דרישות משרד הבריאות לבתי מסחר לתרופות לאחסון והפצה

מגר' יעקב כץ - רוקח מחוז מרכז

מטרות

- להכיר את דרישות משרד הבריאות בישראל לבתי מסחר לתרופות.

Pharmaceutical warehouse Legal Definition

- Pharmacists' Ordinance of 1981 **פקודת הרוקחות**
  Chapter 1; defines a pharmaceutical warehouse for distributing medicinal products. Also found in Eudralax Chap 4
- Article 47 of the Pharmacists Ordinance [New Version] 1981 provides that "a person shall not distribute on a wholesale level unless it is from a registered pharmaceutical warehouse or a warehouse of a health institution". They are licensed for this purpose by the Ministry of Health under the supervision of the authorized registered pharmacist

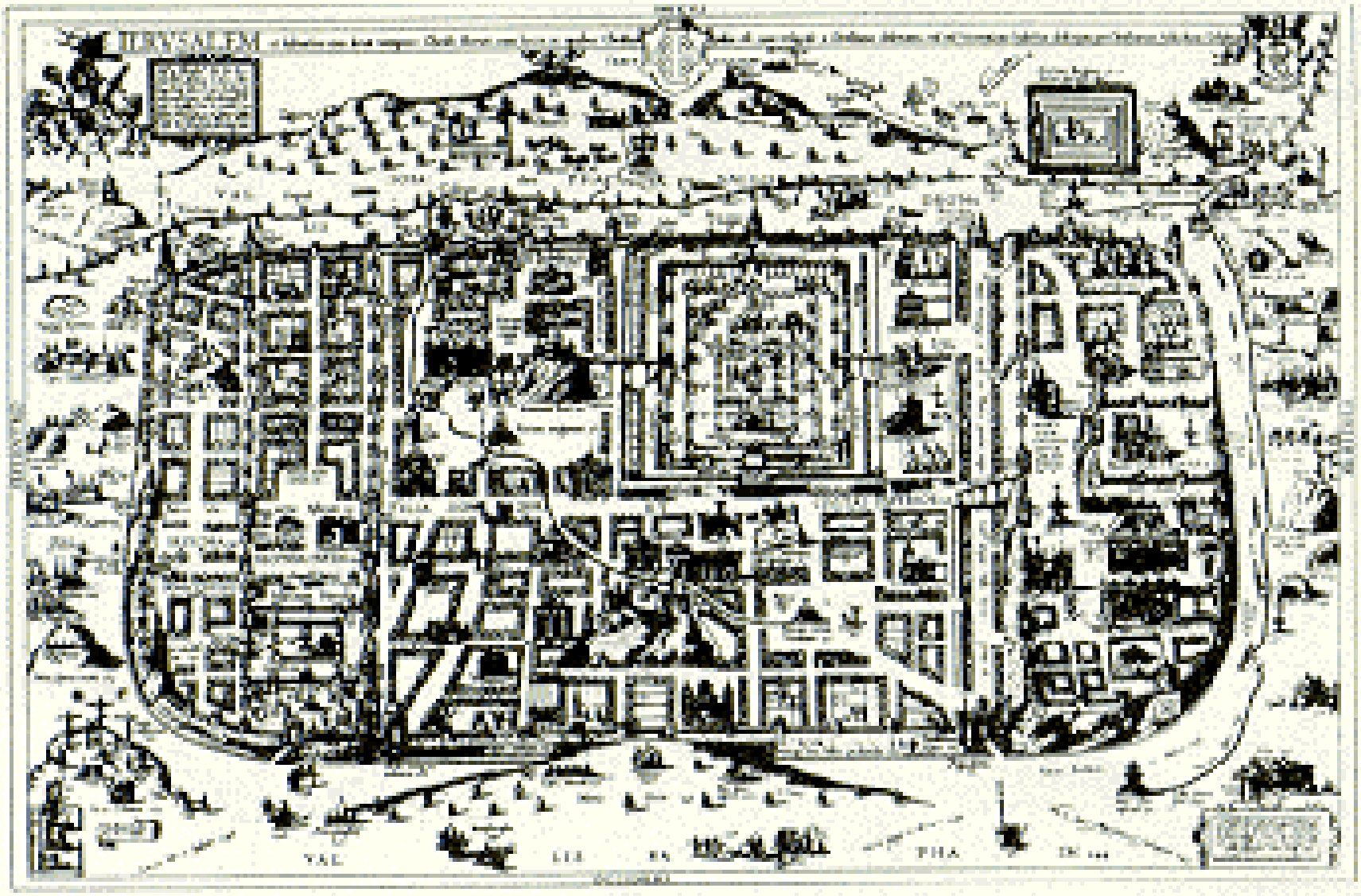
Pharmaceutical warehouse Practically Speaking

