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REVIEW ARTICLE

Pharmaceutical policies in post-communist Albania: Progress and challenges toward European Union membership

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Abstract

Aim: Shifting from a communist regime to a democratic system has affected health system fundamentally in most of the Western Balkan countries including Albania. Albania became a European Union (EU) candidate country in 2014. Since then, one of the main concerns has been to approximate the legislation with the EU framework. The aim of this paper is to review the evolvement of pharmaceutical legislation in Albania and challenges toward achieving full approximation to the EU's respective legislation.

Methods: We used qualitative techniques, especially means of conventional content analysis and two sources to collection data. First, we consulted the Albania's National Publications Office webpage and analysed all available legislation regarding "pharmacy", "medicine" and "pharmaceutical products" from 1994 to 2021. Then, we analysed the National Integration Plans that have been published by the Government of Albania from 2014 to 2021.

Results: The decrease of the price margin system goes in parallel with the increase of the pharmaceutical expenditure, including out-of-pocket expenditure on medicines and lack of adequate and sensitive reimbursement policies. The main pillars of the pharmaceutical sector in Albania are well-covered legally but not fully in concordance with the EU framework.

Conclusion: There is a need to foster laws implementation that regulate the opening of pharmacies; a detailed regulation on pharmacovigilance; and a regulation on medicinal products for paediatric use. Also, the existing legal framework should be aligned with the European one. Medicine pricing methods should go in the same line with the decrease of out-of-pocket expenditure.

Keywords: Albania, European Union membership, legislation, pharmaceutical policies.

Introduction

The Western Balkan countries (WB) – Albania, Bosnia and Herzegovina, Republic of North Macedonia, Kosovo, Montenegro and Serbia – are facing a formidable array of challenges such as demographic, socio-economic and legislative (1). Beside the complex past, WB aspirate to join the European Union (EU) (2). Albania is a EU candidate country since June 2014 and, from March 2020, the EU opened the accession negotiations with Albania (3). The process of European Integration is followed by *"construction, diffusion and implementation of formal and informal rules, procedures, policy paradigms, styles, 'ways of doing things,' and shared beliefs and norms which are first defined and consolidated in the EU policy process and then incorporated in the logic of domestic discourse, identities, political structures and public policy*", known as Europeanization process (4).
The Albanian health system is mainly public, and the state provides the majority of services regarding promotion, prevention, diagnosis, and treatment of diseases (1). The private sector covers mostly the pharmaceutical and dental services, and some specialized diagnostic services (5). Never the less, the Europeanization process in expected to influence health sector and contribute to protection of health, safety and economic interests of consumers (6). In this regard, the government has started to align the pharmaceutical legislation and practices with the EU respective directives including measures to simplify the medicine registration, licensing of professionals and pharmacies, price controls and reimbursement of drugs and implication of ethical standards (7). The process of Europeanization of medicines regulations "*involves harmonization and mutual recognition of regulatory decision making as well as the transfer of some authority from Member States to supranational EU regulatory agencies*" (8). However, there are differences in the way the countries approach new pharmaceutical legislation including how various stakeholders are involved in policy making and how easy it is for the country to implement the new legislative changes (9).
The national European integration plans (NIP) have been regularly published and updated since 2014 aiming at description of achievements and setting new objectives (10). In this regard, the Pharmaceutical Policies have been changing, as it is shown in the NIP and the Official Publications Centre (from 1994 to 2014) (10,11). These changes are reflected in the Law on Medicines and Pharmaceutical Services, Clinical Trials, Medicine Pricing, Reimbursement Policies, the list of Over the Counter Medicines/ Medicines given without prescription (OTC), and the Pharmaceutical Education, laws that regulate the most important parts of the pharmaceutical field in Albania (11). In the same time, the number of the pharmacies in Albania has been increasing from year 1993 to year 2014 (from 1,097 pharmacies in 1994 to 1,600 pharmacies in 2014) (7,12). However, there is not a clear picture of the pharmaceutical legislative development in Albania fostered by the Europeanization process. The aim of this review is to explore how the pharmaceutical legislation of Albania has evolved from 1994 to 2021 and where does it stand toward achieving the full approximation to the EU respective legislation.

