



独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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July 31 to August 4, 2017
GMP Inspection Seminar 2017



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Drugs Reviews

In the review of drug applications, PMDA reviewers, who have degrees in pharmaceutical science, medicine, veterinary medicine, physical science, biostatistics, or other specialties, form a team to evaluate the quality, pharmacology, pharmacokinetics, toxicology, clinical implications, and biostatistics regarding the particular drug product under review. During the review process, the reviewers exchange opinions with external experts (Expert Discussions) to ensure that more effective reviews are conducted by making use of their advanced expertise. In addition, PMDA participates in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has actively incorporated the guidelines agreed upon at ICH into its drug reviews.

PMDA strives to speed up the review process by setting target review times, while clarifying the standards for review by publishing the basic considerations for reviewers on its website.

PMDA's drug reviews encompass not only new drugs but also generic drugs, OTC drugs / "behind-the-counter (BTC)" drugs (requiring pharmacists' advice) that can be purchased at pharmacies without a doctor's prescription, and quasi-drugs. PMDA also conducts re-examinations and re-evaluations of approved drug products.

In FY 2013, a total of 7118 drugs were approved, of which 4008 were prescription drugs (including 504 new drugs), 916 were OTC drugs / BTC drugs, 166 were in vitro diagnostics, and 2028 were quasi-drugs.

- [Points to Be Considered by the Review Staff Involved in the Evaluation Process of New Drug](#)



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Review Reports: Drugs

The following English translations of review reports are intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese originals and the translations, the former shall prevail. PMDA shall not be responsible for any consequence resulting from use of the English versions.

The review reports were selected for translation among those of drugs with a new active ingredient that recently received marketing approval, in consideration of relevant factors including the novelty and priority.

Browse by letter

Name			EN	JP
Samsca	tolvaptan	March 2014		
Seebri	glycopyrronium bromide	September 2012		
Soliris	eculizumab (genetical recombination)	April 2010		
Sovaldi	sofosbuvir	March 2015		
Sovriad	simeprevir sodium	September 2013		
Spiolto	tiotropium bromide hydrate/olodaterol hydrochloride	September 2015		
Squarekids	adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (salk vaccine) combined vaccine	July 2014		
Stelara	ustekinumab (genetical recombination)	December 2010		
Stivarga	regorafenib hydrate	March 2013		
Strensiq	asfotase alfa (genetical recombination)	July 2015		
Stribild	elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate	March 2013		
Suglat	ipragliflozin L-proline	January 2014		
Suiny	Anagliptin	December 2015		
Sunvepra	asunaprevir	July 2014		



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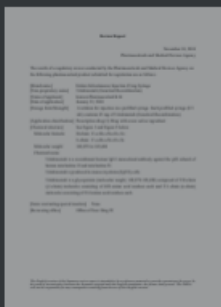
53%



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Report on the Deliberation Results

December 6, 2010

Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

[Brand name] Stelara Subcutaneous Injection 45 mg Syringe
[Non-proprietary name] Ustekinumab (Genetical Recombination) (JAN*)
[Applicant] Janssen Pharmaceutical K.K.
[Date of application] January 21, 2010

[Results of deliberation]

In the meeting held on November 29, 2010, the Second Committee on New Drugs concluded that the product may be approved and that this result should be presented to the Pharmaceutical Affairs Department of the Pharmaceutical Affairs and Food Sanitation Council.

The product is classified as a biological product, the re-examination period is 8 years, and the drug substance and the drug product are both classified as powerful drugs.

The conditions for approval should be modified as follows.

After modification

[Conditions for approval]

The applicant is required to:

1. Conduct a post-marketing drug use-results survey, which covers all the patients treated with the product, until data from a certain number of patients will be accumulated, in order to collect data on the safety and efficacy of the product as soon as possible and to take necessary measures to ensure proper use of the product.
2. Conduct a large-scale post-marketing surveillance study to fully evaluate the safety of the product and to investigate the efficacy and long-term safety of the product, including the occurrence of infections, etc.

Before modification

[Conditions for approval]

The applicant is required to:

1. Conduct a post-marketing drug use-results survey, which covers all the patients treated with the product, until data from a certain number of patients will be accumulated, in order to collect data on the safety and efficacy of the product as soon as possible and to take necessary measures to ensure proper use of the product.
2. Conduct a large-scale post-marketing surveillance study to fully evaluate the safety of the product and to investigate the efficacy and long-term safety of the product and the occurrence of infections, etc.