- **A wholesale business for the distribution of drugs to authorised, final suppliers, of medicines (pharmacies, hospitals etc.)**
- **Permitted to store, sell and distribute medicinal products or pharmacologically active raw materials for the manufacture of medicinal products.**

Infrastructure

- There is no regulation or guideline defining the infrastructure of pharmacy warehouses.
- Infrastructure of pharmacy warehouses is structured by ad-hoc rules laid down by the district pharmacies.
- Rules were approved informally by the pharmaceutical administration.
- Generally speaking require space of 100m2
- Divided into areas as per requirements but need areas to receive and send drugs; storage; quarantine; toilets; canteen etc.

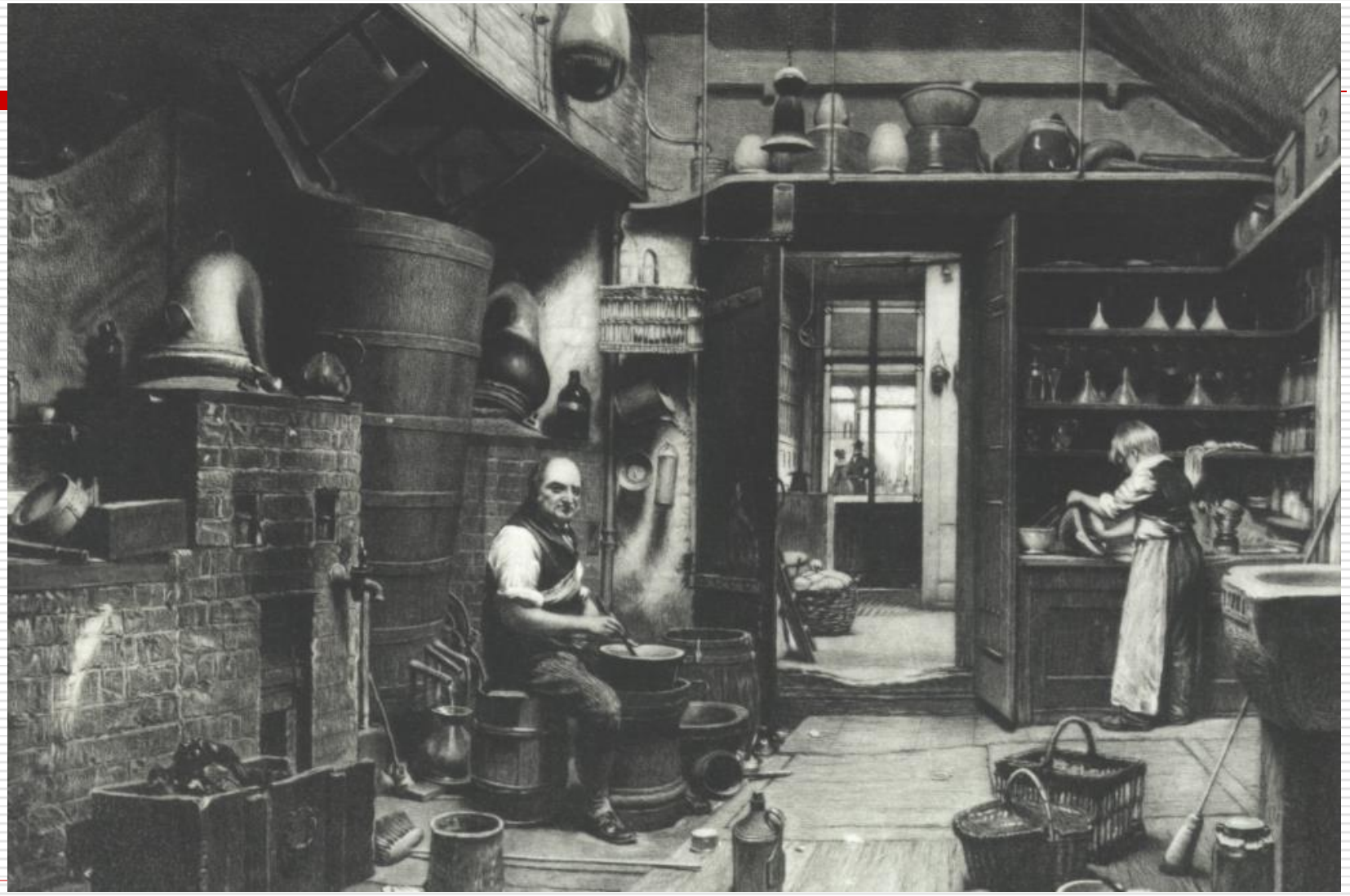
Yerushalyim 1584.



