



Drug registration and labeling issues

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Russia

Miferistone in Russia

From 1999 as Mifegyne and Pencroftone
From 2003 as Mifepristone

Misoprostol in Russia

Up to 2006 use Cytotec and Artrotec
From 2006 Misoprostol labelled for Medical
Abortion as Misoprostol and Mirolut

Methods of abortion in Russia

First trimester

- EVA & MVA
- D&C
- Medical abortion with Mife and Miso (600+400)

Second trimester

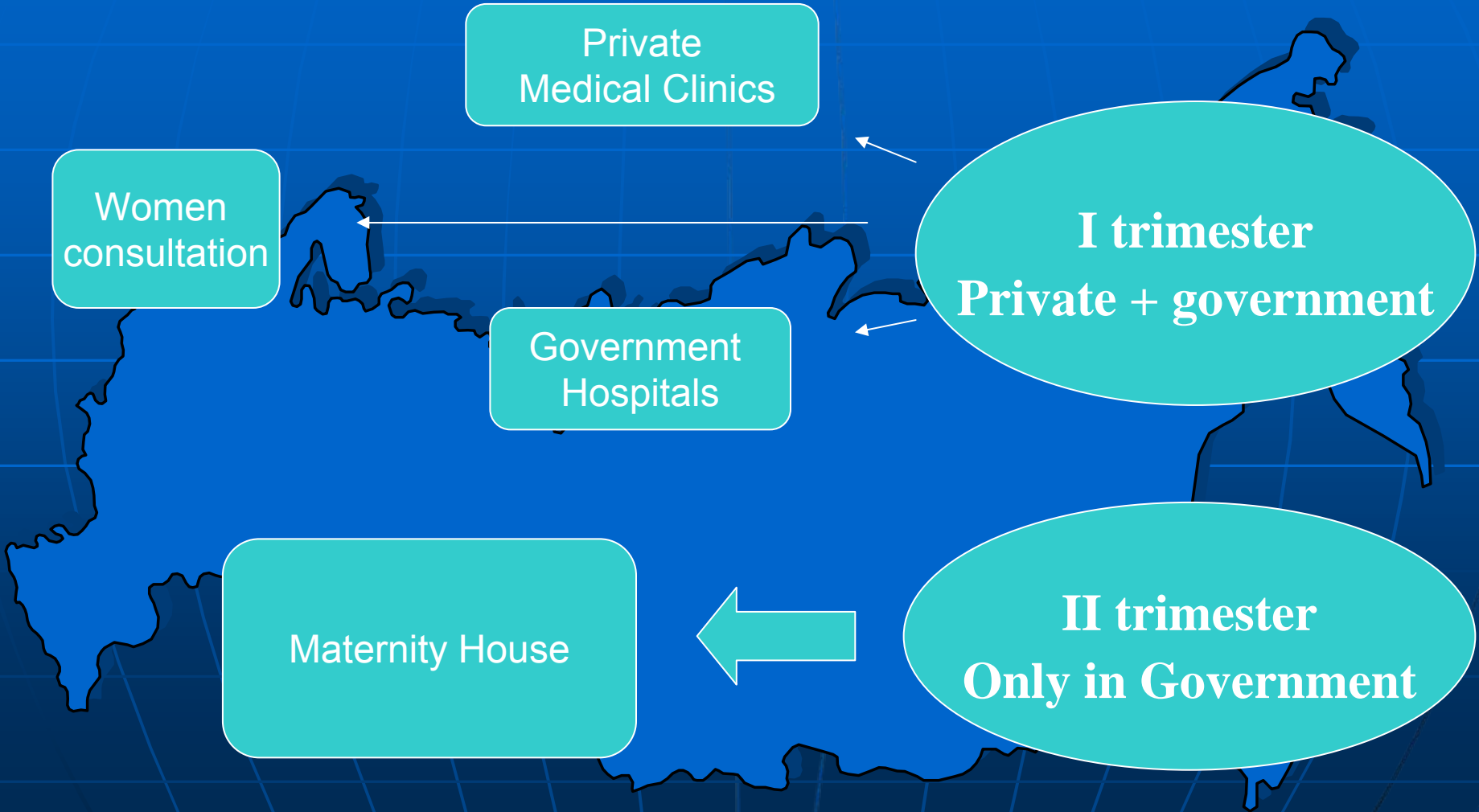
- Intra-amnial hypertonic solution or ethacridine lactate
- D&E
- Intracervical prostaglandins
- D&E very rare

