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REVIEW

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Historical Developments of Bosnia and Herzegovina Pharmaceutical Industry – the Past and the Future Perspectives of Domestic Manufacturing

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ABSTRACT

Background: History of pharmaceutical industry in Bosnia and Herzegovina (B&H) has its roots from 1951. Importance of domestic industry not just from economical aspect but also from public health perspective and as scientific base has not been evaluated previously. **Objective:** The aim of this article was to provide the review of the pharmaceutical industry developments in Bosnia and Herzegovina, its roots, current position and future perspectives.. **Methods:** Research of published scientific papers as well other documents and archives of pharmaceutical manufacturers has been conducted. We have also analysed market trends focusing on domestic producers.

Results and Discussion: Over more than seventy years of B&H pharmaceutical industry has been developing. During Yugoslavia only two companies existed of which one, Bosnalijek is still present, while Sanofarm has been closed. After 1996, expansion of domestic manufacturers started and today six companies are present. They are mainly oriented to generic drugs production in different forms. Total market share of domestic producers in B&H is 20-25% which is relatively low comparing to other countries. Many of domestic manufacturers are exporting their products to some of the most demanding markets in Europe and Middle East. **Conclusion:** Long history of domestic drug manufacturers in B&H gives solid legacy for future developments. Importance of local producers has been confirmed during war in B&H and COVID-19 pandemic as a crisis situation, mainly from public health perspective and sustainable supply of essential medicines. Higher support by state and

collaboration with academia in order to expand portfolio, especially in area of biologic medicines is required in future.

Keywords: Pharmaceutical industry in B&H.

1. INTRODUCTION

The history of pharmacy in Bosnia and Herzegovina, although extensive and interesting, is often not researched in a structured way. There are a few articles regarding retail and pharmacy practice published by authors from Bosnia and Herzegovina (1-3), but important part, such is pharmaceutical industry has not been covered yet.

In this article we will try to provide structured overview of Bosnia and Herzegovina pharmaceutical industry developments and potential future trends.

Usually, the history of pharmacy of Bosnia and Herzegovina is divided into five periods

- the period of the independent Bosnian state (medieval period),
- the period of Turkish rule,
- the period of Austro-Hungarian rule,
- the period of old Yugoslavia,
- the period of socialist Yugoslavia and
- the period of the new state of Bosnia and Herzegovina (4).

In this article we will focus on period of socialist Yugoslavia, which is relevant for pharmaceutical industry and manufacturing as well as period of the modern Bosnia and Herzegovina covering war (1991-1995) and post-war period.

One of the basic obligations of every state is

to take care of the health of all its inhabitants. Accordingly, every country should have a plan for the organization of health protection of the population, which includes a wide range of activities and the functioning of various health institutions.

It is important to note that health care does not only mean diagnosing, treating and monitoring various diseases in the population, but that it also includes many other measures and activities, such as supplying the population with medications and immunizing the population. So, in addition to the organization of primary, secondary and tertiary health care, the development of the domestic pharmaceutical industry also represents a strategically very important aspect of organizing public health.

The development of the domestic and local pharmaceutical industry eliminates numerous health problems, such as shortages of strategically important drugs for the population (mainly drugs for the treatment of chronic non-communicable diseases). Production of domestic vaccines eliminates all the problems of population immunization, such as the importation of vaccines of problematic quality and composition, which arouse the distrust of the population.

The above was recognized in Bosnia and Herzegovina through the adoption of the National Drug Policy in 2011, in which, among other things, special emphasis was placed on supporting the development of the domestic pharmaceutical industry in accordance with European and modern standards in order to ensure competitiveness and quality (5).

2. OBJECTIVE

The aim of this article was to provide the review of the pharmaceutical industry developments in Bosnia and Herzegovina, its roots, current position and future perspectives.

3. MATERIAL AND METHODS

We used descriptive method to review of the available sources, archives, literature, personal contacts and personal experience in contact with the representatives of pharmaceutical industry as well as with persons who actively participated in processes. Position and market trends of domestic pharmaceutical industry has been collected by official reports.