(The underlined parts are the changes.)

This English version of the Japanese review report is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA will not be responsible for any consequence resulting from the use of this English version

*Japanese Accepted Name (modified INN)

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Review Report

November 10, 2010

Pharmaceuticals and Medical Devices Agency

The results of a regulatory review conducted by the Pharmaceuticals and Medical Devices Agency on the following pharmaceutical product submitted for registration are as follows.

[Brand name] Stelara Subcutaneous Injection 45 mg Syringe
[Non-proprietary name] Ustekinumab (Genetical Recombination)
[Name of applicant] Janssen Pharmaceutical K.K.
[Date of application] January 21, 2010
[Dosage form/Strength] A solution for injection in a prefilled syringe. Each prefilled syringe (0.5 mL) contains 45 mg of Ustekinumab (Genetical Recombination).

[Application classification] Prescription drug (1) Drug with a new active ingredient

[Chemical structure] See Figure 1 and Figure 2 below.

Molecular formula: H-chain $C_{220}H_{440}N_{102}O_{171}S_{17}$

L-chain $C_{103}H_{198}N_{27}O_{237}S_6$

Molecular weight: 148,079 to 149,690

Chemical name:

Ustekinumab is a recombinant human IgG1 monoclonal antibody against the p40 subunit of human interleukin-12 and interleukin-23.

Ustekinumab is produced in mouse myeloma (Sp2/0) cells.

Ustekinumab is a glycoprotein (molecular weight, 148,079-149,690) composed of 2 H-chain (γ1-chain) molecules consisting of 449 amino acid residues each and 2 L-chain (κ-chain) molecules consisting of 214 amino acid residues each.

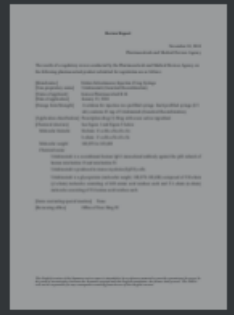
[Items warranting special mention] None

[Reviewing office] Office of New Drug IV

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Heavy Chain

EVQLVQSGAE VKKPGESLKI SKQSGYSPT TVHGLWVRQ PGKZLDWIGL MSFVDSRIY 60
22-24
STSEQQGVTM SVDESIITAY LQWNSLKASD TAMFY APSE PGQGVFRNG QCTLVTVSSS 120
STKGPVSFVL APSSKSTSGG TAALG LVKD YFSPVTVSW NSGALTSQVH TFDVLQSSG 180
148-200
LYSLSSVTV PSSSLQTQTY ICNVNKKPM TKVDEKVEPK SCDKTHY CPD APDLLOP 240
222 228 231
SVFLPPPK DKLMISRTPE VT VVVDVSH EDPEVKFMY VDGVEVNAK TKPREQVMS 300
283-323
TYRVSVLTV LKQWLNGKE YK KVSNKAL DAPIKTIK AKQQRREPQV YTLPPSRDEL 360
TKQVSLTCL VKGFYPSDIA VEWRSNQPE NNYKTPPVL DSDQSFFLYS KLTVDKSRWQ 420
369-427
QGNVFS CSVM HEALHRYTQ KSLSLSPGK 449

Light Chain

DIQWTQSPSS LSASVQDEVT IT CSAGGIS SWANVQOKP EKAPESLIYA ASSLSQVPS 60
21-23
RFSQSGSCTD FTLTISLQD EDFATY COO VNIYPTTPOQ GTKLEIKRTV AAPSVFIQPP 120
SDQLKSGTA SVV LLNNFY PREAKVQKV DNALQSGNSQ ESVTSQDSKD STYLSSTLT 180
134-184
LSKADYEKKH VYAEVTHQG LSSPVTKSPN RGR 214
NG

Figure 1. Heavy and light chains of ustekinumab
Amino acid sequences of the heavy and light chains of ustekinumab are indicated in the single-letter code. Complementarity-determining regions are underlined. H-chain K449: partial processing

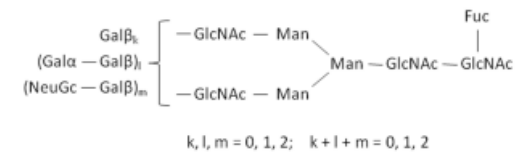


Figure 2. Carbohydrate structure