

DESIGN, DEVELOPMENT AND IMPLEMENTATION OF DATABASES IN PHARMACEUTICAL AND MEDICINE

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Critical Review

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Abstract: This paper presents the design and implementation of databases in pharmacy, points out the most common problems that may be encountered, and describes practical solutions. The paper also describes the structure in terms of linking multiple applications to one single database in terms of achieving business automation.

Keywords: Pharmacy and medicine database design, business automation, multiple applications to one database, SQL.

INTRODUCTION

When talking about pharmacy one immediately thinks of the drug, the pharmacist, and the patient. Complexity in this area of healthcare is evident, since pharmaceuticals requires a good knowledge of chemistry and the human being itself. This brings us to another question: is it possible to record data in this field and in what way? This area is being much more regulated lately, with the development of new international standards and regulations. The answer leads us to three possible segmentations of records.

One of the records is the record of medicines that can be marketed in the country (for which the record is being made), the second is the record of healthcare system patients', and the third record is the record of professionals, which in our case is a graduated pharmacist or a master of pharmacy. Namely, through the institution's registries certain records of these professionals are being created. In the recent history, we have had a situation where we have lacked this personnel and this record was very important because it prevented the misuse of a pharmacist's professional qualification license.

Theoretically, it could happen that one graduated pharmacist worked full-time jobs in 3 wholesales in 3 different cities, which is impossible in practice.

To automate logging in this area, software's with various solutions are created. These software's are made up of an application and databases from which applications pull data and enter new or modify existing ones.

LEGAL REGULATIONS AND STANDARDS

In order to become familiar with the subject of the inspection and construction of the database, we need to familiarize ourselves with the relevant legislation and standards in the Bosnia and Herzegovina.

Bosnia and Herzegovina is regulated in such a way that the national Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina controls the manufacturing, transportation and wholesale distribution of medicines and medical devices, while the entity ministries and the Brcko District control the retail sale.

Relevant national legislation in Bosnia and Herzegovina includes:[2]

- Law on Medicines and Medical Devices (Official Gazette of Bosnia and Herzegovina, No. 58/08);
- Rulebook on the Type, Amount and Method of Payment of Expenses for Performing the Activities of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina ("Official Gazette of Bosnia and Herzegovina", No. 70/09);
- Order on payment account for payment of costs provided by the Law on Medicinal Products and Medical Devices ("Official Gazette of Bosnia and Herzegovina", No. 72/09);
- Order on Amendments to the Payment Accounts for Administrative Fees (Official Gazette of Bosnia and Herzegovina No. 84/13);
- Rulebook on Manner of Quality Control of Medicinal Products ("Official Gazette of Bosnia and Herzegovina", No. 97/09);
- Rulebook on the manner of monitoring defects in the quality of the medicinal product (Official Gazette of Bosnia and Herzegovina, No. 97/09);
- Rulebook on Clinical Trials of Medicines and Medical Devices ("Official Gazette of Bosnia and Herzegovina", No. 4/10);
- Rulebook on Medical Devices (Official Gazette of Bosnia and Herzegovina, No. 4/10);
- Rulebook on Procedure and Manner of Granting Marketing Authorization ("Official Gazette of Bosnia and Herzegovina", No. 75/11);
- Rulebook on Good Manufacturing Practice (GMP) for Medicines ("Official Gazette of Bosnia and Herzegovina", No. 24/10);
- Rulebook on the manner of advertising medicines and medical devices ("Official Gazette of Bosnia and Herzegovina", No. 40/10);
- Rulebook on the Content and Method of Labeling of the Outer and Inner Packaging of the medicinal product (Official Gazette of Bosnia and Herzegovina, No. 40/10);
- Rulebook on Conditions, Circumstances and Procedure for Engaging Authorized Laboratories ("Official Gazette of Bosnia and Herzegovina", No. 60/10);
- Decision on the manner and scope of implementation / selection of parameters for quality control of each batch of imported medicinal product (Official Gazette of Bosnia and Herzegovina No. 60/10);
- Rulebook on the Method of Conducting Pharmaceutical Inspection (Official Gazette of Bosnia and Herzegovina, No. 23/11);
- Ordinance on the disposal of pharmaceutical waste (Official Gazette of Bosnia and Herzegovina, No. 23/11);
- Rulebook on Conditions for Importation of Medicines Not Authorized for Marketing in Bosnia and Herzegovina ("Official Gazette of Bosnia and Herzegovina", No. 23/11);
- Rulebook on Pharmaceutical Inspector Exams ("Official Gazette of Bosnia and Herzegovina", No. 59/11);
- Decision on the program and content of the Pharmaceutical Inspector exam;
- Decision on the procedure for obtaining a license for the import of risk medicines licensed for placing on the market in Bosnia and Herzegovina ("Official Gazette of Bosnia and Herzegovina", No. 23/11);
- Medicines and Medical Devices Policy in Bosnia and Herzegovina ("Official Gazette of Bosnia and Herzegovina", No. 55/11);
- Rulebook on the manner of reporting, collecting and monitoring adverse reactions to medicinal products (Official Gazette of Bosnia and Herzegovina, No. 58/12);
- Rulebook on monitoring of adverse events related to medical devices (vigilance of medical devices) ("Official Gazette of Bosnia and Herzegovina", No. 58/12);
- Guidelines for Good Clinical Practice in Clinical Trials ("Official Gazette of Bosnia and Herzegovina", No. 19/12);
- Rulebook on the Manufacture and Wholesale of Medical Devices ("Official Gazette of Bosnia and Herzegovina", No. 71/12);
- Corrigendum to the Rulebook on Manufacture and Wholesale of Medical Devices ("Official Gazette of Bosnia and Herzegovina", No. 64/13);
- Rulebook on Amendments to the Rulebook on the Content and Method of Labeling of the Outer and Inner Packaging of the medicinal product (Official Gazette of Bosnia and Herzegovina, No. 36/13);