4. RESULTS AND DISCUSSION

The period of Socialist Yugoslavia

Economic and industry reconstruction of Yugoslavia after World War II has been conducted under conception of Yugoslav Communists. In rebuilding of industrial capacities, the state has approached in two phases, according to the methods of state intervention characterized as “unplanned” and “planned” stage. During 1945, political circumstances and little experience in managing the economy, conditioned a voluntarist approach to the reconstruction of destroyed industrial plants. The beginning of 1946 was a turning point, because the state adopted a one-year plan of reconstruction of the country, which precisely defined what and how should be restored, and the organization is therefore raised to a much higher level than in 1945. Overall

Company name	Republic	Headquarter (city)	Year of establishment
Alkaloid	Macedonia*	Skopje	1945
Galenika	Zemun (Belgrade)	Serbia	1945
Pliva	Zagreb	Croatia	1945
Lek	Slovenia	Ljubljana	1946
Bosnalijek	Bosnia and Herzegovina	Sarajevo	1951
Zdravlje	Serbia	Leskovac	1953
Krka	Slovenia	Novo Mesto	1954
Hemofarm	Serbia	Vršac	1960
Jugoremedia	Serbia	Zrenjanin	1961
Belupo	Croatia	Koprivnica	1971

*North Macedonia

Table 1. Pharmaceutical manufacturers in Yugoslavia per republic and year of establishment



Figure 1. Sanofarm production focused for military purposes

conditions were permanently repaired during 1946, which resulted in great achievements in the field of reconstruction, and by April 1947 the reconstruction of the Yugoslav industry was finalized (6). The conceptual approach was to rebuild and not spend resources on the reconstruction of destroyed production facilities, which meant writing off all those economic entities whose purpose no longer corresponded to the current needs of society. By 1971 10 pharmaceutical companies have been founded in Yugoslavia as presented in Table 1.

In the former Yugoslavia, 80% of the need for medicines was covered by own production in sixteen specialized companies for production of medicines (10 of them), medical supplies and vaccines. Four companies were located in Bosnia and Herzegovina – “Bosnalijek” Sarajevo, “Sanofarm” Sarajevo, “Medic” Cazin and “Sanitex” Velika Kladuša. Out of these four only two companies were drug manufacturing and both located in Sarajevo, the capital of Bosnia and Herzegovina – Bosnalijek and Sanofarm (7).

While Sanofarm was oriented towards production for military needs, Bosnalijek produced medicines for the market and export. Bosnalijek is the first pharmaceutical manufacturer in Bosnia and Herzegovina established in

YEAR	PRODUCT	INN
1957	Favistan®	thiamazole
1960	Rodavan N®	dimenhydrinate
1969	Avamigran®	ergot alkaloids
1975	Enterofuryl®	nifuroxazide
1975	Kofan Instant®	paracetamol, propifenazone, caffeine
1976	Lyso-B®	lysozyme
1977	Essaven®	Escin, phosphatidylcholine
1979	Esbeul®	sulfametoksazol, trimetoprim
1980	Ketoprofen®	ketoprofen
1980	Bosnyl®	sulpiride
1984	Kamfart® cream	Camphor based product
1989	Pilfud® lotion	minoxidil
1989	Stomatidin®	hexetidine
1993	Paracetamol®	paracetamol
1996	Lopril®	lisinopril

*still available in portfolio; **available in current portfolio under other name and reformulated; *** still available in portfolio under other name and in a different formulations

Table 2. Important Bosnalijek products development through years



Figure 2. Production of ampules in Bosnalijek started in 1957 and continuously developed through coming years

1951, a five years after similar companies established in Macedonia, Serbia, Croatia and Slovenia. Bosnalijek started its production on 10th of January 1951. It was the first pharmaceutical company from Yugoslavia which established in-licencing agreements and deals with Western European pharmaceutical companies such are: Astra (Sweden), Asta (Germany), Byk Gulden (Germany), Upjohn (USA) and Medarmil (France) (8). Some of the most successful products have been launched in the coming years (Table 2) including export to Soviet Union (SSSR), specially products produced in cooperation with pharmaceutical manufacturers from Western Europe since Yugoslavia had trade relations and access with Soviet Union market that time which was not the case of other countries from the western block. The first product launched in SSSR was Lyso-B in 1982, and in 1990 Ercefuril (Enterofuryl) was launched as well. Production of ampules in Bosnalijek have been established in 1957 (Figure 2).