Anastesia

- Local
- Total
- Analgesia

**Free of charge
for patient!!!!**

Abortion clinics in Russia



Russia

Structure of abortion in Russia (2007)



D&C First Trimester

78,4 %



22,5 %

MVA and EVA
up to 12 week

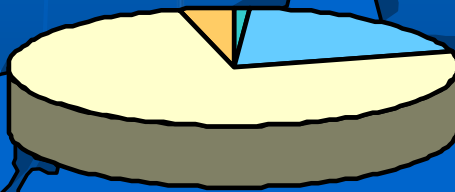
Mife+Miso up to 42d aminorea

1,72 %



>4 %

2 trimester
Intraamniol solution



1 trimester – 1219040 (93,5%)

2 trimester – 63170 (4,85%)

Total 1302480 (official date)

Expert value - more than 2 mln higher

Mifepistone and Misoprostol in Russia (2009)

1 trimester – up to 42 days amenorea c 2002г

2 trimester – not labeled

The only one Maternity House in RUSSIA use Mife+Miso
for second trimester abortion

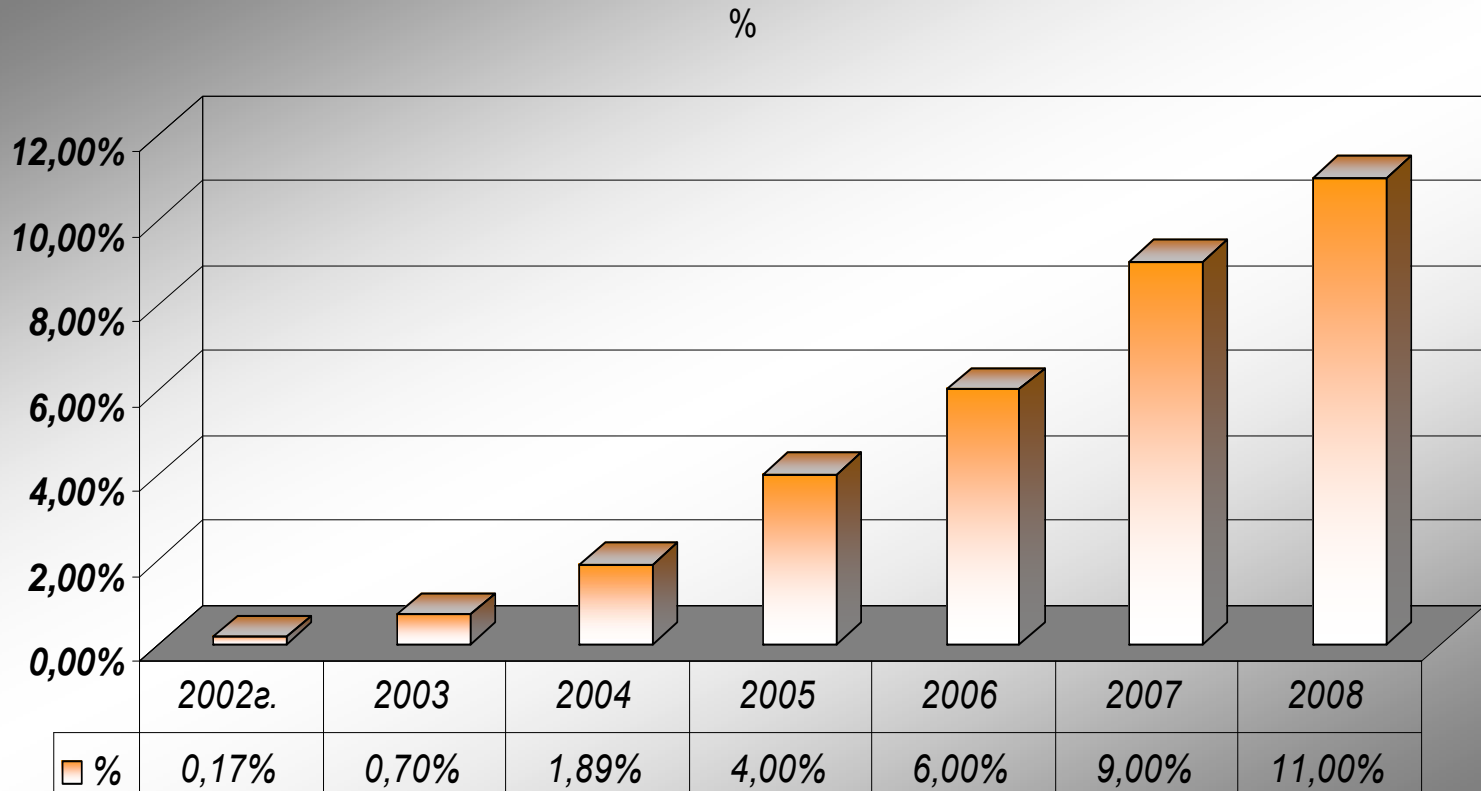
200 abortions for 2007-2008 yy

Method

3 tabs. Mifepristone po (by 200mg each 4 hours) + then
Misoprostol po (200 mkg each 4 hours)