- Rulebook on Good Distribution Practice (GDP) for Medicinal Products for Human Use ("Official Gazette of Bosnia and Herzegovina", No. 75/13);
 - Decision of the Expert Council on Delaying the Application of Data Exclusivity (Official Gazette of Bosnia and Herzegovina, No. 57/13);
 - Rulebook on Conditions for Carriage of Wholesale Medicines ("Official Gazette of Bosnia and Herzegovina", No. 49/14);
 - Instruction on the procedure for import of medicinal products and medical devices of humanitarian character for the territories of Bosnia and Herzegovina endangered by natural or other disasters;
 - Rulebook on the Method and Procedure for Classifying Medicines ("Official Gazette of Bosnia and Herzegovina", No. 69/14);
 - Rulebook on Conditions for Production of Medicinal Products ("Official Gazette of Bosnia and Herzegovina", No. 73/14);
 - Rulebook on the method of price control, the method of pricing medicines and the manner of reporting drug prices in Bosnia and Herzegovina ("Official Gazette of Bosnia and Herzegovina", No. 3/17);
 - RULES ON GOOD MANUFACTURING PRACTICES FOR MEDICAL GAS (Official Gazette of Bosnia and Herzegovina No. 49/18);
 - RULES ON GOOD DISTRIBUTION PRACTICE (GDP) OF MEDICAL RESOURCES ("Official Gazette of Bosnia and Herzegovina", No. 75/18);
 - Law on Prevention and Suppression of Narcotic Drug Abuse (Official Gazette of Bosnia and Herzegovina, No. 8/06) - with lists;
 - Decision on the Designation of International Border Crossings for the Transboundary Movement of Substances and Plants in Tables II, III and IV of the List of Narcotic Drugs, Psychotropic substances, Narcotic Drugs and Precursors (Official Gazette of Bosnia and Herzegovina, No. 58/08);
 - Decision on amendments to the list of narcotic drugs, psychotropic substances, plants from which narcotic drugs can be obtained and precursors ("Official Gazette of Bosnia and Herzegovina", No. 103/08);
 - Decision on amendments to the list of narcotic drugs, psychotropic substances, plants from which narcotic drugs can be obtained and precursors ("Official Gazette of Bosnia and Herzegovina", No. 51/11);
 - Decision to exempt preparations from the application of control measures (Official Gazette of Bosnia and Herzegovina, No. 20/10);
 - Security requirements for issuing a license for the production and marketing of narcotic drugs and psychotropic substances ("Official Gazette of Bosnia and Herzegovina", No. 69/13).
- In addition to these regulations, there are entity and Brcko District regulations.
- The entity's new responsibility is retailing and retail pricing towards end users, patients. Entity and Brcko District regulations are located at the following links:
1. Brcko District [6]
 2. Federation of Bosnia and Herzegovina [7]
 3. Republic of Srpska [8]
- Standards and legislation applicable at national level include part of EU standards and regulations. In the EU countries European Medicines Agency (EMA) has competence in addition to national institutions.
- The European Medicines Agency (EMA) is in the process of implementation of the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP).
- The ISO IDMP standards specify the use of standardized definitions for the identification and description of medicinal products for human use.
- Their purpose is to facilitate the reliable exchange of medicinal products' information in a robust and consistent manner. They help to ensure wide interoperability across global regulatory and healthcare communities, which is critical in ensuring accurate analysis and unambiguous communication across jurisdictions.
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges European Union (EU) Member States, marketing authorization holders and EMA to use the ISO IDMP standards. This will affect many areas of the pharmaceutical regulatory environment, both in the EU and other regions.