In the early stage of Bosnalijek development centre for science and research development has been established

within the company and first clinical trials for internally developed products have been conducted (Figure 3).

As growing local pharmaceutical producer a few acquisitions happened; the first in 1972 merging with Military medical institute and in 1973 with company Astro Sarajevo, a producer of cosmetic, soaps and chemicals.

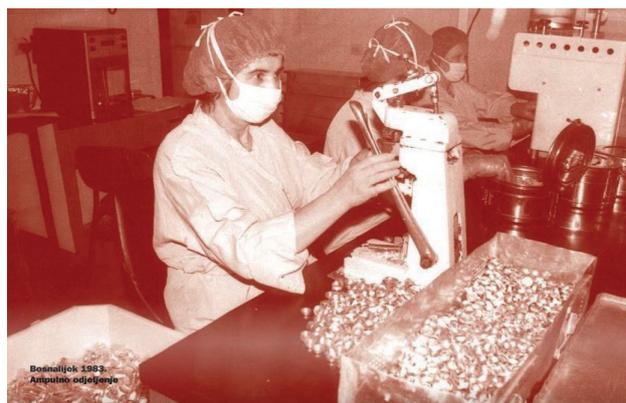
As a part of export orientation and existence of Institute for Educational Research Development, under the supervision of Astra (Sweden), in 1982 Bosnalijek has introduced procedures for manufacturing and quality control which corresponds to Good Manufacturing Practices (GMP) today.

In 1984 Institute for clinical pharmacy, which was a part of Clinical centre Sarajevo, has been joined to Bosnalijek, making basis for future clinical research conducted in house (Figure 4).

The pharmaceutical industry was always partner with scientific community and academia and one of the forces pushing developments of new medicines and formulations (Figure 5).

The period of aggression to Bosnia and Herzegovina (1992-1996)

In 1991 aggression on Bosnia and Herzegovina started, but even under war circumstances Bosnalijek continued its production and supply of medicines. Quick decisions on reorganization and setting up production sites in a se-



cured place, since Sarajevo has been under the siege and constant bombardment as well as loss of professionals—only 15 pharmacists out of 57 stayed in a company. Raw materials at stock and packaging material supplied locally

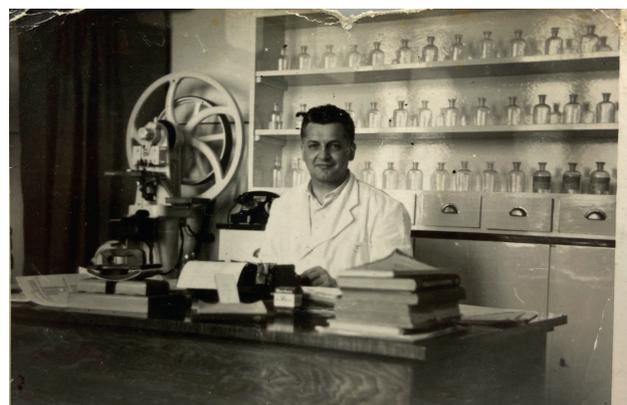


Figure 3. Mr.ph. Tarik Svrzo a head of Bosnalijek Research and development centre (1959)