Methods

This study is based on qualitative research techniques, especially means of content analysis. We used two sources to collect data. First, we consulted the Albania's National Publications Office webpage and analysed all

available legislation regarding "pharmacy", "medicine" and "pharmaceutical products" from 1994 to 2021 (11). The second source of data were National Integration Plans (NIP) that have been published by the Government of Albania from 2014 to 2021 (10). In both cases we included in the analysis the laws and chapters that contained the words "Pharmacy", "Pharmaceuticals", "Price", "Medicine", "Out of Pocket". All consulted documents are available at Appendix 1. Then, we used Conventional Content analysis to group the data and identify the "*coding categories directly from the text data*" (13). Each NIP has 33 chapters that cover different areas. The chapter which covers pharmaceutical issues and medicines is chapter 28 on "Consumer and Health Protection". All data are presented in the results section based on four categories we identified through content analysis: Sale at distance and pharmaceutical indicators; Pricing policy and Pharmaceutical Expenditure; Clinical trials; Marketing Authorization, Distribution and Storage Practices.

Results and Discussion

The law on medicines and pharmaceutical service has changed many times from 1994 to 2014. The latest published version (the 2014 one) is the most compatible to the respective EU directive (Directive 2001/83) (8,9). However, when comparing the EU pharmaceutical legal framework to the Albanian one, it results that the Albanian legal framework lacks many regulations such as the one on pharmacovigilance and the regulation on medicinal products for paediatric use.

Sale at distance and pharmaceutical indicators

After the fall of the communist regime (in 1991), various reforms took place in Albania such as the permission of private service providers to operate, decentralization of primary care management, the privatization of the pharmaceutical and dentistry sectors, and the founding of the Health Insurance Institute (16). Data shows that the number of pharmacies has been increasing from 1994 to 2014 (Table 1) (7,12). This might be related to the opening of pharmaceutical private universities since 2003 which resulted to a higher number of pharmacists graduated annually in Albania (17–19). Even though, the government started to apply the professional state exam (to control the number and professional quality of pharmacist who graduated), the number pharmacists licenced annually continued to increase (11). The increased number of pharmacies is not proportional with the total population (Table 1).

Table 1. Pharmaceutical indicators (7,12,20–22)

INDICATOR	1990	2003	2005	Last year available
Number of pharmacies (total)	-	1097	1000	1600 (2014)
Pharmacists per 100000 inhabitants	36.37	35.28	38.3	108.4 (2018)
Pharmacists graduated per 100000 inhabitants	0.7	1.2	2.8	3.5 (2013)

Only the pharmacies that plan to have a contract with the Compulsory Health Care Insurance Fund (CHIF) must fulfil some conditions before opening the pharmacy (23). As per the Albanian legislation, a pharmacy that signs a contract with the with the CHIF for the first time should, be at least 50 meter square, at least 150 meter linear away from an existing pharmacy and in a distance at least 30 meter from the health care centre (23).

The Law on Medicines and Pharmaceutical Service of 2004 specified that: The pharmacies could be opened in urban areas in a distance lower than 150 meters from each other, depending from population density (one pharmacy for 3000 inhabitants), but the legislations on distance is not in force anymore (compared to the actual law of 2014) (11). Pharmacies are periodically controlled/inspected by the National Agency for Drugs and Medical Devices and CHIF (The Regional Branch and National Office in case the pharmacy has a contract with this institution), by the Order of Pharmacist and the Tax Administration Office (TAO). All these institutions inspect the pharmacies regarding the conditions on storing the medicines; the order/timeline in which they keep the prescriptions; if they give any non-Over The Counter (OTC) without prescription; if they sell medicines that do not have a marketing authorization (contraband medicine); if they store the expired medicines in a non-separate area inside the pharmacy; if the number of the reimbursed medicines is the same with the one shown in the electronic prescription system (only for the pharmacies with a contract with CHIF); if they give a coupon after each sale; or/and if the employed pharmacists are licensed (11,14).