Scope of the ISO IDMP standards [3]

The five standards provide data elements and structures to uniquely identify and exchange information about:

- substances (ISO 11238);
- pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239);
- units of measurement (ISO 11240);
- regulated pharmaceutical product information (ISO 11616);
- regulated medicinal product information (ISO 11615).

These standards cover the following to describe a medicinal product for human use:

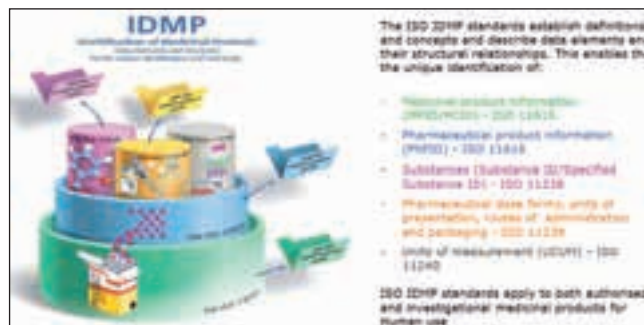
- medicinal product name;
- active substances;
- pharmaceutical product (route of administration, strength);
- marketing authorization;
- clinical data;
- packaging;
- manufacturing.

Medical devices are products or equipment intended generally for a medical use. They are regulated by the national competent authorities, but the European Medicines Agency (EMA) is also involved in the assessment of certain categories of medical device under European Union (EU) legislation.

The adoption of Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices (IVDR) changed the European legal framework for medical devices, introducing new responsibilities for EMA and for the national authorities. Both Regulations entered into force in the May 2017 and have a staggered transitional period.

The MDR has a transition period of three years and will fully apply from 26th May 2020. The IVDR has a transition period of five years and will fully apply from 26th May 2022.

During the transition period, manufacturers can place devices on the market under the currently applicable EU Directives (93/42/EEC, 98/79/EC and 90/385/EEC) or under the new Regulations if they fully comply with these. [4].



Picture 1. Page 6 of presentation *Introduction to SPOR data services* Source: https://www.ema.europa.eu/en/documents/presentation/presentation-introduction-spor-data-services_en.pdf visited: 11/28/2019. [5]

DESIGNING DATABASES

The tools I used to create the database are an MS-SQL server with MS SQL Management Studio, MS Access with ODBC drivers for connecting to the database and data loading. In addition, I used MS Excel to purify the data and to plan the construction of the database by normalizing it. This enabled the Excel worksheet visibility of the duplicated data and thus prevented duplication of records in the database. This web-based solution for Internet data displaying via a web server currently captures read-only database data.

The first version of the database contained an application with a database that included institution's registries. The database of this application is on the MSSQL platform, while the application in Access pulls data through the ODBC driver.

A second database was then implemented on the MYSQL platform with an application that was written in the PHP programming language. The latter database and application belong to the Inspectorate and was separated from the former for the confidentiality reasons. This led to the need for data reload due to the different technology used for the application and due to the disconnection of the databases themselves.

Reports were extracted from the application first and second for the website and periodically modified in PDF format.

The basic idea for the reconstruction of the database and the accompanying applications, was to create 3 applications with a common database, where everyone could use their part, which will be visible to him and will have the possibility to update

in the required segment of the database. In addition, a third application will be used to capture the data and display it on the website automatically after the data input.

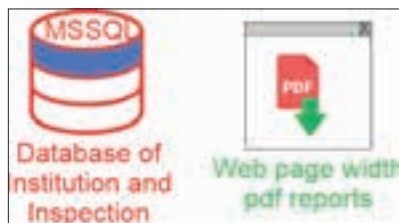
In this way, we will avoid tipping over and enable more efficient business operations, while achieving automation of the business process. This transition will take place in 4 phases.