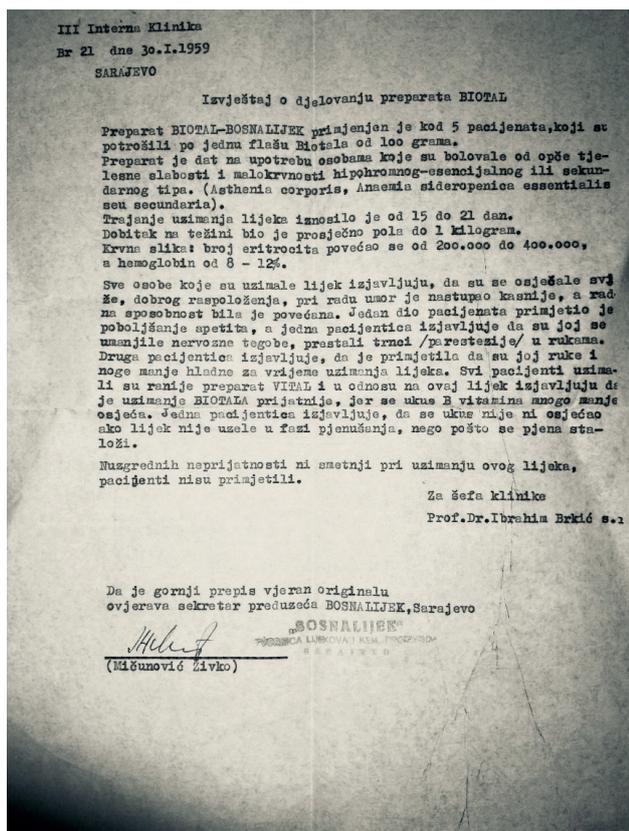


Figure 4. Clinical report for product "BIOTAL" Bosnalijek, 1959

ensured Bosnalijek to respond to new crisis circumstances and ensure supply of civilians and military with essential medicines. Research and development has continued and resulted in launching new product—Paracetamol tablets in 1993. During the war 16 new own generic product and formulations have been developed and launched after the war, still present in portfolio (9).

Other supplies of medicines have been assured through humanitarian aid and donations.

The post war period till present

After the war in 1996 Bosnalijek has launched one of its blockbusters – Lopril (lisinopril). In post war period, intensive renovation and new investments conducted in solid oral forms production site, research and development centre and semisolid and liquid forms production site (Figure 9). New and modern Research and Development centre has been opened in 2004.

Under the new circumstances and post war transition period, private businesses have started growing. Beside the unsatisfied need for new drugs on the domestic market, after the war there was a transition in the economic conditions in the country, and private domestic drug manufacturers are starting to open, while existing ones are entering the privatization process.

PHARMAMED

The company Pharmamed d.o.o. Travnik is established in 1997 in Travnik as small family company, primarily pharmaceutical. First manufacturing facility on current location is built in 2000 (today location for secondary packaging phase), second manufacturing facility is built in 2002 (today production and quality control location),

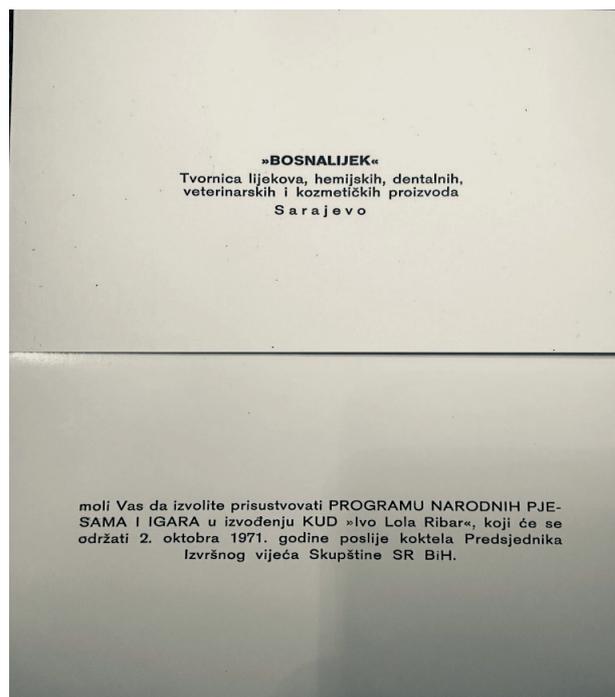


Figure 5. Bosnalijek invitation for social event at Yugoslavian Pharmacists' Congress held in Sarajevo in 1971

and complex of warehouses for raw materials and finished product is built in 2016, and total area is 5000 m² (Figure 7). Today Pharmamed has over 100 employees, quarter of them are high qualified personnel. Pharmamed constantly is sending personnel on education through specializations and other professional educations. Besides pharmacists, chemist, biologist, Pharmamed has specialists of drug control, pharmaceutical technology, phytopharmacy and microbiology.

