.

In the Americas, during the Pan American Conferences on Pharmaceutical Education, standing out is the proposal of the Basic Programme of Pharmaceutical Education [83] and "Proposal for Career Accreditation of Pharmacy Degree in the Americas" [84]. It is a good opportunity for the incorporation of the topic in question into the next revisions of this proposal of accreditation and in the Conferences.

Although there is emphasis made on training of the pharmaceutical professional, it is important to consider the skills of building and training of support staff like service assistants. This resource is essential; therefore, they have direct contact with the patient, hence they should know the relevant principles and values of this framework. As part of working in teams, however, it is essential that the extent of their role in care is clear. This is where it becomes

[i] See the full document on strategies for the development of PHC teams at the following link: *http://new.paho.org/hss/index.php?option=com_content&task=view&id=3306&Itemid=3378&lang=en*

[ii] See chapter: Pharmaceutical services and ethics, p. 62

important that the human resource management clearly define the roles of the different team components, as well as the required competencies and training.

Institutional context for the reorientation of education and links with services and the community

The use of active teaching and learning methodologies include problem-solving, problem-based learning (PBL), the use of formative and summative types of evaluation that consider knowledge, skills and attitudes, like for example, the use of Objectives Structured Clinical Examination (OSCE) and stimulating the development of values and principles of ethics and bioethics, life-long learning and action reflective action (learning to learn).

The new PS should be immersed in education projects that carry on strategic alliances with educational centres: universities and educational institutions. This is with the aim of developing an intellectual conscience, or similarly placing of persons in a capacity to generate creative synthesis of knowledge to project and build initiatives that benefit users of health care services, their families and communities; a knowledge with social contents, useful, ethically responsible, that carries its seal, that shows a personal, independent configuration. According to Botero, *"An intellectual conscience is not only an analytical conscience, but also a critical and self-critical conscience; that is, a conscience that puts self reflection at the centre of the production of meanings or actions of any type by the individual"* [85]

In relation to the different contexts of practice, the following are noted: the need for reorientation from a treatment, hospital-focused perspective towards PHC and an approach focusing on health and its determinants. This should apply for underdegree training as well as internships and postgraduation. However, this does not mean that teaching and hospital internships are less important or should disappear; rather that there should be a balance.

The strategic alliances between services and educational centres extended to set off several initiatives for building and sharing knowledge and life-long learning using an approach from which everyone can benefit. An example is the structuring of *observatories*, like spaces for the creation of information, knowledge, human resource research, critical reflection of policies, programmes, actions and on problems and needs. The *observatories* are a tool for HR policies, development and management, aimed at bringing knowledge and information that qualifies academic programmes and reorients them according to the approaches of the new health care systems, while providing those who take part in the tasks and actions with the best development of their intellectual and ethical potential. From there reports issued to the community, to the same health care professionals, about different aspects of delivering pharmaceutical services.

The change is only possible with investment in the training and life-long learning of human resources. For this, it is essential that all the actors involved in pharmaceutical policies, service professional and academics be involved.

REGULATION OF PROFESSIONALS, SERVICES, MEDICINES

Beck [43] described the "risk societies" which is also mentioned in the beginning of this document, which provide a good framework for presenting the regulation. In this context, in regard to **the role of the State, as part of its steering and regulatory roles, to guarantee health safety.** Durand [86] considers that the perception of risk by the public is variable and, in some way, influences the apprehension of risk by decision-makers. He thinks that the problem lies in making a cost/benefit analysis taking into account the advantages of an activity as it relates to health and its risk, but also as it relates to socio-economic circumstances. This analysis forms part of the State's function and its mission to develop public policies on risk management, considering collective and individual responsibilities to guarantee health safety. Regulation must be part of these policies.

According to the author, there are two great principles that determine health safety: **The separation of functions and the principle of precaution**. There are different visions and possible conflicts of interest between profit according to capitalist thinking and the guarantee of social rights, including health,

Under the first principle, in a coherent health care system, regulation entrusted to an authority with the autonomy to make decisions, so that only health concerns are on the table, with purely economic interests excluded. Such authority assigned adequate resources, a body of experts vested with enforcement powers and their expertise should correspond to the principle of independence, with transparency and without conflict of interest. This function has to be clearly separate from the service/products provision.