The first phase will be data purification, upgrade and preparation of the database design according to user development requirements.



Picture 2. Phase 1, consolidation and cleaning data

The second phase will be the reconstruction of the existing database by adding an inspection data, with the migration of existing data.



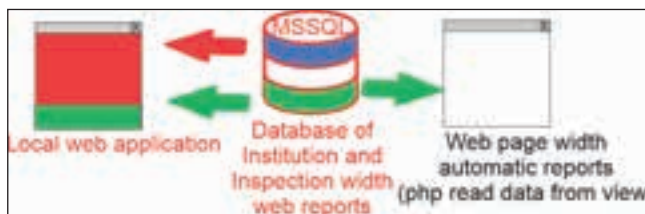
Picture 3. Phase 2 database upgrade with inspection data migration

The third phase will be publishing of the data from MSSQL View via the PHP platform to the web site.



Picture 4. Phase 3 Same database width 2 application, and automatic web reporting site width data form database

The fourth and the final phase will involve the creation of a web-based local application with local user authority segmentation.



Picture 5. Database width local web application and automatic web reporting data from database

After this phase, they could go a step further and enable online users to submit online applications. However, this requires further analysis due to the security aspect. Security testing is a type of software testing which purpose is detecting system’s vulnerabilities. It checks whether the system data is protected from unauthorized access, during which data could be altered or deleted.[1]

Data input

With the data input we will divide basic data and inspection data.

Namely, the basic information entered by the officials is about the registration of a wholesale distributors or manufacturers of medicines or medical devices.

The inspector who performs the inspection of all these legal entities can see all the above-named data, and have possibility to modify them. He can also enter additional amount of data about inspection control, as well as the ordered measures. Further upgrading of the database could allow the automatic download of data about the drugs from the Drug Database, or the automatic download of data about medical devices from the Medical Devices Database. This is not currently automated, but there is possibility for further development of the base.

Processing

In order to compare the difference, I will show the main table.

Namely, in the first phase, this table contained almost all data about the legal entity. This later changed in such a way that only the basic data remained, because the primary key rjesenjeID has taken other data from table Rjesenje that can be changed by the institution when changing the solution. In addition, the field of inspection was added.

Table 1. MAIN TABLE Institution on Phase 1 – list of data

| Name | Field type | Allowed blank | Primary key |
|-----------------|--------------|---------------|-------------|
| UstanovaID | Int | Unchecked | yes |
| RegistarskiBroj | Int | Checked | no |
| VrstaUstanoveID | Int | Checked | no |
| Ustanova | nvarchar(50) | Checked | no |
| Adresa | nvarchar(50) | Checked | no |
| MjestoID | Int | Checked | no |
| Telefon | nvarchar(10) | Checked | no |
| Telefax | nvarchar(10) | Checked | no |
| [E-mail] | nvarchar(30) | Checked | no |
| BrojRjesenja | nvarchar(21) | Checked | no |

| | | | |
|--------------------|---------------|---------|----|
| DatumRjesenja | datetime | Checked | no |
| OblikSvojine | nvarchar(100) | Checked | no |
| DatumPrestankaRada | datetime | Checked | no |
| Napomena | Ntext | Checked | no |
| Dokumentacija | Ntext | Checked | no |
| IDStatus | Int | Checked | no |

```
USE [ru]
```

```
GO
```

```
/***** Object: Table [dbo].[Ustanova] Script Date: 28.11.2019. 14:19:39 *****/
```

```
SET ANSI_NULLS ON
```

```
GO
```

```
SET QUOTED_IDENTIFIER ON
```

```
GO
```

```
CREATE TABLE [dbo].[Ustanova](
```

```
    [UstanovaID] [int] IDENTITY(1,1) NOT NULL,
```

```
    [RegistarskiBroj] [int] NULL,
```

```
    [VrstaUstanoveID] [int] NULL,
```

```
    [Ustanova] [nvarchar](50) NULL,
```

```
    [Adresa] [nvarchar](50) NULL,
```

```
    [MjestoID] [int] NULL,
```

```
    [Telefon] [nvarchar](10) NULL,
```

```
    [Telefax] [nvarchar](10) NULL,
```

```
    [E-mail] [nvarchar](30) NULL,
```

```
    [BrojRjesenja] [nvarchar](21) NULL,
```

```
    [DatumRjesenja] [datetime] NULL,
```

```
    [OblikSvojine] [nvarchar](100) NULL,
```

```
    [DatumPrestankaRada] [datetime] NULL,
```

```
    [Napomena] [ntext] NULL,
```

```
    [Dokumentacija] [ntext] NULL,
```

```
    [IDStatus] [int] NULL,
```

```
CONSTRAINT [PK_Ustanova] PRIMARY KEY CLUSTERED
```

```
(
```