Pharmamed complies with all major norms applicable to the pharmaceutical industry, such as GMP, GDP, ISO, HACCP. Pharmamed also has environmental license.

Pharmamed is approved for production of medicines in form of syrups and for secondary packaging, for production of medical devices, for production of food supplement and cosmetics with special purpose. The company has its own Quality Control which performs daily testing of all raw materials, intermediates and final products. Quality Control is doing stability testing and ongoing stability testing. Laboratory has GMP certificate and laboratory accredited for laboratory testing for third parties and clients. Pharmamed has its own R&D/RA department, marketing, sales department and distribution.

Pharmamed offers more than 180 products to the market aimed at preventing diseases and preserving health. All products are distributed by two distribution channels: pharmacies and retail.

Pharmamed is leader in Bosnia and Herzegovina in production of herbal medicines, food supplements and cosmetic with special purpose, especially herbal syrups for cough, cosmetics with special purpose and solid dosage forms.

Besides domestic market Pharmamed is exporting to CIS countries (Azerbaijan, Ukraine), Southeast Europe (Montenegro, Croatia, Kosovo, North Macedonia, Slovenia, Serbia), Middle East and North Africa (Kuwait, Lebanon, Saudi Ara-



Bosnalijek, marta 1998. godine, pred početak rekonstrukcije Pogona za proizvodnju čvrstih oralnih formi lijekova. Uz Alufa Mujčinca, vođu ovog projekta, tada i direktora proizvodnje u Bosnalijeku, a danas člana Uprave Društva, su (zdesna) Miran Setnikar, direktor IMP "Klima montaža", firme iz Slovenije koja je bila glavni izvođač radova, Tone Gerbec iz "Leka", Medeljko Todorović, vođa projekta u "Klima montaži" i Dušan Magdić, direktor "Ingrada", podizvođača na poslovima ugradnje laminiranih stijena u čistim prostorima, sa saradnicima



Figure 6. Reconstruction of solid oral forms production site in Bosnalijek started in 1998



Figure 7. Pharmamed facility in 2000 and 2022

bia, Morocco, UAE, Oman, Qatar), Australia, Germany, USA.

FARMAVITA

In 1991 a group of enthusiasts recognized an opportunity in the social and political circumstances for the establishment of a private pharmaceutical wholesale company. Farmavita's focus was to supply the local market and its citizens with necessary products. The war period (1992-1996) was characterized by the interruption in business operations; however, shortly after the war Farmavita managed to execute a quick and efficient restructuring of the client-supplier network. Major milestone appeared to happen in year 2004, which was marked with redesigned business strategy and long term development goal to establish itself as a leading local generic drugs manufacturer. In 2005, the company built the state-of-the-art production infrastructure and warehouses in line with the internationally recognized standards, Farmavita met additional prerequisites for further development of business operations and expansion of production assortment. The end of 2005 was marked by the GMP certification of the plant and the production license for medicines. In the ensuing period, Farmavita saw a significant increase in the offer of medications manufactured at new manufacturing site: starting with 7 generic medications in 10 dosage forms and strengths in 2005 and reaching the present more than 90 generic medications in 200 dosage forms and strengths.

Professional business determination, modern procedural

solutions, and flexible production capacities additionally increased the interest of other manufacturers of medications in the region, and even beyond, for versatile business relations with Farmavita.

In such circumstances, a mutual interest was recognized in 2008 between Farmavita and the renowned and well-established foreign partner – Belupo from Croatia. The company's midterm and long-term strategic objectives were revised, focusing at the enlargement of generic drugs assortment and capacities for production of new-generation drugs.