Approval to open pharmaceutical warehouse

- **Whichever type of activities it is engaged in, requires a business licence from the local authorities; which is only granted after approval by the district pharmacist.**
- **Step I: Plans of the warehouse and fee for preliminary approval submitted to the district pharmacist.**
- **Step II: If found to be satisfactory, the district pharmacist issues a certificate of approval in principal.**
- **Work proceeds on building the warehouse.**
- **Application is made to the district pharmacist for approval of the responsible pharmacist**
- **Step III: After completion of building the district pharmacist performs an inspection for approval.**
- **Application for a work permit approved and distribution of medications begins.**

Secundum artem



Types of Pharmaceutical warehouse (1)

Distributor only

- About 40 in Israel (15 in the Central Region)
- Products distributed may be of Israeli manufacture or imported.
- All types of authorized wholesaling companies are permitted to distribute drugs only after the drugs in question are released for use in the local market according to local regulations.
- GMP Regulations. "No facility can manufacturer, market, or store a medicinal product, without approval.

Types of pharmaceutical warehouse.(2) Importer/manufacturer and distributor.

- 94 in Israel and 56 in Central District.
- The act of subdivision or repackaging of a pharmaceutical product at the wholesale level is legally defined as a manufacturing operation; thus requiring licensing as "manufacturer. /importer“
- The law requires that all these wholesalers meet the requirements of the G.M.P regulations.
- This guideline relates to the storage and distribution conditions of all drugs including both human and veterinary drugs and drugs for use in clinical trials

Guideline Ex-015/01
Authorization as a manufacturer/importer

- **Procedure for manufacturers and importers to obtain, renew, and change authorization.**
- **Explains how authorization may be suspended or cancelled.**
- **The guideline is relevant to :**
  ***Manufacturers performing complete or partial process towards producing a medical drug. (including sub division or repackaging)**
  ***Importers who perform sub division or repackaging of medicinal drugs.**
  ***Does not apply to suppliers of drugs on an individual basis (pharmacies).**
- **QA is responsible for compliance.**

תפקידי בבית מסחר

רוקח אחראי ← רוקח מחוזי משה"ב ← נהלי משה"ב מס' 130, 139

מאושר ע"י — ע"פ דרישות

רוקח ממונה ← אגף הרוקחות ← נוהל משה"ב מס' 50

מאושר ע"י — ע"פ דרישות

רוקח QP (משחרר אצוות) ← המכון לביקורת ותקינה ← נהלי המכון ואגף הרוקחות

מאושר ע"י — ע"פ דרישות

My job


SOMETIMES I FEEL THAT I HAVE THE WORST JOB IN THE WORLD!
YA...RIGHT!

Responsible Pharmacist

- **A pharmaceutical warehouse is defined in the pharmaceutical ordinance of 1981 as a business that operates under the authority of a responsible pharmacist.**
- **Not to be confused with the position of appointed pharmacist appointed by a drug manufacturer or importer to handle drug registration.**
- **The responsible pharmacist is legally responsible for all professional matters relating to the location in question and must perform his duties as defined in the Guideline 139 which defines the duties of the responsible pharmacist in a pharmaceutical warehouse. April 2015.**
- .

Responsible Pharmacist

- All types of warehousing facilities are required by law to appoint a "responsible pharmacist"
- The responsible pharmacist is authorized by the district pharmacist or the pharmaceutical administration.
- Approval is given after interviewing the candidate and ensuring that he has the necessary qualifications including a minimum of 2 years of experience after gaining his licence to practice pharmacy.
- A licence to act as the responsible pharmacist is valid for up to 5 years and must be renewed after this period.

Guideline 139

- **Duties and authorization of the responsible pharmacist in a pharmaceutical warehouse. April 2015.**

- **Guideline 65 Permitted Activities at the Medicinal Product Warehouse.2006. Cancelled.**

Role and functions of Responsible Pharmacist

- **In order to import, manufacture (repackaging) or distribute drugs the premises in concern must be under the direct professional supervision of a "responsible pharmacist" who is legally responsible for all professional matters relating to the location in question.**
- **Guideline concisely defines the obligations of the responsible pharmacist and the framework of his duties within the warehouse.**
- **Defines how he/she receives his/her authorization to act as the responsible pharmacist and how this approval may be cancelled.**

Guideline 139

Role and functions of Responsible Pharmacist

- The responsible pharmacist is obligated to ensure that the commercial enterprise is managed according to all the laws and rules and regulations of the M of H.
- The business must adhere to all of the demands of the Ministry concerning GDP of pharmaceutical medications and pharmacologically active raw ingredients.
- Also includes storage conditions ensuring that there is strict adherence to the supply chain regulations in order to preserve public health requirements.
- The pharmaceutical warehouse may also be licensed as an importer and or manufacturer (referring to relabelling activities etc.). Cancellation of importer status will cause closure of the warehouse.