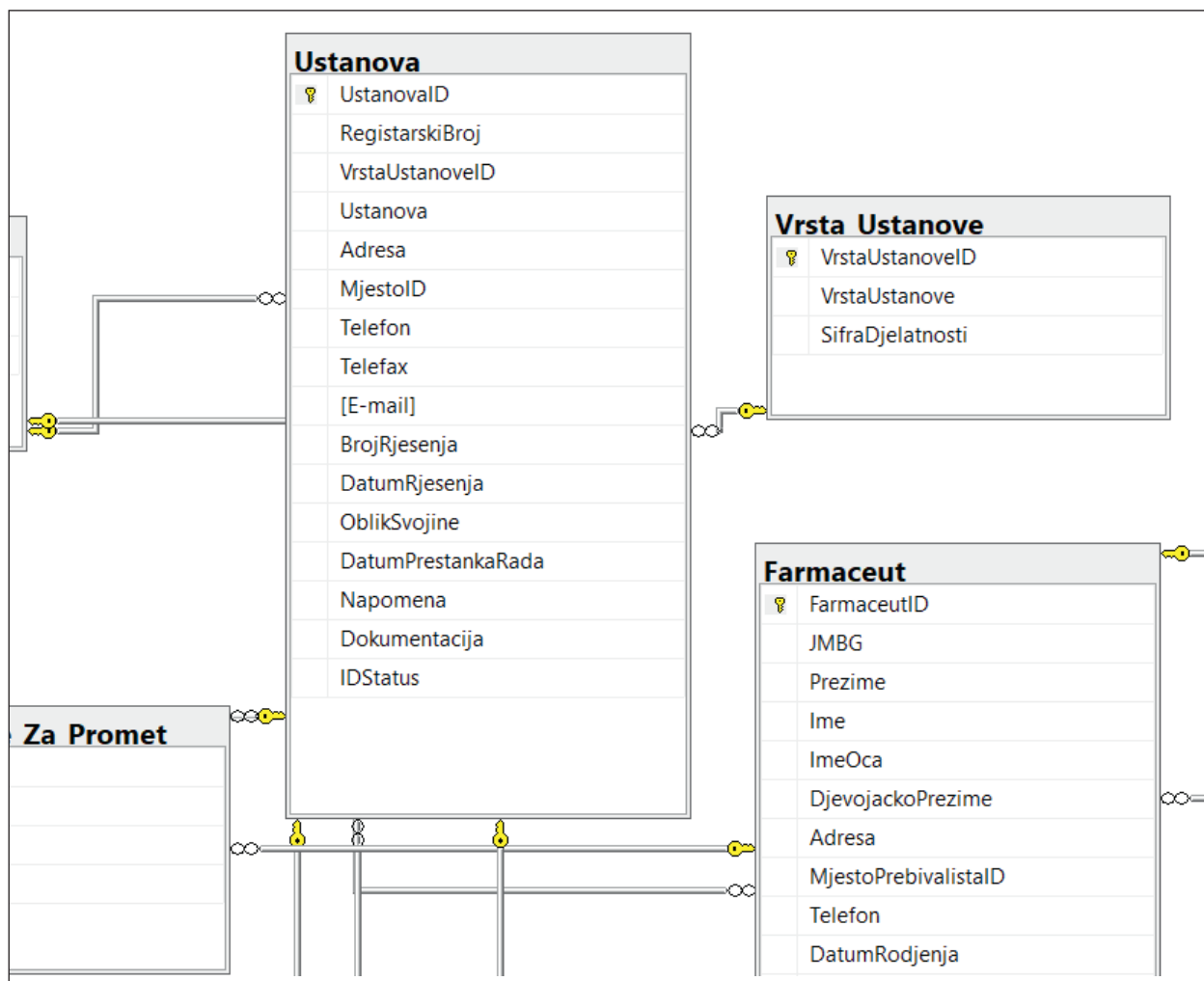
```
    [UstanovaID] ASC
```

```
)WITH (PAD_INDEX = OFF, STATISTICS_NORECOMPUTE = OFF, IGNORE_DUP_KEY = OFF, ALLOW_ROW_
```

```
LOCKS = ON, ALLOW_PAGE_LOCKS = ON) ON [PRIMARY]
```

```
) ON [PRIMARY] TEXTIMAGE_ON [PRIMARY]
```

```
GO
```