A yearly report from the State Central Inspectorate mentions that in 2017 were inspected and controlled 424 subjects out of which 352 were pharmacies and pharmaceutical agencies and 48 were pharmaceutical distributors or importing warehouses. In this regard, 25 administrative measures were taken (24).

In 2018, the same report showed that out of 603 controlled subjects, 592 were pharmacies and pharmaceutical agencies, 11 were pharmaceutical distributors or importing warehouses, 14 inspections for expired medicines upon request of the subjects themselves and one inspection in collaboration with the State Policy (Sector against economic and financial crime). Overall, 182 administrative measures were taken (25).

The European Directive (2001/83) specifies the sale at distance to the public (15). In this regard, taking in consideration the existing Albanian Law on Medicines and Pharmaceutical Service 105/2014, the selling of medicines at distance to the public is difficult to be monitored (14).

Pricing policy and pharmaceutical expenditure

Medicine pricing in Albania is done by an official committee assigned by the Minister of Health (19). This committee aims at achieving a lower price of the medicines regardless the quality. The Committee uses a specific formula and the reference price to calculated the medicine price (20).

The pricing policy since 2014 is as follows:

i) The medicine reference price for Albania should be the lowest among:
   - The wholesale prices in the reference countries.
   - The retail price the medicine has in its origin place.

- The price that the medicine has had in the last 12 months of import (11).

ii) The generic medicine price should be 80% of the patent medicine price registered in the National Agency for Drugs and Medical Devices. In case the patent medicine does not have a marketing authorization in Albania, then its price in the origin place should be taken into consideration (19).

iii) The retail selling price of the medicine should be the same with the price of the medicine in the origin place (19).

In the meantime, the price margin has changed – Table 2 shows the price margins during the period 2005-2006.

Table 2. Regressive margin system for medicines in Albania
[*Source:* Imasheva & Seiter, 2008 (7)]

TYPE OF MEDICINES	Importer and wholesale margin	Retail margin
Most Expensive	8%	15%
Moderately expensive	10%	20%
Non-expensive	15%	30%
Least Expensive	18%	33%

The purpose of such regressive price margin is to reduce the incentive for pharmacists to recommend expensive, branded medicines over cheaper generics (7). Until 2015, the price margin system has changed by decreasing the wholesale and retail margin (11). The decision No.143 date 18.02.2015 stated that the margin of the wholesale margin should be 11% (divided 8% for the importer and 3% for the distributor) and 25% for the retail seller (25% of the price that the medicine has once distributed to the pharmacy) (11). Since 2015, in WB a lot of attention has been devoted to pharmaceuticals, which have become one of the largest and fastest growing components of health expenditure (26). The National Health Strategy NHS aims at increasing of the medicine quality, safety and affordability in accordance with the European Standards (27). This is planned to be achieved by:

Reducing the prices and improving access through a progressive expansion of the reimbursable medicine list.

- Registration of medical devices.
- Establishing a tracking system to maintain, strengthen and ensure quality during all phases: production, import, distribution and sale at the final point.
- Achieving quality on pharmaceutical service available throughout the country.
- Strengthening the National Agency for Drugs and Medical Devices (27).

Table 3 indicates that the pharmaceutical expenditure as part of the total health expenditure has been increasing. It indicates a considerable out of pocket expense on medicines and also lack of reimbursement policies.