As for the principle of precaution, Durand [86] considers it an essential element of coherence, where the authority must act to protect, beyond the simple prevention measures for known risks, although there might be no scientific evidence to confirm the presence or absence of risk. He considers that the public power should act, although it may be to impose a moratorium, which scientists call a form of regression in research.

Regulation, as part of the public policies that guarantee health safety, is an important and essential element for the provision of quality services and products. This function should be outlined in the national health care and pharmaceutical policies.

What is regulation?

Regulation and **supervision** in healthcare defined as:

The capacity to generate new laws and regulations aimed at improving the health of the population, as well as promoting the development of healthy surroundings;
The institutional capacity to develop the regulatory framework to protect public health

and supervise compliance;

The protection of citizens on their interactions with the healthcare system;

The execution of all these activities to ensure compliance with regulations in a timely, correct, congruent and complete manner.

The regulation of Pharmaceutical Services (PS) elaborated in accordance with this function. The regulatory function can be organised in different ways and with different levels of decentralisation.

As it relates to the separation of functions mentioned by Durand [86], regulation should not be a direct responsibility of pharmaceutical services, but they should contribute and facilitate the actions of the National Regulatory Authority to the person to whom it falls to carry out this role.

- It is essential that the key regulatory functions be carried out:
- Legal/regulatory framework;
- Best practice standards;
- Monitoring mechanisms;
- Supervision and other mechanisms for carrying out the regulatory framework.

How far does regulation go in the pharmaceutical field?

Traditionally, regulation of medicines is carried out and due to it facilities involved in their manufacturing, storage and sale or dispensing are regulated. In this sense, the regulation of the so-called "chain of medicines" has been consolidated over the years, with the development of recommendations and international guides that have turned into important references for harmonisation processes and have been adapted by different countries into their national regulations with different degrees of development.

The WHO has had a pivotal role in this process, since it is part of one of the functions enshrined in its Constitution. Several important for discussion and collaboration have been established for the harmonisation and strengthening of the regulation of medicines, namely the International Conference of Drug Regulatory Authorities (ICDRA), held every two years by the WHO and in the Americas region, the Pan American Network for Drug Regulatory Harmonization (PANDRH).

Table 6 shows some examples of recommendations and guides from PAHO/WHO.

Table 6. Examples of guides on good practices in the pharmaceutical field

Area	*Guides*	*Reference document*
Research and development	Good Clinical Practices	PANDRH
Production	Good Manufacturing Practices	32 reports from the

		Committee of specifications for pharmaceutical preparations from WHO Annex 9.1992
Quality control	Good laboratory practices	Report 36 WHO Parisi
Storage and Distribution	Good distribution practices	Annex 6 of report 40
Prescription	Good Prescription practices	Good Prescription Practice – WHO
Dispensation	Good Pharmacy practices	GPP 1997, WHO
Pharmacovigilance	Good Pharmacovigilance practices	PANDRH document

Source: Own drafting

On the other hand, in several countries, they have been consolidating the regulation of services in institutions, like clinics and hospitals, towards the guarantee of patient safety and the prohibition of practices that put life and health at risk. In the 80s, strategies developed were in large measures to control hospital infections.

Traditionally, the aim of the regulation of PS is ensuring that the medicines acquired come from authorised and reliable sources that carry out custody, storage and conservation of medicines. Also included are other health products, vigilance, control and custody of medical prescriptions to oversight of compliance with good practices, from the requirements of operations and the fulfilling of the quality assurance required by health authorities, as well as cooperation in implementing local and national laws and regulations.

However, pharmaceutical services have not been regulated under the category of "service" since it is not considered as a location of "health care services" Delivery. It is precisely this important change needed – since services delivered by these facilities be regulated.

In this sense, it is important to define:

- Mission, objective and functions of the services;
- Conditions of operation, for example in terms of physical structure, infrastructure, personnel, equipment; and especially
- "soft" technologies needed for the development of the services.

Additionally, there is also the regulation of actions by professionals involved in the delivery of PS, mainly the pharmacist and the prescriber, who should comply with the standards of professional practice and with the established deontological requirements in health and professional legislation.

Like all services committed to health production, PS should establish its management commitments, related to health indicators, linked to the health plans in their area of influence.

