The Ministry of Health and Social Protection (MHSP) is the main body in charge of health and pharmaceutical regulation in the country. The MHSP supervises a number of national-level institutions, including the National Centre for Preventive Health Medicine, the Republican Institute for Mother and Child Health and the National Centre for Public Health and Health Management. The MHSP also supervises health administrations of the country's 32 districts, three autonomous municipalities and two territorial units. Pharmaceutical policy implementation is regularly monitored and assessed by the Medicines Regulatory Authority (MRA) at the MHSP.

Key pieces of pharmaceutical market regulations include the 1993 Law on Pharmaceutical Activity, which was first amended in 1998. Legislation specifies licensing requirements for the production, importing and registration of drugs. The 1997 Law on Pharmaceuticals deals with quality, manufacturing and clinical trials. A Pharmaceuticals Agency has been created within the MHSP for the specific purpose of overseeing market authorisation and licensing of new pharmaceuticals, as part of the wider EU/Moldova Action Plan. Drug registration times reportedly range between six months and two years.

Medicines sold in Moldova require marketing authorisation. There are explicit and publicly available criteria for assessing the applications for marketing authorisation of pharmaceutical products. In January November 2011, there were 6,345 pharmaceutical products registered in Moldova. Legal provisions ensure that the MRA makes the list of registered pharmaceutical products available publicly.

A fee has to be paid for medicines' market authorisation (registration) based on applications. The amount per application for a pharmaceutical product containing a new chemical entity and a generic product are **US $1,125 and US$750**, respectively.

Mutual recognition mechanisms are not in place. However, there are exceptions, and waivers for registration do exist. According to the MHSP and the WHO, legislation allows the import of unauthorised products, but not the sale.

Annex N1 to the Order

of the Ministry of Health

Nr. 344 from 18.11.2004

REGULATIONS ON MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS FOR HUMAN USE

Chapter I. Basic notions

1.1 ***Marketing authorization of medicinal products for human use*** comprises the processes of evaluation, approval and registration of medicinal products for human use.

1.2 ***Evaluation*** is the process of complex expertise of product and its registration documentation, which is made by a group of specialists (pharmacists, pharmacologists and medical doctors etc.), resulting in establishment of conformity (or non-conformity) of product and authenticity of file and data contained there.

1.3 ***Approval*** is the procedure of official acknowledgement, including the elaboration of evaluation report and official approval of evaluation results at the Medical Commission, resulting in approval or denial of the product registration.

1.4 ***Registration*** is the process of issuance the Ministry of Health Order, granting the Registration Certificate and inclusion in the State Register of medicinal products authorized in Republic of Moldova and therefore the marketing authorization of medicinal product for human use.

1.5 ***Registration Certificate*** is the official document issued on the base of positive decision of Medical Commission and Ministry of Health Order, which allows the presence in the country and medical use of the product for which the particular Certificate is issued.

Chapter II. General provisions

2.1 The Ministry of Health authorize for marketing, on the base of positive decision of Medical Commission, the following medicinal products for human use:

- products which contain chemical substances;
- radiopharmaceutical products;
- biological products;
- phytotherapeutic products;
- homeopathic products;
- Products obtained through biotechnology; and also biologic reagents for "*in vitro*" diagnostic (antibodies including serums and/or imunoglobulines).

2.2 Medicinal products for human use can be marketed only after the granting of Registration Certificate by the Medicines Agency on the base of Ministry of Health Order and Medical Commission decision.

2.3 The Registration Certificate is granted for medicinal products for human use, which fulfill the quality, efficacy and safety conditions mentioned in the present regulations and other decisions of Ministry of Health.

2.4 The applicant for a Marketing Authorization should be Moldavian manufacturer, juridical person owning functioning authorization issued according to the legislation in force or foreign manufacturer authorized in accordance with the legislation in the country of origin, with representative office in Republic of Moldova or Moldavian juridical person empowered by the manufacturer, with specialized personnel employed (physicians or pharmacists).

2.5 Foreign manufacturers, which have registered or intend to register their products in Republic of Moldova should have representative office or specialized personnel – residents of Moldova employed, empowered in accordance with the legislation in force.