Russia

Expert value rate of MA in Russia

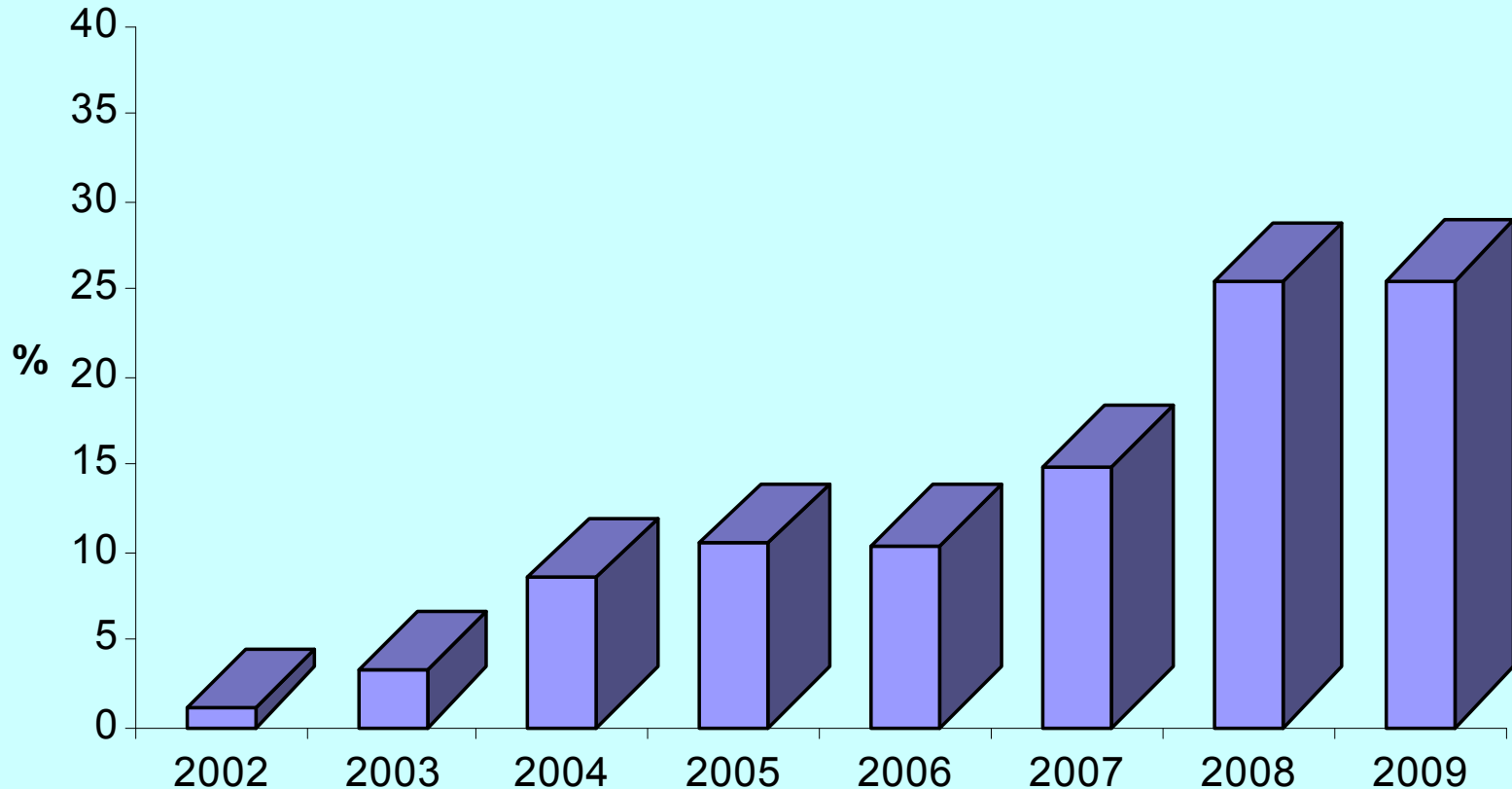


Official rate by MOH -1,56%
France 56%, Sweden 51%

Russia

Grow of Mifepristone sales in Russia

Total figure (together all distributors appr. 400000 packages by 3 tabl)



Russia

Mifepristone in Russia

The only one official protocol – “French protocol” 600mgMife+ oral 400mkgMiso.

Some of our clients work with modern protocol 200mgMife+ subling 400mkgMiso.

BUT NOT OFFICIAL

Nobody has any problem

Some of our clients work by “own” protocol 600-200mgMife+ 400-600mkgMiso.

Russia

Issues Associated with a Broader Distribution of Medical Abortion Technology in Russia

1. Current inability to use modern protocols legally. There are incremental changes but no major ones.
2. The need to educate doctors and convince them of the merits of modern technology; their fear of using new technologies, stemming from legal issues.
3. Limitations of the operation of the public healthcare system, stemming from the prohibition of fee-based services.
4. High cost of medical services in commercial clinics.
5. Government's indifference toward the need to improve the situation with respect to abortion and its exclusive focus on the demographic situation.

Positive Aspects

1. Patients like this method, and they have knowledge of it.
2. It is available in all regions of Russia.
3. There is a constant supply of medications, and there is consumer choice (competition between distributors).

Georgia

Pencroftone from 2004

Start of real sales from 2008
Through FAMILY Doctors

Total packages 2008-09 - 800 by 3 tabl.

Armenia & Azerbaijan

