

## Key Performance Indicators in 2012

|                              |  |           |
|------------------------------|--|-----------|
| LICENSING OF HUMAN MEDICINES | Number of licensed medicines until 31.12.2012                                | 7 175     |
|                              | Number of procedures until 31.12.2012  | 3 593     |
|                              | Number of applications   | 9 414     |
|                              | Number of marketing authorisations for new medicines                         | 551       |
|                              | Number of new SIDC codes   | 4 109     |
| MEDICAL DEVICES              | Number of registered and notified medical devices until 31.12.2012           | 73 410    |
|                              | Number of new codes  | 1 583     |
|                              | Number of updated codes  | 5 309     |
|                              | Number of incidents of medical devices made available on the SK market       | 984       |
| PHARMACOVIGILANCE            | Number of suspected adverse reactions reported to SIDC                       | 966       |
|                              | Number of suspected serious adverse reactions reported to SIDC               | 408       |
| QUALITY CONTROL              | Number of medicines analysed   | 220       |
|                              | Number of magistraliters analysed  | 1 459     |
|                              | Number of analytical batch certificates controlled                           | 491       |
|                              | Number of medicines recalled from market                                     | 17        |
| CLINICAL TRIALS              | Number of applications for clinical trials                                   | 129       |
|                              | Number of approved applications for clinical trials                          | 149       |
|                              | Number of rejected applications for clinical trials                          | 6         |
|                              | Number of applications for new clinical facilities regarding clinical trials | 88        |
| INSPECTIONS                  | Inspections of Good Pharmacy Practice  | 1 067     |
|                              | Inspection of Good Manufacturing Practice                                    | 33        |
|                              | Inspection of Good Distribution Practice                                     | 48        |
|                              | Inspection of Good Practice for Preparation of Blood Products                | 22        |
|                              | Inspection of Good Clinical Practise   | 4         |
|                              | Inspection of Good Pharmacovigilance Practise                                | 0         |
| DRUG PRECURSORS              | Number of approved licences to dispense drug precursors                      | 196       |
|                              | Number of newly authorised medicines containing drug precursors              | 1         |
| ADVERTISEMENT OF MEDICINES   | Number of notifications concerning advertisement activities                  | 1 178     |
|                              | Number of controlled advertisement activities                                | 23        |
| FINANCIAL BALANCE            | Revenues transfered to state budget  | 6 595 259 |
|                              | Expenditures   | 3 818 370 |
|                              | Number of SIDC staff   | 165       |