2.6 Representatives of foreign manufacturers should be in possession of Certificates issued by the Medicines Agency to confirm their ability to represent the interests of the manufacturer during the registration process in Moldova.

2.7 With effect from 01.01.2005 manufacturers applying for the registration in Republic of Moldova should present a written information regarding their official distributors.

Chapter III. Submission of applications for authorization/renewal of the marketing authorization

3.1 In order to start the procedure for marketing authorization/renewal of the marketing authorization of a medicinal product for human use, the applicant submits to the Medicines Agency an application form presented in Annex I and Annex II of "Norms regarding the documentation required for marketing authorization or renewal of the marketing authorization of medicinal products for human use", supporting documentation in accordance with the provisions mentioned in Annex 2 which is part of the present regulations and the following materials in the view of laboratory verifications:

- finished product samples presented in the packaging to be placed on the market in sufficient quantities to allow the verification of all quality parameters from the quality specification and in accordance with the methodology presented in the chemical, pharmaceutical and biological documentation;
- international or national reference substances, additional reagents;
- degradation products (where appropriate);
- Impurities (where appropriate).

3.2 The documentation should be submitted in one copy, with the exception of administrative part and chemical, pharmaceutical and biological documentation that will be submitted in 2 copies.

3.3 The documentation for imported and domestic products can be presented in Moldavian, Russian or English. The label, packaging and patient information of domestic medicinal products can be presented in Moldavian and any of internationally accepted language, for imported drugs – in Moldavian or Moldavian and Russian languages.

3.4 The authorization fee established by Government Decision is paid at the submission of the application if the documentation is completed (the completeness of documentation is attested in the course of preventive expertise).

3.5 The preventive expertise is made at the Department of Drug Registration of the Medicines Agency within 10 days and consists in the verification of existence of all necessary documents, their arrangement in the requested order and also the existence of finished product samples, reference substances, impurities and degradation products, where applicable.

3.6 If the documentation and materials submitted by the applicant are not in accordance with the present regulations, the authorization application is rejected and the applicant is informed within 3 days after verification.

3.7 After the payment of the authorization fee and after the money transfer in the Medicines Agency's account, the authorization documentation is distributed to evaluation groups and control department of the Medicines Agency.

3.8 Control department verify the control methodology described in the documentation and the received materials, and in case of absences or vagueness, an address with completion requests in which all requests of control department are included, is send to the applicant within 20 days from the date the products were distributed in the control department.

3.9 If the applicant does not answer integrally to all requests of control department by a single address and in maximum 6 months from the date of receiving the requests, the authorization procedure is interrupted.

3.10 The evaluation process of authorization documentation is finalized with the granting, depending on the case, of:
- a final report with requests for completion or clinical trials;
- a final report with recommendation for authorization or
- A final report with rejection of the authorization.

3.11 In the case of the final report with the requests for completion, in maximum 6 months from the receipt of the requests, the applicant should integrally answer to all formulated requests. Otherwise the registration procedure is interrupted.

3.12 After the expiration of 6 months period in which the applicant should answer the requests, the procedure can be resumed from the submission of a new application for marketing authorization accompanied by complete documentation and samples for laboratory verifications and the authorization fee.

3.13 After the issuance of the complete evaluation reports, these, together with the laboratory control results are presented in the meetings of the Medical

Commission, which decides upon conformity of drugs to the legislation requirements and the possibility to include them in the Order of Ministry of Health.

3.14 In the situation in which completions of the documentations were not necessary, and the documentation was presented complete along with finished product samples and reference substances, the period stipulated to finalize the procedure for Marketing Authorization is 1 month after the money transfer in the Medicines Agency's account and the confirmation by the accountancy of the Medicines Agency of receiving the corresponding registration fees. In the situation of clinical trials the period to finalize the registration procedure is prolonged with the time interval in which the clinical trials were conducted.

3.15 In the case completions of the documentation were necessary, the period to finalize the procedure is prolonged with the time interval in which the completions were transmitted and supplementary evaluations were led (the correspondence takes place accordingly).

3.16 During the evaluation process, the Drug Registration Department may ask for an inspection to the manufacturing site(s) and/or to the pre-clinical and/or clinical trials site(s) conducted by the experts of Medical Commission.