Made the clinical research in 2008 with Penicrftone , Mifepristone and Misoprostol in cooperation with Gynuity Health Project

We try to find the commercial organization for distribution drug in the regions.

Uzbekistan

Pencroftone has the registration certificate, but do not distribute on the territory. Main reason is economical situation with foreign currency.

Made the clinical research in 2008 with Pencrftone and Misoprostol in cooperation with Gynuity Health Project

We try to find the commercial organization for distribution drug in the regions.

Kazakhstan

Mifepristone and Misostol registered in the region (by Chinese factory)

A map of Kazakhstan is shown in a light blue color, centered on a dark blue background with a grid of latitude and longitude lines. The text is overlaid on the map.

CIS countries

Issues Associated with a Broader Distribution of Medical Abortion Technology in Russia

1. The search for a suitable distribution partner is underway; it is possible to utilize the latest protocols. No significant problems with registration.
2. There is a need for comprehensive education of doctors and arguments for the use of modern technology. The fear of some leaders to “let the genie out of the bottle” sometimes prevents the implementation of new technologies.
3. Limitations of the operation of the public healthcare system, stemming from the prohibition of fee-based services.
4. High cost of medical services in commercial clinics.
5. Government’s indifference toward the need to improve the situation with respect to abortion and its exclusive focus on the demographic situation.

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