



научный центр
экспертизы средств
медицинского применения

First results of the expert evaluation and authorization on the common market. Objectives and future expectations

Yuri Olefir,
General Director

23 October 2019

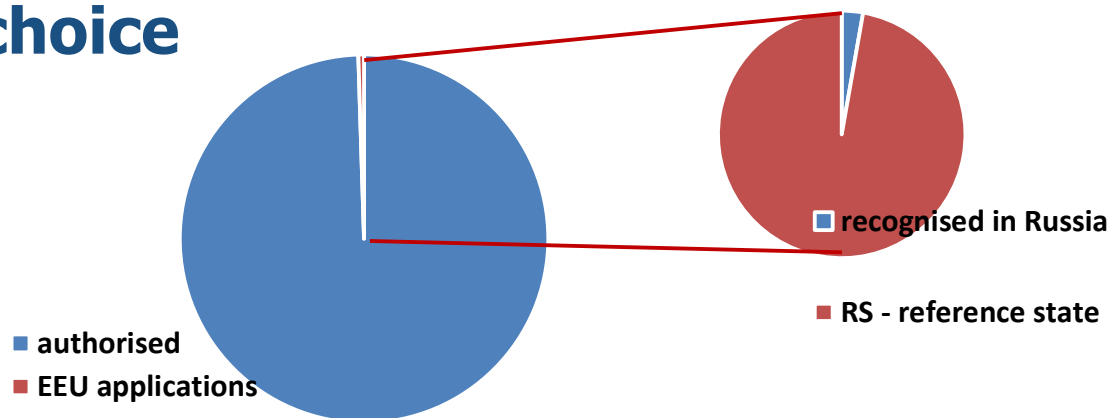
Federal State Budgetary Institution

"Scientific Centre for Expert Evaluation of Medicinal Products"

Of the Ministry of Health of the Russian Federation



Applicant's choice



START

Incoming No.
in IISU
36



April 2019

Incoming No.
in IISU
105



October 2019

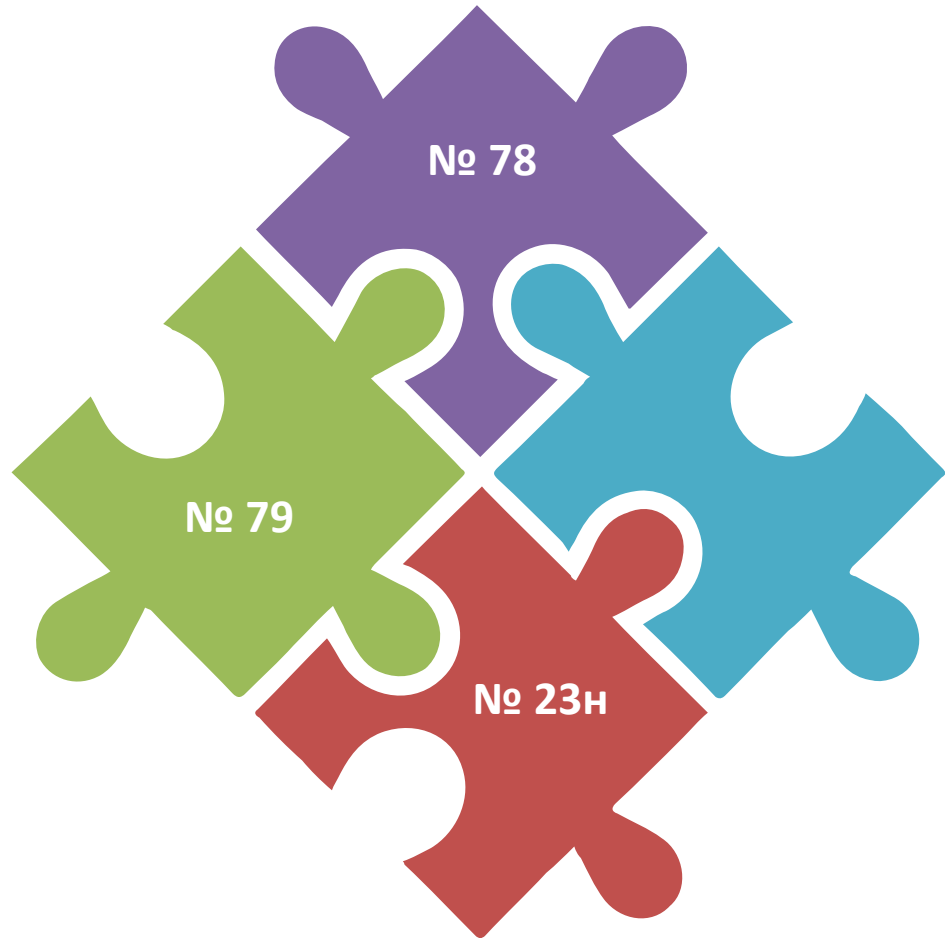


Russia as a reference state

Resolution No. 78 “On the rules of marketing authorisation and expert evaluation”