In order for there to be a quality delivery of service, following the standards established for functions, there must be technical direction/supervision and professional conduct from pharmacists and support staff who will lend assistance in technical, administrative and logistical tasks. They should all be adequately trained and of an appropriate number to the volume, type and complexity of the activity and opening hours of the service.

It is essential to inform and sensitise the population and other health care professionals about the potential risks and necessary precautions in using medicines, the importance of regulating medicines and pharmaceutical services and to encourage and cooperate in the "supervision" of compliance with the regulation.

PHARMACEUTICAL SERVICES AND ETHICS

Healthcare activities present idiosyncratic issues related to living condition as a society. Interpersonal relations, both with patients and with other professionals considered to be in the context of PHC, aiming to improve the quality of life and achieving the best possible standard of health for individuals, family and community. These relationships need guidance by ethics and bioethics.

The reorientation of pharmaceutical services as proposed in this document has its basis on professional ethics (deontology), bioethics and social ethics. In the current healthcare services, three problems stand out that affect the healthcare sector – especially the pharmaceutical sector – in a structural way: the medicalisation of society; the deviation from medical rationale; and the processes of accumulating capital in this sector, with different interests. In addition, medicines have an idiosyncrasy where, according to agency theory, the user is the one with the least information and needs the advice of professionals in order to select medicines adequately, as well as to evaluate and monitor their quality and safety. The manufacturers/producers in turn are the ones with the most information, but they have different interests that can cause an imbalance (profit and health). In this sense, a major challenge is to guarantee that health comes before economic interests.

Aspects of professional ethics

It is essential that relations between professionals and users and between different professionals be guided by the principles and values of PHC. Although this paper is targeted to pharmaceutical services, we briefly discuss pharmaceutical deontology, once the pharmacist is a key professional in those services.

The **Tokyo Declaration** [32] represents a key framework in the reorientation according the renewed PHC principles. Of the greatest importance are the implications for ethical aspects, especially on establishing a new level of responsibility, once extended beyond "delivering medicines" and seeks to establish a link with the user and a commitment to health care outcomes.

In addition, recognising the pharmacist as the health care dispenser, reinforces the change in direction as no longer being focused on the medicines, but rather on the health of the individual and the group, as part of a health care team.

The importance of ethics and bioethics in professional practice is such that it must be a key element in the life-long training of professionals. However, the approach must go further than a principle-based approach considering not only aspects of health care, but also ethical aspects of decision-making in both the clinical and managerial context, research that involves human beings, the interrelation between members of the health care team and the community,

environmental aspects, among others. It is important to consider the socioeconomic reality, values and conventions instituted by a determined community or society.

The document *Developing pharmacy practice: A focus on patient care* [35], already cited, presents a new paradigm for pharmaceutical practice where various aspects related to ethics are presented. In relation to the practice inherent in pharmacotherapy, it states that the pharmacist must assume responsibility for the care, monitoring and evaluation of the determined treatment.

The relationship between pharmaceutical services and users/patients

This same document highlights some aspects related to compliance that also have implications for ethics and the quality of services. Reasons for these issues include aspects of management and organisation of services, such as "long waiting times, indifferent staff, uncomfortable environments, inadequate stocks of medicines and great distances between the patient and health care". In addition, the document presents examples based on patient statues of some countries, with important aspects on the rights and responsibilities of patients as it relates to the health care offered [35]:

- Be treated with dignity;
- Be attended by a pharmacist whom they can identify by name;
- Receive pharmaceutical services in a pharmacy that complies with the standards of pharmaceutical best practices;
- Expect the highest degree of honesty from their pharmacist in processing their medical insurance;
- Be advised and counselled on the appropriate use of medicines;
- Receive the correct medication and in the correct quantity;
- Receive safe, quality and effective medicines;
- Be able to complain or express a need;
- Participate in making decisions about the issues affecting their health and their medicines;
- Get a second opinion.

At the same time, patients too have responsibilities:

- Be reasonable and polite;
- Help their pharmacist comply with the legal requirements with regard to medicines;
- Use medicines with care;
- Communicate any problems that may arise with their medication.

It is essential that patients be informed about the options they have when faced with their illness.

The information and communication component is essential to the relationship between pharmaceutical services and users, since it is as important as the medicine; information is how the relationship and communication with clients is established, especially in PHC [87]. The concept of "taking ini", in this sense, is what makes an important difference.