3.17 The Registration Certificate is issued on the base of positive decision of Medical Commission and Order of Ministry of Health and contains the product identification data (trade name, pharmaceutical form, strength, manufacturer, manufacturing site, Registration Certificate holder).

3.18 The Registration Certificate is valid for 5 years from the date of its granting by the Medicines Agency and can be renewed after this period at the request of its holder.

3.19 The Medicines Agency may issue Temporary Registration Certificate which are valid for 12 months for domestic medicinal products applied to the registration for the first time and / or the registration documentation was not complete in accordance with the requirements of the "Norms regarding the documentation required for marketing authorization or renewal of the marketing authorization of medicinal products for human use".

3.20 During the validity period of Temporary Registration Certificate the manufacturer will make all the necessary investigations in order to complete the authorization documentation as required by the present regulation.

3.21 The medicinal products, which have Registration Certificate, will be entered in the Register of medicinal products authorized in Republic of Moldova.

3.22 The granting of the Registration Certificate does not diminish the civil and criminal responsibility of the manufacturer for the quality and inofensivity of product allowed on the market.

3.23 During the authorization procedure, the applicant may ask for the procedure interruption. The documentation and registration fee will not be returned. The Medicines Agency will retain this documentation for 5 years.

Chapter IV. Refusal of the application for marketing authorization

4.1 The Medicines Agency may refuse the application for marketing authorization of a medicinal product in the case the verifications do not proof its quality, safety and efficacy or in case of biological reagents for "*in vitro*" diagnosis, the quality parameters of the product are not sufficiently demonstrated by the manufacturer.

4.2 In case of an unfavorable opinion of the Medical Commission, the applicant is announced in writing about the refusal of application for marketing authorization. The refusal is accompanied by a justificative report, which is based on the conclusions of evaluation reports.

4.3 Within 30 days from the receiving of the refusal report, the applicant may transmit to the Medicines Agency an appeal, which should be accompanied by detailed justifications for its support.

4.4 Within 60 days from the receiving of the appeal and justificative documents, the Medicines Agency should communicate an answer regarding the solution of the appeal.

Chapter V. Renewal of marketing authorization

5.1 The Registration Certificate can be renewed upon its holder request.

5.2 The renewal application is submitted to the Medicines Agency, 6 months prior to previous authorization expiration date and should be accompanied by the documents and materials as stipulated in "Norms regarding the documentation required for marketing authorization or renewal of the marketing authorization of medicinal products for human use".

5.3 The steps for renewal of the Registration Certificate are identical with the ones presented at Chapter III.

5.4 If changes on parameters of quality specification and control methodology comparing to the documentation presented at previous authorization did not occur and the medicinal product was not rebutted at the import, laboratory control is not performed.

5.5 If for a medicinal product, the renewal of the Registration Certificate is not requested within the term stipulated at item 5.2, it can be maintained in the therapeutic circuit until the exhaustion of quantities distributed in pharmaceutical network but not longer than 12 months from the expiration of the Registration Certificate validity. After the validity expiry of Registration Certificate the import of medicinal product ant manufacture of new production lot of domestic product is prohibited.

Chapter VI. Suspension and erasure of Registration Certificate

6.1 The Ministry of Health may decide the temporary suspension of Registration Certificate of a medicinal product for human use when the manufacturer changed any of the data from the dossier which was the basis of its authorization without announcing the Medicines Agency.

6.2 The suspension cease when the manufacturer will fulfill the parameters from the initially approved dossier or as a consequence of variation approvals.

6.3 In order to protect the human and animal health or the environment, the Ministry of Health may suspend or withdraw the Registration Certificate of a certain medicinal product which has been authorized in accordance with the present regulations.

6.4 The Medicines Agency will inform the manufacturer regarding the suspension or of withdrawal Registration Certificate.

6.5 The withdrawal of the Registration Certificate is decided by the Ministry of Health in the following situations:

- when the medicinal product is outrun by the therapeutic progresses, its efficacy is unsatisfactory, does not correspond to quality parameters, presents an unsatisfactory benefit/risk ratio;
- when severe adverse effects or other harmful properties occur;
- When the manufacturer decides to discontinue the manufacture.

6.6 The Medicines Agency will inform the manufacturer about the withdrawal of the Registration Certificate within 60 days.