Table 3. Pharmaceutical expenditure in Albania (28)

Pharmaceutical expenditure as a proportion of total health expenditure	1993 (earliest year available)	2007 (last year available)
	23%	28%

In Albania, annual expenditures on reimbursed medicines increased from ALL 3.5 billion in 2007 to ALL 8.4 billion in 2013, due to a variety of reasons such as: expansion of the health insurance scheme, reimbursement of innovative medicines, the tendency of the physicians to prescribe expensive therapies, lack of rules and regulations controlling this sector, and lack of significant policy for using generic medicines as substitutes for expensive products with the same active substances (26). A study conducted on the affordability of healthcare payments in Albania showed that the average nominal annual amount spent out of pocket per person increased with 37%, from 2009 to 2015 with an annual average growth rate over 5% (29). Some of the main issues that come out of the NIP, are:

- The health sector remains a major challenge; new initiatives aim significant changes in health care financing systems and achieving universal coverage of ongoing initiatives. New programs for periodic population examinations will improve disease prevention. Introduction of universal coverage system is expected to improve the health care system and the provision of health services. (Appendix1)
- The National Medicine Control Strategy 2018–2022 is envisaged for approval in the last quarter of 2018. (The NIPs of 2018-2020).
- The National Health Strategy 2016-2020 was approved in May 2017 and aims to achieve universal healthcare coverage. (The NIPs of 2019-2021).
- In terms of public health, significant progress needs to be made to implement the policy framework and ensure health care coverage for all in Albania. Regarding medical devices, Law 89/2014 "On medical devices" has been revised pursuant to the European regulation on medical devices. The revision of the law was made following the process of approximation of Albanian legislation with the European one and aims to increase safety during the use of medical devices after their placement on the market and increase access for patients. (The NIPs of 2021-2023) (11).

The National Health Strategy (NHS) cites that the medicine market in Albania is well-regulated, while medicines and pharmaceutical services are offered by the private sector (27). The legislation, is progressively improved in line with the EU directives (27). The National Agency for Drugs and Medical Devices has been established in 2014, before it was known as the National Centre of Drug Control (27). In order to increase the access to safe medicines and reduce their financial burden, in 2015 a series of medicines were traded at prices around 30% cheaper compared to 2013. Also, the list of essential medicines has been updated with 200 new medicines compared to 2013, while the list of reimbursable medicines was updated with about 80 new medicines (27). In the last two years, cytostatic medicines are doubled, while medical materials for cardiology have increased by 50% (27).

Clinical trials

Clinical Trials have been a specific chapter of the Albanian Law on medicines since 1994 and later 2004 (11). In March 2018 for the first time the order on approving the guidelines for clinical trials was published (30). This regulation is nearly harmonized with the EU Directive 2001/20 on the approximation of the laws, regulations and administrative provisions of the Member States in relation to the implementation of good clinical practice during the conduct of clinical trials on medicinal products for human use (30). The European Commission Directive 2005/28/EC of 8 April 2005 on laying down principles and detailed guidelines for good clinical practice (including investigational medicinal products for human use, the requirements for authorization of the manufacturing or importation of such products) is far more detailed than the before mentioned Albanian ordinance on guidelines on conducting clinical trials (31). Therefore, this part of the pharmaceutical legislation lacks detailed regulation on conducting clinical trials.

Marketing authorization, distribution and storage practices

Regarding the granting of marketing authorization for medicines for human use, the procedure is nearly the same as in the EU (11). There is also a specific regulation on granting the marketing authorization for medicines for human use in Albania, Decision No.299 dated 08.04.2015 on the Approval of the Regulation on Granting the Medicines Marketing Authorization (11). Until 2018, no specific regulation existed in Albania on distribution and storage practice, although this chapter was part of the law on medicines on pharmaceutical service 105/2014 (14,32). This law states that a regulation regarding the good distribution and storage practices should be approved by the minister of health and should be obligatory for the importers, exporters, pharmaceutical distributors, pharmacies and pharmaceutical agencies (14). In the law 105/2014, existed an administrative offense for each pharmacy that did not comply with the foreseen practices, even though such regulation was not in place yet (14). Such issues were solved out in 2018, when the regulation on distribution and storage practice was implemented for the first time (32). This ordinance was based on the European Medicines Agency's scientific guidelines on the quality of human medicines; Regulation (EC) No 726/2004 of the European Parliament; World Health Organization Technical Report Series, No. 908, 2003, Guide to good storage practices for pharmaceuticals; US Pharmacopoeia 1079, Good Storage and Distribution Practices; Guidelines of 5 Nov EC ember 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01); Guidelines for the Storage of Essential Medicines and Other Health Commodities 2003; and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Distribution Practice for Medicinal Products (32).