Ethics in decision-making processes

Traditionally, ethics are not discussed in this context, however in the decision-making processes and throughout the entire chain of the medicines – i.e. the steps for the development, regulation, management and consumption of medicines – there are ethical and bioethical implications, from research and development, to dispensing and promotion, as well as other processes that form part of the pharmaceutical service, with repercussions for the individual and collective rights of the population.

The health care results see notable improvement when there is good management along the chain of medicines that includes the elimination of anti-ethical practices, which can take many forms, such as bribes, falsifying tests or manipulating conflicts. The countries with the highest frequency of corruption show higher mortality rates below the age of 5[88].

Corruption has an impact on the following areas:

- The patient;
- There is a deviation of medicines, affecting their availability and access to the population in health care establishments;
- Use of dangerous, ineffective, counterfeit and poor quality products or products that have approved without having all the guarantees for approval, with possible consequences for the life or death of the population;
- Loss of resources: it is estimated that approximately 30% of health care resources in a county are invested in medicines [88]. Those resources are limited such that fraud involving healthcare resources destroys the capacity of healthcare institutions to provide good care. This leads to the consideration that in some countries the healthcare system seen as the most corrupt public service, which leads to a drop in the population's faith in the system.

Below are some examples that illustrate some difficulties in combining these aspects of rights. A prescription is a quite serious decision-making process with numerous ethical implications. For example, in choosing the essential medicine for a particular patient, this prescriber is not only contributing to rational use, but also to the cost-effective use of resources. On the other hand, in

[i] Receiving the user on his arrival; taking responsibility for him, listening to his complaint, allowing him to express his concerns, anxieties and, at the same time, setting the necessary limits, guaranteeing care that will find solution and coordination with the other services for continued assistance when necessary.

a universal public system, where resources are limited, prescribing an expensive medicine that is not on the national list for a treatment when there are more cost-effective options on the list that are available, has major implications for the sustainability of the system and creates an imbalance between individual and collective rights.

There are also situations like those in which only certain new and very expensive medicines can maintain the life of an individual with a rare illness, as is the case with *Gauchet* syndrome, among others, but in the majority of cases, the safety of new medicines is not sufficiently proven.

In a universal public health system of limited resources, there also exists an imbalance between the guarantee of the right to individual and collective health. In countries like Brazil, this type of situation has generated quite a lot of controversy, leading to a perverse deviation known as "judicialization of healthcare." Many times, the person or persons who decides on the provision of medicines is the judge and not the professionals who prescribe or dispense the medicines, since, as is said, "Judicial orders are not discussed, they are to be complied" [89, 90]. In some states in Brazil [91], collaboration processes between health professionals and the judicial system with the use of evidence-based clinical protocols, have represented a recovery of this balance between aspects of individual and collectives rights.

At the same time, if a medicine were prescribed that is not authorised by the health authority, it could jeopardise the health of the user by exposing him or her to a treatment whose safety, quality and effectiveness have not been proven.

As discussed earlier, this is a sector where there are different interests. Let us analyse, for example, the decisions involved in the management of medicines. An area where a lot of attention has been paid to guaranteeing transparency and reporting has been the public purchasing of medicines, with the adoption of mechanisms to minimise conflicts of interest, like, for example, prequalification of suppliers, carrying out public tenders and transparency of criteria for awarding contracts, prices and purchasing. In many cases, these measures have made the rationalisation of resources, and other things, possible. Attention drawn must be to an important aspect: that purchasing by lowest price without guaranteeing the safety, effectiveness and quality of medicines also has ethical implications regarding exposing users to avoidable risks.

Also of note is the need to consider various practices in the context of private pharmacies, where professionals' fees are usually a markup of the retail price, and can be a conflict of interest for the delivery of service. Another case that also raises an alarm in this sense is where in some countries, certain pharmaceutical companies offer incentives for the dispensation of their products (as a bonus payment).

Another aspect to consider is the relationship between the prescriber and the pharmacist at the time of dispensing. When dispensing medicine, the pharmacist must interpret the prescription and in a case of doubt or problems (incomplete or illegible prescription, dubious or incompatible dosage or posology, or medicinal interaction) he should contact the prescriber (doctor or dentist) to clarify the situation. In the case of not making contact or on not receiving confirmation, the pharmacist should not dispense the medicines and should write a statement

of explanation on the back of the prescription. The same care should be with prescriptions for compounding.