Chapter VII. Variations to the marketing authorization

7.1 After the Registration Certificate was granted, the manufacturer has the obligation in respect of methods of manufacture and control to follow the scientific and technical progress and to make those improvements, which are necessary in order to enable the product to be manufactured and checked through generally accepted scientific methods.

7.2 Such changes named minor variations (type I) or major variations (type II) to the registration documentation, which has been the basis for obtaining the actual registration as well as changes which lead to granting of a new Registration Certificate should be submitted to Medicines Agency and should have its approval.

7.3 Type I variations (minor)

7.3.1 Refers to changes in the content of documentation presented in the support of previous authorization which do not lead to a fundamental change from the point of view of the quality, safety and efficacy of the authorized medicinal product, requiring only the update of product information, that is:

- change of the Registration Certificate:
- change of the name of medicinal product (either invented or common name);
- change of the name and / or address of the Registration Certificate holder;
- replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients);
- change in the product coloring system (addition, deletion or replacement of a colorant (s));
- change in the product flavoring system (addition, deletion or replacement of a flavour (s));
- change in coating weight of tablets or change in weight of capsule shells;
- change of qualitative composition of immediate packaging material;
- deletion of an indication;

- deletion of a route of administration;
- change of manufacturer or manufacturers of active substance;
- minor change of manufacturing process of the active substance;
- change of batch size of active substance;
- change in specifications of active substance;
- minor changes in manufacture of the medicinal product;
- change in size of finished product batch;
- change in specification of the medicinal product;
- change in synthesis / recovery of non – pharmacopoeial excipients which had been described in the original dossier;
- change in specification of excipients in the medicinal product (excluding adjuvants for vaccines);
- extension of shelf life foreseen at the time of authorization;
- change in the shelf – life after first opening;
- change in shelf – life after reconstitution;
- change of storage conditions;
- change in test procedure of the active substance;
- change in testing procedures of the medicinal product;
- changes to comply with supplements to pharmacopoeias (in cases where the marketing authorization refers to the current edition of the pharmacopoeia, no variation application is required provided the change is introduced within six months of adoption of the revised monograph);
- change in testing procedures of non – pharmacopoeial excipients;
- change of testing procedure of primary (immediate) packaging;
- change of testing procedure of administration device;
- change in the pack size of the medicinal product;
- change in the container shape (immediate packaging);
- change of imprints or other markings (except scoring) on tablet or printing of certain signs on capsules including addition or changing of inks used for marking the product;
- Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitative composition and mean weight.

This particular list is not exhausted and will be completed with new not foreseen examples.

7.3.2 Regarding the approval of a type I variation, the marketing authorization holder will submit to the Medicines Agency the variation application supported by required documentation.

7.3.3 After the payment confirmation Drug Authorization Clinical Evaluation and Pharmacovigilance Department and experts of Medical Commission of the Medicines Agency will make the evaluation of the application and documentation for variation.

7.3.4 The Medicines Agency is in position to review the validity of Registration Certificate should it be necessary.

7.4 Variation type II (major)

7.4.1 Type II variations (major) are changes which lead to an important modification from the point of view of the quality, safety and efficacy of the

medicinal product but not require granting of a new Registration Certificate, those are:

- changes in the manufacturing of active substances;
- changes in the finished product composition (introduction of a new excipient, modification in the product preservants system, modification of excipients, with significant change in pharmaceutical or therapeutic properties of medicinal product, etc);
- changes in the immediate packaging of finished product;
- Changes in the therapeutic indications of medicinal product (introduction of a new therapeutic indication which leads to a change in the third level ATC (Anatomical, Therapeutically, Chemical) requires a new authorization).

7.4.2 Regarding the approval of a type II variation, the marketing authorization holder will submit to the Medicines Agency the variation application supported by required documentation.

7.4.3 After the payment confirmation Drug Registration Department and experts of Medical Commission of the Medicines Agency will make the evaluation of the application and documentation for variation.

7.5 Changes which lead to granting of a new marketing authorization

7.5.1 Changes which lead to granting of a new Registration Certificate are modifications which fundamentally alter the term of marketing authorization and impose the submission of an application with a view to granting of a new Registration Certificate.