HEMOFARM

The company Hemofarm d.o.o. Banja Luka was founded in 1996, as part of the leading regional generic pharmaceutical company Hemofarm A.D. The factory of solid forms of medicines was opened in 2003 in Novakovići near Banja Luka. The first molecule produced by the Banja Luka plant was Methyldopa 250 mg.

Since 2006, Hemofarm has been a member of the German STADA group, which markets its products in approximately 120 countries around the world and employs 12,500 people, and about 300 million euros have been invested in equipment, infrastructure, processes and the most modern standards. STADA group is one of the largest manufacturers of generic drugs and consumer health products that are issued without a prescription.

All stages of production up to the finished product take



Figure 8. Farmavita production site (outer and inner view)



Figure 8. Hemofarm production site and line for solid oral forms



place within the Banja Luka production plant. The factory is one of the most modern in the region, and over 1.4 billion tablets came out of its facilities in 2021 alone.

Hemofarm is the leader on the pharmaceutical market in BiH and operates in 34 countries, on four continents. It has the most important GMP certificate, and the portfolio includes over 380 different forms and dosages: drugs, medical devices, dietary supplements and cosmetics.

The portfolio itself is focused on the most important pharmacotherapeutic groups, such as preparations for cardiovascular diseases, antibiotics and neuro-psychiatric preparations.

The company's business imperative is to constantly improve its portfolio with newer generations of drugs, which are of high quality and affordable. The key to faster growth is cooperation with international companies such as Sanofi, Natures aid, Wallmark

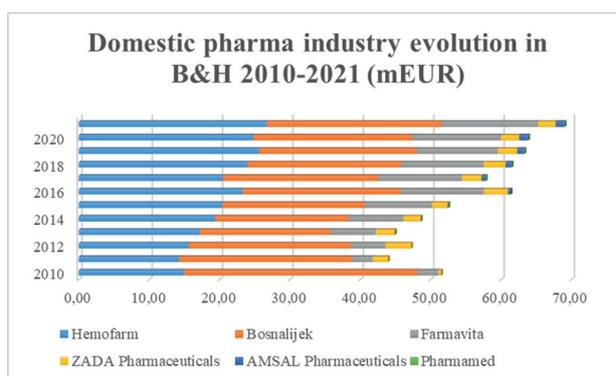
Other domestic manufacturers

ZADA Pharmaceuticals was founded in 2007 starting its production in 2010. The company is equipped with state-of-the-art equipment for the production and control of solid oral forms: tablets, film tablets, capsules and granules with portfolio of 150 medicines in 9 ATC groups and dietary supplements. Beside local market, this company is exporting its products of the Western Balkans, the Middle East and North Africa (10).

AMSAL is a private pharmaceutical company based in Sarajevo and opened in 2013 focused on the production and distribution of generic drugs, prescription, over the counter and food supplements (11).

Position and future of domestic pharmaceutical industry

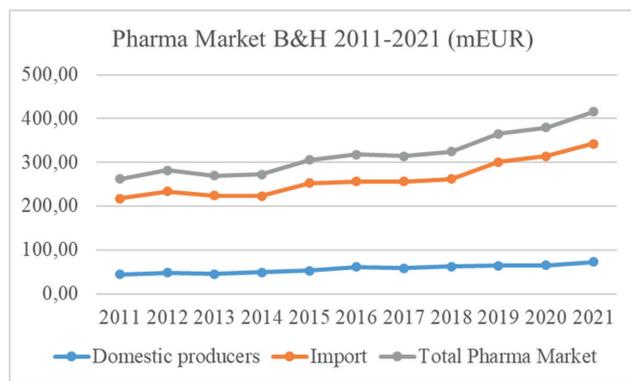
Documents such is National Drug Policy of Bosnia and Herzegovina recognises importance of domestic pharma-



Graph 2. Evolution of pharmaceutical market in Bosnia and Herzegovina in last 10 years and market share of domestic manufacturers

ceutical industry in terms of state orientation to support its development. It is also well known that domestic pharmaceutical industry can assure access to essential medicines and continuous supply, especially in crisis period such was the case during COVID-19 pandemic (12). Taking care of the health of the population must still remain a priority, and the supply of medicines and vaccines is an indispensable part of public health. It was the new situation with the coronavirus pandemic that indicated that in the future the development of the domestic pharmaceutical industry in public ownership will have a strategic importance almost like food production.

