PATENT PROTECTION AND DATA SECURITY
PROTECTION

- Patent
- Supplementary Protection Certificate (SPC)
- Data security (data exclusivity, market exclusivity)
- Trade mark protection
PATENT

- The right to the exclusive use of an invention for a defined period of time - 20 years.
- Requires its disclosure, presentation of the essence of the adopted solution.
- Protects the interest of potential users of the invention. Provides guarantee of its value, makes it reliable.
- Patent application regarding substances or the method of production.
- The application is filed when it is not yet known whether a given product will be useful in the future.
SUPPLEMENTARY PROTECTIVE CERTIFICATE (SPC) (1/2)

Additional protective law extending the patent protection period for a maximum of 5 years (2.5 years on average).

The subject of SPC may be any patent protected medicinal product or plant protection agent that has obtained marketing authorisation.

The SPC application is filed within 6 months from the date of granting the marketing authorisation and if the patent was granted later, the period runs from the date of patent granting.
SUPPLEMENTARY PROTECTIVE CERTIFICATE (SPC) (2/2)

The certificate is valid until the end of the period of patent protection.

The protection applies to product covered by authorisation and such uses which were permitted before patent expiry.
SPC – WHAT IS THE DURATION OF THE PROTECTION PERIOD?
DATA SECURITY

• the possibility of a generic medicine marketing authorisation - after 8 years from the reference medicine marketing authorisation (DATA EXCLUSIVITY)

• the possibility of the introduction of generic medicine on the market - after 10 years from the introduction of the reference medicine on the market (MARKET EXCLUSIVITY).

• period extension to 11 years (+1 year) if within the first 8 years one or more additional therapeutic indications are registered and regarded as significantly beneficial compared to the existing therapy.

• 1 year of data exclusivity for the change of medicine status from prescription to OTC and for new indications for products with well-established medical use.
TRADE MARK PROTECTION (TRADEMARK)

• Medicine name protection in the form of a trademark which is registered in an appropriate Patent Office.
• The procedure takes about 1 year.
• The trademark protection is granted for 10 years.
• After filing an application the trademark ™ symbol may be used and after obtaining trademark protection the ® symbol may be used.
SUMMARY

• The medicine patent protection period is 20 years and may be extended for a maximum of 5 years with a supplementary protection certificate.

• A generic medicine manufacturer may apply for its registration after 8 years from the original medicine registration and it can be marketed after 10 years.

• Trademark registration allows for the use of the trademark symbol ®.