Picture 6. Main table at database diagram - Phase 1

Table 2. MAIN TABLE Institution on Phase 2 – list of data

| Name | Field type | Allowed blank | Primary key |
|------------------|------------|---------------|-------------|
| UstanovaID | Int | Unchecked | yes |
| RegistarSKI Broj | Int | Checked | no |
| RjesenjeID | Int | Checked | no |
| InspekcijaID | Int | Checked | no |
| IDStatus | Int | Checked | no |

```
USE [ru]
GO
```

```
/****** Object: Table [dbo].[Ustanova] Script Date: 28.11.2019. 23:45:35 *****/
SET ANSI_NULLS ON
GO
```

```
SET QUOTED_IDENTIFIER ON
GO
```

```

CREATE TABLE [dbo].[Ustanova](
    [UstanovaID] [int] IDENTITY(1,1) NOT NULL,
    [RegistarskiBroj] [int] NULL,
    [RjesenjeID] [int] NULL,
    [InspekcijaID] [int] NULL,
    [IDStatus] [int] NULL,
    CONSTRAINT [PK_Ustanova] PRIMARY KEY CLUSTERED
(
    [UstanovaID] ASC
)WITH (PAD_INDEX = OFF, STATISTICS_NORECOMPUTE = OFF, IGNORE_DUP_KEY = OFF, ALLOW_ROW_
LOCKS = ON, ALLOW_PAGE_LOCKS = ON) ON [PRIMARY]
) ON [PRIMARY]
GO

```

```

ALTER TABLE [dbo].[Ustanova] WITH CHECK ADD CONSTRAINT [FK_Ustanova_Mjesto] FOREIGN
KEY([InspekcijaID])
REFERENCES [dbo].[Mjesto] ([MjestoID])
GO

```

```

ALTER TABLE [dbo].[Ustanova] CHECK CONSTRAINT [FK_Ustanova_Mjesto]
GO

```

```

ALTER TABLE [dbo].[Ustanova] WITH CHECK ADD CONSTRAINT [FK_Ustanova_Status] FOREIGN
KEY([IDStatus])
REFERENCES [dbo].[Status] ([IDStatus])
GO

```

```

ALTER TABLE [dbo].[Ustanova] CHECK CONSTRAINT [FK_Ustanova_Status]
GO

```

```

ALTER TABLE [dbo].[Ustanova] WITH CHECK ADD CONSTRAINT [FK_Ustanova_Vrsta_Ustanove] FOREIGN
KEY([RjesenjeID])
REFERENCES [dbo].[Vrsta_Ustanove] ([VrstaUstanoveID])
GO

```

```

ALTER TABLE [dbo].[Ustanova] CHECK CONSTRAINT [FK_Ustanova_Vrsta_Ustanove]
GO

```

Output data

The output contains a report.

We have four reports in the phase 1, but in the phase 2 we have 13 reports. In the phase 3 we have 14 reports.

List of reports in the phase 1:

1. REGISTRY OF DRUG MANUFACTURERS IN BOSNIA AND HERZEGOVINA
2. REGISTRY OF MEDICAL DEVICES MANUFACTURERS IN BOSNIA AND HERZEGOVINA
3. REGISTRY OF MEDICINAL PRODUCTS WHOLESALE DISTRIBUTORS IN BOSNIA AND HERZEGOVINA
4. REGISTRY OF MEDICAL DEVICES WHOLESALE DISTRIBUTORS IN BOSNIA AND HERZEGOVINA

List of reports in the phase 2:

1. REGISTRY OF DRUG MANUFACTURERS IN BOSNIA AND HERZEGOVINA
2. REGISTRY OF MEDICAL DEVICE MANUFACTURERS IN BOSNIA AND HERZEGOVINA LICENSED FOR THE CLASS I MEDICAL DEVICE MANUFACTURING AGENCY