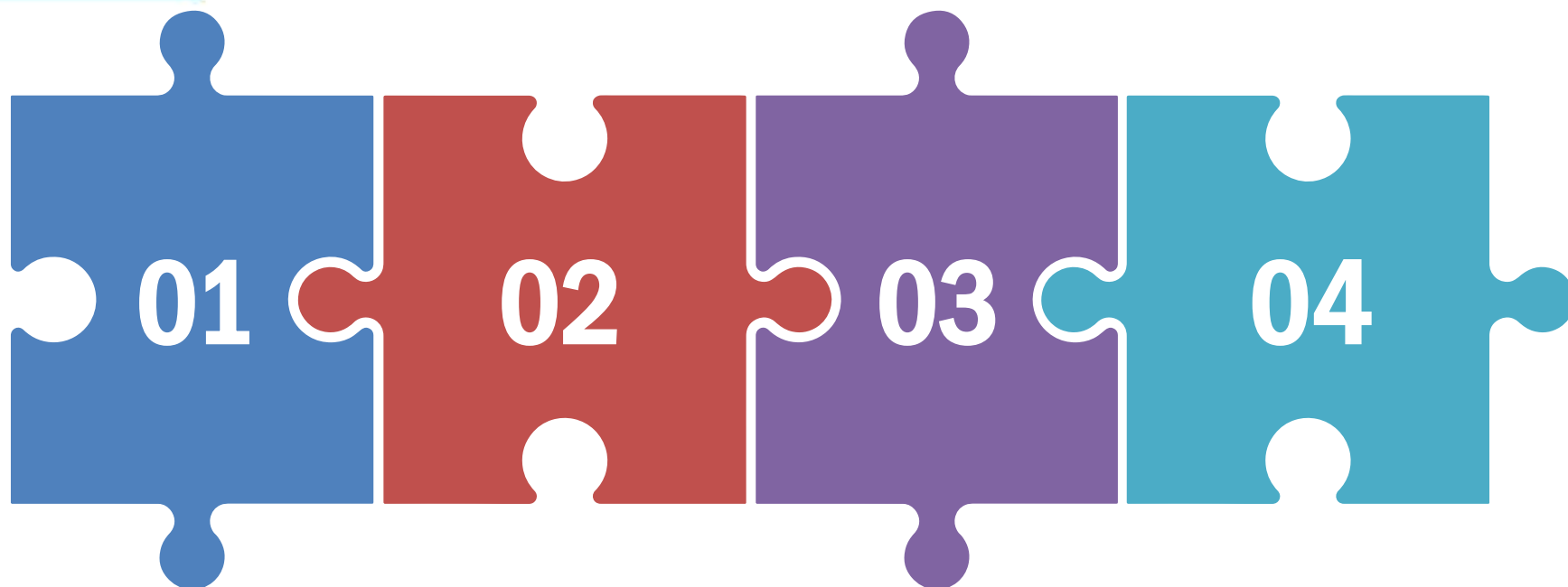
Resolution No. 79 “On the requirements to MAAs and master files in electronic form”

Administrative policy of the MoH of Russia, Order No. 23n





Technical validation of a master file



Compliance of the master file to XML format

Compliance of the document structure in electronic form to R.022 v.1.0.0 format

Availability and compliance of the master file modules to the appropriate procedure

Availability and compliance of the master file documents to the document type codes



Perform in a timely manner

2019

14000 MAs

2025

2021

At least 2500
master files
should be
made
compliant

2022

At least 2500
master files
should be
made
compliant

2023

At least 2500
master files
should be
made
compliant

2024

At least 2500
master files
should be
made
compliant



Follow our recommendations

Specialist
conferences.
RegLek,
November 2019

03

Information in the
applicant's profiles.
Leaflets, recommendations

01

02

Workshops of the
Training Centre



Thank you for your attention!



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