- Changes to the active substance(s):

- addition of one or more active substances, including antigenic components for vaccines;
- deletion of one or more active substances, including antigenic components for vaccines;
- quantitative change to the active substance(s);
- replacement of the active substance(s) by a different salt/ester complex/different derivative (with the same therapeutic moiety);
- replacement by a different isomer or by a different mixture of isomers, replacement of a mixture by an isolated isomer (e.g., racemate by a single enantiomer);
- replacement of a biological substance or of a product of biotechnology with one of a different molecular structure; modification of the vector used to produce the antigen/ source material including the holder of the cell bank from a different source;
- A new ligand or coupling mechanism for a radiopharmaceutical product.

- Changes to the therapeutic indications(*):

- addition of an indication in a different therapeutic area, either treatment, diagnostic or prophylaxis;
- Change of the indication to a different therapeutic area, either treatment, diagnostic or prophylaxis.

- Changes to strength, pharmaceutical form and route of administration(**):

- modification of bioavailability;
- modification of pharmacokinetics (e.g., change in the rate of release);

- addition of a new strength;
- modification or addition of a new pharmaceutical form;
- Addition of a new route of administration.

7.5.2 If a new Registration Certificate is granted, the previous authorization is erased.

7.5.3 The necessary timeframe for approval of a variation which lead to granting of a new Registration Certificate is maximum 3 months (new therapeutic indication) and maximum 4 months (changes to the active substance(s), pharmaceutical form, strength, route of administration).

7.5.4 When a new pharmaceutical form, which change the rate of release, is added (for example: slow release) or when a new route of administration is proposed, the applicant has to present as the support documentation the results of clinical trials.

(*) Therapeutic area is defined as the third level of Anatomical, Therapeutic, Chemical code (ATC).
(**) For parenteral administration it is necessary to distinguish between intra-arterial, intra-venous, intramuscular, subcutaneous and other routes.

Standard registration request

Of the medicinal product for evaluation and DNT examination:

1. Trade name of the product: _____
2. Pharmaceutical form, dosage, strength or concentration, route of administration: _____
3. Name of the active ingredient:_____
4. Holder of the marketing authorization /contact person/company
4.1 Holder of the marketing authorization

Name:	
Address:	
City:	
Country:	
Telephone:	
Fax:	
E-mail:	

4.2 Person ☐ Company ☐ Authorized for communication with the Medicines Agency during the registration / renewal procedure

Name:	
Address:	
City:	
Country:	
Telephone:	
Fax:	
E-mail:	

4.3 Person ☐ Company ☐ Authorized for communication between the MA holder and Medicines Agency after registration and if it is different Person / company from pt. 4.2.

Name:	
Address:	
City:	
Country:	
Telephone:	
Fax:	
E-mail:	

4.4 Person ☐ Authorized to pay the registration fee ☐ Company	
Name:	
Address:	
City:	
Country:	
Telephone:	
Fax:	
E-mail:	

5. Countries where the product has been registered

Name of the country:	*MA number:*	*Date of granting:*

6. Countries where the applicant sent an application for registration

Name of the country:	*MA number:*	*Date of granting:*

7. Countries where the application for registration is pending(1)

Name of the country:	*Refused:*	*Suspended:*	*Revoked:*

(1) - specify the reasons for each situation

8. Application is supported by:

The application files (in 2 examples)	

Sample		
Reference standard		
I. A	**ADMINISTRATIVE DATES**	Page
1.	Application for registration	
2.	***Certificate of a Pharmaceutical Product, which conforms to the format recommended by the WHO completed at all columns and annexes***	
	- number, date:	
	- certifying authority:	
	- validity:	
3.	***GMP certificate***	
	- number, date:	
	- certifying authority:	
	- validity:	
4.	***Marketing Exporting (certifying) issued***:	

	- country:		
	- number, date:		
	- certifying authority:		
	- validity:		
	Or other countries (MA number, date of granting, validity):		
5.	***Manufacturing license (MP[1])***		
	- number, date:		
	- certifying authority:		
	- validity:		
I.B.1	Summary of the Product Characteristics		
	- in Romanian / Russian:		
	- in English		
I.B.2.1	Package leaflet		
	- in Romanian / Russian:		
	- in English		