Research ethics

The Declaration of Helsinki of the World Medical Association [92] and the Council for International Organizations of Medical Sciences (CIOMS), as well as the WHO itself, during the last six decades have established the ethical principles for in research involving human subjects, including research on identifiable human material and patient data.

The general orientation of the research involving human subjects based on the premise cited in the same Helsinki Declaration [93]: "In medical research involving human subjects, concern for the well-being of the human subject must take precedence over sciences' and society's interests."

The International Ethical Guidelines for Biomedical Research involving Human Beings (CIOMS) of 2002 [94] reiterates the general ethical principles of research involving human beings already outlined in the 1979 Belmont report. Thus including [95]: autonomy, non-maleficence, beneficience and justice, as well as aspects related to the continuity of care.

As it relates to research data and information, several aspects stand out. For example, the confidentiality of user data, documentation, storage and adequate treatment of data, guarantees that the results are precise and reliable and are for the assurance of transparency in the processes.

Generally, an important aspect of the research is the possibility of production and dissemination of knowledge. It is essential that by participating in research, professionals can benefit from the capacity-building process in areas that are important to the improvement of the service or health care system in which they operate.

On the other hand, conducting clinical trials is quite common in the development of new medicines or in improving existing ones with new applications or formulas, for example. In the Americas Region, the Buenos Aires Declaration on Ethics and Clinical Trials [96] is an important framework. This Declaration unanimously approved during the First Latin American Workshop on Ethics and Clinical Trials, which was held on the May 12-13, 2008 in Buenos Aires, where 17 Latin American organisations supported the Declaration and placed their names at the end of the document. It is also important to highlight the Good Clinical Practices developed by the Pan American Network for Drug Regulatory Harmonisation (PANDRH) approved by the regulatory authorities in the IV Conference of PANDRH.

Intellectual property and access to medicines

The innovation and development of new medicines in the current patent system in the member countries of the World Trade Organization (WTO), the guarantee of Intellectual Property Rights, especially with regard to pharmaceutical patents, have important ethical implications.

At the same time that intellectual property systems guarantee the use of the patent as a return on an investment, in many cases it represents a barrier to guaranteeing access to medicines.

It is important that countries be able to implement, in their national legislation and patent systems, safeguards and flexibilities foreseen in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), particularly the possibility of issuing mandatory licences, the authorisation of parallel imports and the application of the Bolar clause for the early marketing of generic medicines. This takes into account the DOHA Declaration approved during the fourth WTO Ministerial Conference in 2001, which recognised that based on WTO norms, no country should be prevented from adopting measures to protect the health and life of persons and animals or the preservation of vegetation, or for the protection of the environment.

Recently, both the World Health Assembly (WHA) and the PAHO/WHO Board of Directors adopted several resolutions related to the overlapping of public health, trade and intellectual property, including the Global Strategy on Public Health, Innovation and Intellectual Property [97].

Regulation of pharmaceutical services and medicines

Regulation is detailed in another chapter. Therefore, with regard to the ethical aspects of regulation, it is important to ensure the absence of conflicts of interest. Here, we draw attention to certain aspects, such as the importance of the regulation activity and its role in guaranteeing the availability of information based on evidence, avoiding the influence of medicines promotion, as well as ensuring the right to health and the availability/access to adequate medicine. In this sense, the presence, practice and technical direction of the services by a pharmacist with adequate training are important requirements.

In conclusion, the ethical aspects related to pharmaceutical services are present in the legal frameworks, in the general aspects of policy and in management, at the national level as well as in institutional level and professional practice. Therefore, to seek the reorientation of the services, it is essential that ethics form part of their values and principles.

RESPONSIBILITIES AND INTERSECTORAL COOPERATION

The proposal presented involves various actors with different responsibilities and degrees of involvement in the elaboration, planning, execution and evaluation of Pharmaceutical Services. In accordance with the definition, mission, vision and established values, four main actors identified are: (1) governments, (2) the industry and pharmaceutical trade, (3) health care professionals and (4) the population/users.

1. Governments

Governments have the responsibility to define, coordinate and control the execution of the National Health Policy of the country with the participation of an organised civil society.