Conclusion

In conclusion, the main pillars of the pharmaceutical sector in Albania are well-covered legally but not fully in concordance with the EU framework. There is a need to reinforce the laws that regulate the opening of pharmacies; a detailed regulation on supervising and controlling the online sale of medicines and taking administrative measures where appropriate; a regulation on implementing the track and trace system of medicines. There is no regulation regarding pharmacovigilance in Albania. Also, unlike the EU, in Albania, there is no regulation on medicinal products for paediatric use.

Conflicts of interest: None.

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Appendix 1. List of consulted legislation, directives and orders

No.	The consulted legislation	Link	Last Accessed
1	Law Nr.10 171, date 22.10.2009 on regulated professions in Republic of Albania	https://www.arsimi.gov.al/wp-content/uploads/2017/10/LIGJ_NR_10_171_PRR.pdf	16.05.2021
2	Law of medicine and pharmaceutical services 2004	https://qbz.gov.al/eli/ligj/2004/11/25/9323/25d3c84f-e0ad-4a23-980c-d948f6c7a430;q=299	17.05.2021
3	Decision no. 781, date 14.11.2007 on "Technical functional characteristics of fiscal equipment; integrated computerized system for periodic and automatic transferring of financial declarations; communication system on procedure and documentation for its approval; and the criteria for the equipment authorized from the authorized companies for offering fiscal equipment.	https://qbz.gov.al/preview/302da00f-7476-47a5-a2d7-c583698f8c4e/cons/20181031	15.05.2021
4	Law no. 10 383, date 24.2.2011 on Compulsory Health Insurance in Republic of Albania	https://qbz.gov.al/preview/1af1180f-c82e-4ec7-b37b-9904e9aab976/cons/20170211	17.05.2021
5	Order no.645 date 01.10.2014 on establishment and operation of the Commission on Medicine Pricing	https://qbz.gov.al/eli/vendim/2014/10/01/645/c05dd224-5c03-40ba-99d9-0dc03882fa1c	17.05.2021
6	Order no.143 date 18.02.2015 on designation of trade and fabrication margins of medicines	https://qbz.gov.al/eli/vendim/2015/02/18/143/6d99b717-9493-41ae-b77a-8ff1edc5ff63	17.05.2021
7	Law on Medicine and pharmaceutical services 1994	https://qbz.gov.al/eli/ligj/1994/04/20/7815/6103b566-80d1-4ccc-a6a9-9a67dcbc8559;q=299	15.05.2021
8	Order no 299 on "On approving the regulation on granting the medicines marketing authorization and their classification on the Republic of Albania"	https://qbz.gov.al/eli/vendim/2015/04/08/299/60e02154-8b2b-49ea-aa45-6e3e1e849892;q=299	16.05.2021
9	National Health Strategy 2016-2020	https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/albania/draft_strategt_albania_2016-2020.pdf	16.05.2021

10	National European Integration Plan 2014-2020	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2014-2020.pdf	14.15.2021
11	National European Integration Plan 2015-2020	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2015-2020.pdf	16.05.2021
12	National European Integration Plan 2016-2020	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2016-2020.pdf	16.05.2021
13	National European Integration Plan 2017-2020	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2017-2020.pdf	17.05.2021
14	National European Integration Plan 2018-2020	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2018-2020.pdf	15.05.2021
15	National European Integration Plan 2019-2021	http://integrimi-ne-be.pu-netejashtme.gov.al/wp-content/up-loads/2020/04/PKIE-2019-2021.pdf	15.05.2021
16	National European Integration Plan 2021-2023	https://qbz.gov.al/eli/vendim/2021/02/17/90/b8a74244-4688-4227-bfb6-f75c873a5708;q=plani kombëtar	16.052021
17	Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32001L0083	17.05.2021
18	Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0028	16.05.2021
19	Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf	17.05.2021