Qualified Person (QP)

- **In order to import drugs the importer, or a warehouse facility that additionally imports drugs, is required to employ a Q.P. and to receive a GMP certificate from the institute. This is in addition to all the other licences mentioned above.**
- **This GMP certificate is issued as outlined in the guideline on "GMP in pharmaceutical factories" GMP 055/03 The guideline is based in turn on the Good Manufacturing Practice Regulation 2008,**

Guideline 130

- **Importers are governed by the GMP regulations.**
- **Guideline No. # 126 Requirements for storing and transporting Medications (GDP) was updated in November 2011. At this time all instructions relating to GDP in pharmacy warehouses were deleted.**

GDP

- **GOOD DISTRIBUTION PRACTICES**
- **Right time;**
  Right place
  Right conditions and
  Right person!


Sorry, wrong house.

Guideline 130
GDP relating to pharmacy warehouses.

- Delineates the standards required in order to reach a level of acceptable Good Distribution Practice (GDP) in pharmaceutical warehouses.
- Applies to pharmaceutical warehouses, as defined in the Pharmacists Ordinance [New Version] 1981 as well as those of health institutions engaged in storage and distribution of drugs.
- The guideline falls on entities with permits as "manufacturer / importer", according to the GMP regulations; who store, distribute or re-label drugs that whether or not they are the MA holder.

Guideline 130
GDP relating to pharmacy warehouses.

- Israel has adopted the European guidelines on the subject of GDP, whilst adapting them to the regulatory requirements of Israel.
- All relevant professional principles also apply to other bodies dealing with drugs at various stages of the supply chain, including brokers and registered warehouses.
- Subcontracted distributors of drugs will be inspected and approved according to the same standard as warehouses licensed as "manufacturer./importer"
- The M of H reserves the right to audit sub-contractors, as part of their regular inspection programme.

Guideline 130
GDP relating to pharmacy warehouses.

- GDP is an integral part of the supply of medicines and involves a large number of factors.
- The guideline gives professional guidance and tools to assist in the GDP.
- Awareness of the rules and the principles of this guideline will guarantee control and supervision of the supply chain.
- The guideline applies to all activities included in the terms storage conditions and appropriate distribution, including brokerage operations, procurement, transportation, supply and export.

תנאי הפצה נאותים לתכשירים
נוהל 130

כלי עזר ודגשים לעסק המבקש
תעודת GDP

כללי – נוהל 130
Operation

- הסמכת ספקים
- הסמכת לקוחות
- קבלה
- אחסון
- השמדה
- ליקוט
- אספקה
- ייצוא

תיעוד

DOCUMENTATION

STRUCTURE AND EQUIPMENT
ציוד ומבנה

- מבנה
- ניטור סביבתי
- ציוד
- מערכות ממוחשבות
- ולידיות
- תיעוד

Operation

כללי – נוהל 130

- הסמכת ספקים
- הסמכת לקוחות
- קבלה
- אחסון
- השמדה
- ליקוט
- אספקה
- ייצוא

ניהול האיכות
QUALITY MANAGEMENT

- ***מערכת איכות***
- ***פעילויות במיקור חוץ***
- ***סקר הנהלה***
- ***ניהול סיכונים***

משאבי אנוש
HUMAN RESOURCES

- רוקח אחראי
- מנהל אבטחת איכות
- עובדים בחברה
- הדרכות
- היגיינה

תלונות, חשד לזיוף והחזרות
COMPLAINTS,SUSPICION OF FORGERY, RETURNS

- נהלים
- תלונות
- מוצרים מוחזרים
- מוצרים החשודים בזיוף
- החזרות מהשוק

פעולות במיקור חוץ
OUTSOURCING

- כל פעולה תתבצע תחת חוזה
- נותן החוזה
- מקבל החוזה

הובלה
TRANSPORT

- הגנה מפני נזקים
- הובלה
- אריזה ותיווך
- מוצרים הדורשים תנאים מיוחדים

מתווך (ברוקר)
BROKERS

- מערכת איכות
- כוח אדם
- תיעוד

ביקורות עצמיות
Self audit

על ידי גוף פנימי או חיצוני

Finally

- Thank you for your attention.
- I hope you enjoyed listening to me as much as I enjoyed speaking to you.