The Ministry of Health, with its steering role of health sector, should lead the processes related to pharmaceutical services and promote cooperation with the other sectors. Even if discussion about and formulation of Pharmaceutical Policies is a shared responsibility among different ministries, it should be directed by the Ministry of Health. Similarly, the Ministry should be present at all negotiations on international regional and bilateral trade agreements, where access to medicines may be compromised.

At decentralised systems, regional or provincial government health authorities are responsible for the implementation of policies and oversight of compliance with laws and regulations issued at the national level or their own norms when the country is a federal state. The delivery of direct services, including pharmaceutical services, is usually under the domain of local administrations or Health Units.

The economic area plays an important role in the regulation of the prices of medicines, mainly essential medicines and in the provision of adequate financing. It is also essential that participation in international, regional and bilateral agreements on access to medicines be carried out under the principles of protection of public health.

In the area of education, coordination is important for improved development and life-long education of human resources needed in pharmaceutical services and for the support of the rational use of medicines.

The areas of industry and technology are fundamental to agreeing on policies that prioritise necessary actions, in innovation and technological development as well as production, which would result in a supply of medicines guided by health needs.

2. Industry and pharmaceutical trade

It is the responsibility of the pharmaceutical industry to guarantee the effectiveness, safety and quality of the pharmaceutical products that it makes available to the population. This responsibility begins with carrying out clinical studies that must use procedures that follow Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).

Also of importance is the role of the industry and pharmaceutical trade in guaranteeing the quality of pharmaceutical products throughout the process including production, distribution and transport. It is essential that there be a commitment from both parties in complying with the guidelines set out by Good Manufacturing Practices (GMP), and Good Storage and Distribution Practices.

Finally, the pharmaceutical industry has a great responsibility for the ethical promotion of medicines, for which it must adopt its own code of conduct based on that of the International Federation of the Pharmaceutical Manufacturers and Associations [98], as well as the ethical criteria of the WHO on the promotion of medicines [31](WHO 1988).

Private pharmacies, as part of the integrated network of services, should provide quality pharmaceutical services, heeding ethical principles and complying with Good Pharmacy Practices.

3. Health care professionals

Individually and by type of organisation, health care professionals involved in PS are key actors in the execution of pharmaceutical policies and in the development of pharmaceutical services. In the countries, encouragement given to compliance with WHO resolutions on the role of the pharmacist and the agreements of the Pan American Conferences on Pharmaceutical Education on the commitment of pharmacists to health care goals and PHC strategy.

4. The population/users

Popular participation in the area of public policies, allows for social control, no longer exercised by the State, but by the citizens. In the case of pharmaceutical services, the very definition establishes the development of actions with the participation of the community.

In general, users and the organisations that bring them together are important allies in supporting actions oriented towards access and rational use of medicines and have generally had a very important advocacy role.

PROPOSALS FOR IMPLEMENTATION (STRATEGY / TOOLS)

Below are the strategies proposed in the Working Group meeting in Dominican Republic.

Strategies

Consolidation of the group and elaboration of the guidelines

1. Formalise and give visibility and transparency to the working group;
2. Draft a position paper with the conceptual framework based on more operational documents (what is being done in this current effort);
3. Draft and propose a Resolution to the PAHO/WHO Board of Directors.

Advocacy

1. Design a communication and information plan:
    a. With the drafting of an abridged position paper (background and justification), with wide dissemination;
    b. With the publication and dissemination of the guide;
    c. Oriented to academic community, professional groups, professional associations and NGOs;
    d. With the possibility of using methodology that considers the design of strategies based on expected results (eg. WHO COMBI).

Mobilisation of resources

1. Create the necessary mechanisms to strengthen intersectoral collaboration;
2. Promote the development of networks, alliance and collaborating centres, as well as the exchange of experiences;
3. Guarantee the development of human resources needed to implement pharmaceutical services in the PHC framework, incorporating an interdisciplinary team approach;
4. Mobilising resources for the development, sharing and implementation of the proposals for strengthening PHC-based PS.

Implementation

1. Identify, systematise and record similar experiences to find synergies and alliances, disseminate them and support their development (e.g. FCH/PAHO and Human Resources);
2. Develop instruments for strengthening PHC-based pharmaceutical services:
    a. Tools/methodology to evaluate pharmaceutical services;
    b. Pilots and tools to support the model;
3. Establish indicators and monitoring methodology to record progress in the implementation of PS in PHC, establishing a base line and monitoring.