3. REGISTRY OF MEDICAL DEVICE MANUFACTURERS IN BOSNIA AND HERZEGOVINA AUTHORIZED FOR THE CLASS II MEDICAL DEVICE AND OTHER/LOWER CLASSES OF MEDICAL DEVICES MANUFACTURING
4. LIST OF RESPONSIBLE PERSONS FOR PLACING THE MEDICINE ON THE MARKET IN BOSNIA AND HERZEGOVINA
5. REGISTRY OF MEDICINAL PRODUCTS WHOLESALE DISTRIBUTORS WITH A LICENSE FOR IMPORT AND MARKETING OF MEDICINES IN BOSNIA AND HERZEGOVINA
6. REGISTRY OF MEDICINAL PRODUCTS WHOLESALE DISTRIBUTORS IN BOSNIA AND HERZEGOVINA WITH LICENSE FOR NATIONAL WHOLESALE
7. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED TO WHOLESALE ALL MEDICINAL PRODUCTS
8. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF MEDICAL DEVICES
9. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS I MEDICAL DEVICES
10. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS II MEDICAL DEVICES
11. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS II AND OTHER LOWER CLASSES OF MEDICAL DEVICES
12. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED SOLELY FOR THE TRANSPORT OF MEDICAL DEVICES
13. LEGAL ENTITIES WITH A PERMANENT OR TEMPORARY PROHIBITION OF ACTIVITIES

List of reports in phase 3:

1. REGISTRY OF DRUG MANUFACTURERS IN BOSNIA AND HERZEGOVINA
2. REGISTRY OF MEDICAL DEVICE MANUFACTURERS IN BOSNIA AND HERZEGOVINA LICENSED FOR THE CLASS I MEDICAL DEVICE MANUFACTURING AGENCY
3. REGISTRY OF MEDICAL DEVICE MANUFACTURERS IN BOSNIA AND HERZEGOVINA AUTHORIZED FOR THE CLASS II MEDICAL DEVICE AND OTHER/LOWER CLASSES OF MEDICAL DEVICES MANUFACTURING
4. LIST OF RESPONSIBLE PERSONS FOR PLACING THE MEDICINE ON THE MARKET IN BOSNIA AND HERZEGOVINA
5. REGISTRY OF MEDICINAL PRODUCTS WHOLESALE DISTRIBUTORS WITH A LICENSE FOR IMPORT AND MARKETING OF MEDICINES IN BOSNIA AND HERZEGOVINA
6. REGISTRY OF MEDICINAL PRODUCTS WHOLESALE DISTRIBUTORS IN BOSNIA AND HERZEGOVINA WITH LICENSE FOR NATIONAL WHOLESALE
7. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED TO WHOLESALE ALL MEDICINAL PRODUCTS
8. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF MEDICAL DEVICES
9. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS I MEDICAL DEVICES
10. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS II MEDICAL DEVICES
11. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED FOR THE TRANSPORT OF CLASS II AND OTHER LOWER CLASSES OF MEDICAL DEVICES
12. REGISTRY OF WHOLESALE DISTRIBUTORS AUTHORIZED SOLELY FOR THE TRANSPORT OF MEDICAL DEVICES
13. LEGAL ENTITIES WITH A PERMANENT OR TEMPORARY PROHIBITION OF ACTIVITIES
14. ADMINISTRATIVE PROHIBITION MEASURES IMPOSED DURING INSPECTION SUPERVISION AS OF 01.01.2015

Registry of manufacturers of Medicinal Products in Bosnia and Herzegovina

SELECT UstanovaID, RegistarSKI Broj, VrstaUstanoveID, Ustanova, Adresa, MjestoID, Telefon,

Telefax, [E-mail], BrojRjesenja, DatumRjesenja, OblikSvojine, DatumPrestankaRada, Napomena, Dokumentacija, IDStatus, DatumPrestankaRada AS Expr1, VrstaUstanoveID AS Expr2
 FROM dbo.Ustanova
 WHERE (VrstaUstanoveID = 10) AND (DatumPrestankaRada > { fn NOW() })