According to the United Nations Industrial Development Organization, local pharmaceutical production (LPP) can help vulnerable populations gain access to quality medicines, reduce dependency on international donations, and facilitate control of fraudulent drug products entering emerging markets (13). In addition, local manufacturers



Graph 2. Evolution of pharmaceutical market in Bosnia and Herzegovina in last 10 years and market share of domestic manufacturers

generally provide products that serve local populations, regulators have greater control over quality, and the local economy benefits from the income generated by local workers (14).

Domestic pharmaceutical manufacturers today are offering wide range of most common chronic diseases therapeutics (cardiovascular disease, diabetes, ant infectiveness etc). Their financial results depend on portfolio offered as presented in Graph 2 and Graph 3.

Based on data form 2015 local manufactures in Canton Sarajevo employed more than thousand employees, same number of cooperates and create export in about 40 million of euro (15).

However, there are a few problems to ensure better position of domestic pharmaceutical companies like there are no adequate subsidy measures for innovations or grant programs from the state, and the lack of loyalty of domestic consumers towards domestic products is also evident.

Although some cantons have introduced measures for preferring domestic manufacturers on drug reimbursement lists (16), the legislation in Bosnia and Herzegovina limits such measures and they are often annulled by Council of Competition of Bosnia and Herzegovina (17).

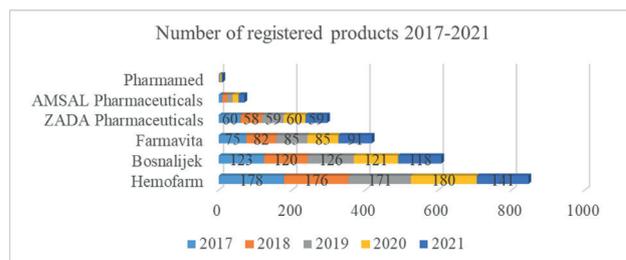
Domestic pharma companies are holding only about 18% of total markets in Bosnia and Herzegovina and showing slow increase while total market is driven by import medicines and foreign companies (Graph 1).

Taking care of the health of the population must still remain a priority, and the supply of medicines and vaccines is an indispensable part of public health. It was the new situation with the coronavirus pandemic that indicated that in the future the development of the domestic pharmaceutical industry in public ownership will have a strategic importance almost like food production.

5. CONCLUSION

The manufacture and production of drugs with chemical entities as active pharma ingredients (APIs), both patented and generic, will continue for a long time. However, the number of patented chemical drugs is dwindling and this will lead to a reduction in generics in the future.

The pharma industry has now invested in developing biologics and biosimilar and, for the past two decades, we've seen remarkable growth in this area. Currently, there are more than 300 patented biologics, half of which are likely



Graph 3. Number of domestic pharmaceutical manufacturers' registered products in period 2017-2021

to go off-patent in the next few years, which will lead to a rise in new biosimilar.

For years, it's been common knowledge that we need to improve the efficacy of drugs and reduce their side-effects. It is a known fact that the actual quantity of drug in the final dosage form is more than that required for action, allowing for losses during metabolism and transport to the site of action.

Therapeutics have thus seen the rise of new philosophies, such as targeted delivery and personalised medicine. Both of these disciplines can help to reduce overall dosages and side-effects while maintain the same or, in some cases, enhanced levels of efficacy.

There is still huge potential for domestic pharma industry to get better positions on domestic market which will require higher efforts and support by the government to create better market conditions. On the other side, new trends in pharmaceutical industry toward biosimilar could be challenging for domestic companies, especially in terms of export and will also require faster adaptation and investments, including private-public partnering, cooperation with academia and in-licencing deals to enter this area and become competitive in future.

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