I.B.2.2	Proposal for packing, and labeling	
	- in Romanian / Russian:	
	- in English	
I.C.	**EXPERT REPORT ON CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL DOCUMENTATION, including:**	
I.C.1	Critical evaluation	
I.C.2	Tabular part	
I.C.3	Information about qualification and training of the expert	
II.	**CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL DOCUMENTATION**	
II.A	**COMPOSITION**	
II.A.1	Composition of the medicinal product	
II.A.2	Recipient	
II.A.3	Formula used in clinical studies	
II.A.4	Pharmaceutical development	
II.B.	**METHOD OF PREPARATION**	

II.B.1	Manufacturing formula (including the data about batch size)	
II.B.2	Process of manufacture	
II.B.3	Validation of the technological process	
II.C	**CONTROL OF STARTING MATERIALS**	
II.C.1	Active ingredient (s)	
II.C.1.1	Specifications and routine tests	
II.C.1.1.1	The active ingredient included in Pharmacopoeia - Certificate presentation according to FE[2]	
II.C.1.1.2	Active ingredient written and not written in pharmaceutical form according to FE - presence of the DMF[3] or scientific dates	
II.C.1.1.3	Analysis bulletin	
II.C.2	Excipients	
II.C.2.1	Specification and routine tests	
II.C.2.2	Scientific dates	
II.C.2.3	Analysis bulletin	
II.C.3	Packing materials (Primary packing)	
II.C.3.1	Specification and routine	

	tests	
II.C.3.2	Scientific dates	
II.C.3.3	Analysis bulletin	
II.D	**CONTROL TESTS ON INTERMEDIATE PRODUCTS**	
II.E	**CONTROL TESTS ON FINISHED MEDICINAL PRODUCTS**	
II.E.1	Specification and routine tests for finished medicinal products	
II.E.1.1	Product specification and delivery tests	
II.E.1.2	Control methodology	
II.E.2	Scientific dates	
II.E.3	Analysis bulletin	
II.F	**STABILITY**	
II.F.1	Stability of the active ingredient	
II.F.2	STABILITY OF THE FINISHED MEDICINAL PRODUCTS	
II.G	**BIOAVAIBILITY STUDIES**	

II.H	**ENVIRONMENTAL RISK ASSESSMENT FOR PRODUCTS CONTAINING GMO`S**	
II.Q	**OTHER INFORMATIONS**	
III	**PHARMACO – TOXICOLOGICAL DOCUMENTATION**	
- Toxicological documentation		
III.A	Sharp toxicity	
	- Toxicity after repeated dosages	
III.B	**CHRONIC TOXICITY**	
	- Toxicity after repeated dosages	
III.C	**EMBRIO/FOETAL AND PERINATAL TOXICITY**	
III.D	**MUTAGENIC POTENTIAL**	

III.E	**CARCINOGENIC POTENTIAL**	
III.F	**LOCAL TOLERANCE**	
- Pharmacological documentation		
III.G	**PHARMACODYNAMICS**	
III.G.1	Pharmacodynamic potential	
III.G.2	General pharmacodynamics	
III.G.3	Interaction with other medicaments	
III.H	**FARMACOKINETICS**	
III.H.1	After one dose administration	
III.H.2	After repeated dose administration	
III.H.3	Tissue distribution (normal and pregnant animals)	
III.H.4	Biotransformation	
IV	**CLINICAL DOCUMENTATION**	
IV.A	**CLINICAL PHARMACOLOGY**	

IV.A.1	Pharmacodynamics	
IV.A.2	Pharmacokinetics	
IV.A.3	Interactions	
IV.B	**BIOAVAILABILITY / BIOEQUIVALENCE**	
IV.C	**CLINICAL EXPERIENCE**	
IV.C.1	Clinical experiments	
IV.C.2	Post-recording experience	
IV.C.3	Published and unpublished clinical experience (other than p.IV.C.1)	
IV.C.4	Brief information about continuation of the clinical studies and uncompleted studies	

Note:

1. MP – domestic products
2. EPh – European Pharmacopoeia
3. DMF – Drug Master File

I guarantee the authenticity and completeness of the information given about the product.

Date .....

Nome .....

Function .....

Signature .....

Checked validity of exposed dates:

Date .....

Nome .....

Function .....

Signature .....

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