| Reg. br. | Vrsta ustanove | Naziv ustanove | Adresa | Mjesto | Telefon | Telefax | E-mail | Broj izdavanja | Datum izdavanja | Ugledni: nađ. doc. |
|-----------------------|---------------------|-----------------------|---------------------------|----------------|------------|------------|------------------------|----------------------|-----------------|--------------------|
| Banja Luka | | | | | | | | | | |
| 10 | Proizvođač lijekova | HEMOKRAM D.O.O. | Novoski 00 56 | Banja Luka | 051 331810 | 051 331823 | info@hemokram.com | 10-07-12-7-4180-3/17 | 17.12.2018. | 20.12.2019. |
| Lukavac | | | | | | | | | | |
| 1 | Proizvođač lijekova | ZADA PHARMACEUTICALS | Bistarski Brijeg 11 8 | Lukavac | 051 911140 | 051 551130 | zada@zada.ba | 10-07-12-7-40-1/15 | 17.02.2019. | 18.02.2019. |
| Sarajevo | | | | | | | | | | |
| 15 | Proizvođač lijekova | ARIAL PHARMACEUTICALS | Igrišnja 38, Vogošća | Sarajevo | 031 580780 | 031 580740 | info@arijal.ba | 10-07-12-9-3095-1/19 | 10.06.2019. | 09.06.2020. |
| 11 | Proizvođač lijekova | BONNLIJER | Jahorina br. 38 | Sarajevo | 031 254400 | 031 844871 | info@bonnlijer.ba | 10-07-12-4-4305-3/16 | 14.03.2019. | 13.10.2021. |
| 1 | Proizvođač lijekova | FARMAVITA | Igmenica br. 88 | Sarajevo | 031 476320 | 031 476311 | farmavita@farmavita.ba | 10-07-12-7-1300-1 | 06.07.2015. | 05.07.2020. |
| Brodski Brijeg | | | | | | | | | | |
| 14 | Proizvođač lijekova | NATURA PHARM D.O.O. | Slavko Stanić 58, Kladuša | Brodski Brijeg | 031 812115 | 031 812114 | info@natura-pharm.ba | 10-07-12-9-1079-1/19 | 26.12.2018. | 25.12.2019. |
| Travnik | | | | | | | | | | |
| 13 | Proizvođač lijekova | PHARMAMED | Dolac na Ljubici 56 | Travnik | 050 512000 | 050 515007 | OCJPHARMAS.MED.BA | 10-07-12-9-2319-1/18 | 13.04.2019. | 12.04.2021. |

Picture 7. Report Registry of manufacturers of Medicinal Products in Bosnia and Herzegovina source: http://www.almbih.gov.ba/_doc/proizvodjaci/rpl.pdf?5

Izvršene upravne mjere zabrane u inspekcijakom nadzoru od 01.01.2015.godine:

| Naziv firme | Adresa | Mjesto | Broj | Datum | Opis | Zabrana Važi od: | Datum ukidanje zabrane: |
|-----------------------------|-------------------|----------------|---------------------|-------------|--|------------------|-------------------------|
| SANITEX d.d. Velika Kladuša | Tone Hrovata br.2 | Velika Kladuša | 07-07-7-9-5548-5/19 | 11.11.2019. | Privremeno se zabranjuje da u prostorima Pogona masa i nanašanja i Pogona za konfekcioniranje flastera, vrši proizvodnju flastera. | 15.11.2019. | |
| SANITEX d.d. Velika Kladuša | Tone Hrovata br.2 | Velika Kladuša | 07-07-7-9-5548-3/19 | 11.11.2019. | Privremeno se zabranjuje proizvodnja i distribucija medicinskog sredstva-vazelinske komprese | 15.11.2019. | |
| | | | | | Zabranjuje se promet medicinskim sredstvom Wöhlik Conditioner Cliner mini duo, otopina za čišćenje i čuvanje trdnih | | |

Picture 8. Administrative prohibition measures imposed in the inspection supervision as of 01.01.2015: Source: <http://www.almbih.gov.ba/inspektorat/visited>: 28.11.2019.

CONCLUSION

Establishing a database in the control of the pharmaceutical market in Bosnia and Herzegovina will facilitate cooperation and business in the field of classification and supervision of legal entities engaged in the wholesale distribution of pharmaceutical and medical products.

Namely, databases in pharmacy are important for the classification of data and for the monitoring of the traceability of administrative proceedings and penalties against legal and natural persons who make offenses. We have seen in the paper that, in addition to being tracked, wholesale owners are also classified by the type. Sometimes we have a situation where the owner tries to maximize profits at the expense of noncompliance and does not want to comply with the minimum legislative requests. Sometimes we have a situation where a healthcare professional, pharmacist or a doctor tries to maximize profits by breaking the rules. In both cases, there is a procedure that first points to the need to eliminate deficiencies and return within legal frame, and if he fails to comply with repressive measures in the form of penal provisions and other sanctions, and even prison sentences. Namely, repressive sanctions are rigorous because the health of the population is threatened.

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