Sub-regional level

1. Define strategy for the sub-regional groups, bearing in mind their specialities, with advocacy at this level;
2. Host sub-regional conferences with participation from decision-makers, highlighting medicines as an essential product and PHC-based health care systems: (a) discussion of the document and (b) presentation of positive experiences (c) intersectoral task forces and (d) develop a pilot in countries with few lines of action.

Country level

1. Identify in-country references/focal points to monitor the pilot experience of the country;
2. Give visibility to the in-country PS task force, including mentioning its work in documents that are produced on the topic;

For PAHO/WHO

1. Sensitise the in-country PAHO/WHO Representations to include PS in PHC in the Biennial Working Plan (BWP);
2. Facilitate the participation of the working group members in the online PHC course;
3. Seek to include the Guidelines for the development of Pharmaceutical Services based in PHC in the series on renewed PHC developed in PAHO/WHO.

Tools

On developing the Guide, it is important to have a series of tools that can contribute to the implementation of recommendations and the proposed model, such as:

1. Regulatory framework for pharmaceutical services: the change in orientation of the services with new functions and responsibilities requires the development of a new regulatory framework or a change in the existing ones. In this sense, work done on training key actors in the area of health legislation and developing draft legislation;
2. Developing supporting material, such as guides on good practices, protocols, informative and dissemination material;
3. Programmes of strengthening human resources: the paradigm shift and reorientation of practices are only possible with trained human resources. It is proposed to act from the introduction of the elements proposed by the guide in the graduation of health care professionals, mainly of the pharmacist, and in offering life-long learning programmes to professionals in the service;

It is expected to be able to achieve the development of these tools from the establishment of collaborative centres and collaborative networks in the region and in the national context.

Proposals also made for groups of work tools at the country level, by modules, according to complexity and level of care, topics or other matter that looks after national needs.

List of Acronyms and Abbreviations

ACP	Africa, Caribbean and Pacific Islands
CCSS	Costa Rican Social Security (from the Spanish: Caja Costa Rican Social Security Costarricense del Seguro Social)
CENDEISSS	Lifelong Learning Centre, Costa Rica
CFS	Critical factors to success
COHAN	Hospitals Cooperative of Antioquia-Medellin (from the Spanish: Cooperativa de Hospitales de Antioquia),
DR	Documentary Research
EM	Essential medicines
ENSP	National School of Public Health (from the Portuguese: Escola Nacional de Saude Publica), Brazil
EU	European Union
FIOCRUZ	Oswaldo Cruz Foundation (from the Portuguese: Fundacao Oswaldo Cruz), Brazil
HR	Human Resources
HSS	Health Systems and Services based on Primary Health Care
HSSN	Health Services Networks
ICDRA	International Conference of Drug Regulatory Authorities
IFC	Individual, Family and Community
IHCSN	Integrated Health Care Services Network
ILO	International Labour Organisation
INN	International Non-Proprietary Name
LHCS	Local Health Care Systems
MDG	Millennium Development Goals
ME	Monitoring and evaluation
MT	Medicines and Health Technologies Project
NGO	Non-Governmental Organizations
OCPC	Office of Caribbean Programme Coordination
OD	Organisational Development
OMS	World Health Organization (from the Spanish: Organizacion Mundial de la Salud)
OPS	Pan-American Health Organisation (from the Spanish: Organizacion Pan-Americana de Salud)
OSCE	Objectives Structured Clinical Examination
OTC	Over The Counter

PAHO	Pan-American Health Organisation
PANDRH	Pan American Network for Drug Regulatory Harmonization
PDVSA	Petroleo de Venezuela SA
PHC	Primary Health Care
PLWHA	Persons Living with HIV/AIDS
PS	Pharmaceutical Services
PRM	Problems Related to Medicines
STD	Sexually Transmitted Disease
UFC	University of Ceara (from the Portuguese: Universidade do Ceara), Brazil
UFGRS	University of Rio Grande do Sul (from the Portuguese: Universidade do Rio Grande do Sul), Brazil
WG	Working Group
WHA	World Health Assembly
WHO	World Health Organization

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